

[COMMITTEE PRINT]

94th Congress }
1st Session }

SENATE

{ REPORT
No. —

**NURSING HOME CARE IN THE UNITED
STATES: FAILURE IN PUBLIC POLICY**

Supporting Paper No. 2

**DRUGS IN NURSING HOMES: MISUSE, HIGH COSTS,
AND KICKBACKS**

PREPARED BY THE
SUBCOMMITTEE ON LONG-TERM CARE
OF THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE



JANUARY 1975

Printed for the use of the Special Committee on Aging

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¹ Senator Alan Bible, D., Nevada, resigned from the Senate effective December 17, 1974.

² Senator Edward J. Gurney, R., Florida, resigned from the Senate effective December 31, 1974.

PREFACE

Federal support of long-term care for the elderly has, within a decade, climbed from millions to billions of dollars.

What is the Nation receiving for this money?

This report explores that, and related questions.

It concludes that public policy has failed to produce satisfactory institutional care—or alternatives—for chronically ill older Americans.

Furthermore, this document—and other documents to follow—declare that today's entire population of the elderly, *and their offspring*, suffer severe emotional damage because of dread and despair associated with nursing home care in the United States today.

This policy, or lack thereof, may not be solely responsible for producing such anxiety. Deep-rooted attitudes toward aging and death also play major roles.

But the actions of the Congress and of States, as expressed through the Medicare and Medicaid programs, have in many ways intensified old problems and have created new ones.

Efforts have been made to deal with the most severe of those problems. Laws have been passed; national commitments have been made; declarations of high purpose have been uttered at national conferences and by representatives of the nursing home industry.

But for all of that, long-term care for older Americans stands today as the most troubled, and troublesome, component of our entire health care system.

It is costly and growing costlier.

It is increasing in numbers, already providing more beds than there are beds in general hospitals.

And there is every reason to believe that many more beds will be needed because the population of old persons in this Nation continues to grow faster than any other age group.

Nursing home care is associated with scandal and abuse, even though the best of its leaders have helped develop vitally needed new methods of care and concern for the elderly, and even though—day in and day out—underpaid, but compassionate, aides in many homes attempt to provide a touch of humanity and tender care to patients who, though mute or confused and helpless, nevertheless feel and appreciate kindness and skill.

This industry, which has grown very rapidly in just a few decades—and most markedly since 1965, when Medicare and Medicaid were enacted—could now take one of three courses:

It could continue to grow as it has in the past, spurred on by sheer need, but marred by scandal, negativism, and murkiness about its fundamental mission.

It could be mandated to transform itself from a predominantly proprietary industry into a nonprofit system, or into one which takes on the attributes of a quasi-public utility.

Or it could—with the informed help of Government and the general public—move to overcome present difficulties, to improve standards of performance, and to fit itself more successfully into a comprehensive health care system in which institutionalization is kept to essential minimums.

Whatever course is taken, it is certain that the demand for improvement will become more and more insistent.

Within the Congress, that demand has been clearly expressed in recent years. But often congressional enactments have been thwarted by reluctant administration, or simply have been ignored. Now, facing the prospect of early action upon a national health program for all age groups, the Congress must certainly consider long-term care a major part of the total package. Wisely used, the momentum for a total health care package could be used to insure better nursing home care.

Within the administration, there has been drift and unresponsiveness to congressional mandate since 1965. There are signs, however, that rising costs and rising public concern have aroused certain members of the executive branch to see the need for long-term care reform more clearly than before. Their actions and initiatives are welcome, but it is essential that the Department of Health, Education, and Welfare take far more effective, well-paced action than it has thus far.

Everywhere, the demand for reform is intensifying. People know that a nursing home could be in everyone's future.

They ask why placement in such a home should be the occasion for despair and desperation, when it should be simply a sensible accommodation to need.

The Subcommittee on Long-Term Care of the Senate Special Committee on Aging continually has asked the same question.

Care for older persons in need of long-term attention should be one of the most tender and effective services a society can offer to its people. It will be needed more and more as the number of elders increases and as the number of very old among them rises even faster.

What is needed now? As already indicated, the forthcoming debate over a national health program will offer opportunity for building good long-term care into a comprehensive program for all Americans.

But the issues related to the care of the chronically ill are far from simple. Tangled and sometimes obscure, technical questions related to such matters are reimbursement, establishment of standards, enforcement, and recordkeeping, often attract the attention of policy-makers, to the exclusion of other questions, such as:

Could nursing homes be avoided for some, if other services were available?

What assurance is there that the right number of nursing homes are being built where they are most needed?

What measures can Government take to encourage providers themselves to take action to improve the quality of nursing home care?

What can be done to encourage citizen action and patient advocacy at the local level?

Such questions intrude even when the best of care is given. In other settings, however, scandal and calamity enter the picture; and dark new questions emerge.

The subcommittee, in this report and succeeding Supporting Papers, recognizes the importance of the nursing home industry; and it pledges every effort to continue communication with representatives of the industry and with members of the executive branch.

For these reasons, the subcommittee has devised an unusual format: After publication of the Introductory Report, a series of follow-up papers on individual issues will follow; then we will publish a compendium of statements invited from outside observers; after this will come our final report. In this way, the subcommittee can deal with the many parts needed to view long-term care as a whole.

Testimony from many, many days of hearings and other research have been tapped for this report, which is extensive and heartfelt. Concern about people has been at the heart of this effort. The subcommittee has, therefore, been especially dependent upon responsive staff effort. Mr. Val Halamandaris, associate counsel for the Senate Special Committee on Aging, deserves specific mention for his role in assuring that subcommittee inquiries remained directed at their real target: to wit, people in need of good care. Mr. Halamandaris has had the primary responsibility for directing the subcommittee's hearings; he is responsible for the excellent research on data and for writing this report. He is more than a skilled and attentive attorney; his investigatory skills are rooted in concern and, when necessary, outrage. He has made it possible for this subcommittee to compile and offer more information and insights into the nursing home industry than the Congress has ever had before.

He has been helped considerably by other committee personnel. Staff Director William Oriol has provided guidance and consultation leading to the design and special points of emphasis in this report. Committee Counsel David Affeldt has given generously of his legislative expertise, as well as painstaking attention to detail.

Particularly fortunate for the subcommittee was the fact that a professional staff member, John Edie, had special qualifications for making a substantial contribution to this effort. Mr. Edie, an attorney, formerly served as counsel to a program on aging in Minneapolis, Minn. When the subcommittee went to that city for intensive hearings on scandalous shortcomings in nursing home care there, Mr. Edie testified and then continued his efforts on behalf of reform. In the preparation of this report, he has worked closely and at length with Mr. Halamandaris and his associates.

The subcommittee also stands in debt to a select group in the nursing home industry and within the executive branch. Usually without much attention or encouragement, these public servants have stubbornly refused to compromise their goal, seeking high, but reasonable, standards of care.

With the publication of the Introductory Report, the subcommittee begins a final exploration of issues. We will publish responsible comments on findings expressed in this document and the Supporting Papers which will follow. And we will, in our final report, perhaps 8 to 10 months from now, make every effort to absorb new ideas or chal-

lenges to our findings. The care of chronically ill older Americans is too serious a topic for stubborn insistence upon fixed positions. Obviously, changes are needed. Obviously, those changes will occur only when public understanding and private conscience are stirred far more than is now the case.

FRANK E. MOSS,
Chairman, Subcommittee on Long-Term Care.

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NURSING HOME CARE IN THE UNITED STATES: FAILURE IN PUBLIC POLICY

SUPPORTING PAPER NO. 2

DRUGS IN NURSING HOMES: MISUSE, HIGH COSTS, AND KICKBACKS

ABOUT THIS REPORT

To deal with the intricate circumstances and governmental actions associated with nursing home care in this Nation, the Subcommittee on Long-Term Care of the U.S. Senate Special Committee on Aging is issuing several documents under the general title of *Nursing Home Care in the United States: Failure in Public Policy*.

An Introductory Report, published in November, declared that a coherent, constructive, and progressive policy on long-term care has not yet been shaped by the Congress and by the executive branch of this Nation.

Examining the role of Medicare and Medicaid in meeting the need for such care, the report found that both programs are deficient.

Further, it raised questions about current administration initiatives originally launched personally by President Nixon in 1971.

These shortcomings of public policy, declared the report, are made even more unfortunate by the clear and growing need for good quality care for persons in need of sustained care for chronic illness. It called for good institutions and, where appropriate, equally good alternatives, such as home health services.

(A more detailed summary of major findings from the Introductory Report appears later in this section of this report.)

Supporting Paper No. 2, "Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks," analyzes drug distribution in America's 23,000 nursing homes. It gives specific examples of loose controls and the dire consequences to nursing home patients and the taxpayer.

THE FACTUAL UNDERPINNING OF THIS STUDY

Fifteen years of fact-gathering preceded publication of this report. In 1959, the Senate Committee on Labor and Public Welfare established a Subcommittee on Problems of the Aged and Aging. Findings from subcommittee reports and hearings have been evaluated. That subcommittee acknowledged in 1960, as this report acknowledges in 1974, that nursing homes providing excellent care with a wide range of supportive services are in the minority.

With the establishment of the U.S. Senate Special Committee on Aging in 1961, additional hearings were conducted. The most recent phase began in 1969 with hearings on "Trends in Long-Term Care." Since 1969, 22 hearings were held and some 3,000 pages of testimony were taken, as of October 1973.

These hearing transcripts have provided valuable information and expert opinions, as have several supplementary studies by the subcommittee staff, the General Accounting Office and private groups such as Ralph Nader's Study Group on Nursing Homes in 1971. The Library of Congress and other congressional committees, as well as professional organizations such as the American Nursing Home Association, have also been helpful. Finally, a great portion of the data is from the Department of Health, Education, and Welfare and other administrative or independent agencies, such as the Securities and Exchange Commission. The assistance of State officials proved especially helpful.

ORGANIZATION OF THIS STUDY

The Introductory Report and this Supporting Paper will be followed by other Supporting Papers to be published at approximately monthly intervals over the next few months. Each will deal with a fairly specific issue, and each of these issues will be examined in the detail needed for understanding, not only by legislative and health specialists, but by laymen.

A study of this magnitude would be incomplete without reaction by the nursing home industry and by representatives of the executive branch. Accordingly, national organizations and appropriate governmental units will be invited to submit statements within 2 months after publication of the final Supporting Paper. Finally, the subcommittee will issue a concluding report intended to update earlier information and to analyze the situation at that time.

The format is unusual, perhaps unprecedented. But the nursing home industry is too vital a part of our health system and of the national scene for lesser treatment.

MAJOR POINTS OF THIS SUPPORTING PAPER

The average nursing home patient takes from four to seven different drugs a day (many taken twice or three times daily). Each patient's drug bill comes to \$300 a year as compared with \$87 a year for senior citizens who are not institutionalized. In all, \$300 million a year is spent for drugs, 10 percent of the Nation's total nursing home bill.

Almost 40 percent of the drugs in nursing homes are central nervous system drugs, painkillers, sedatives, or tranquilizers.

Tranquilizers themselves constitute almost 20 percent of total drugs—far and away the largest category of nursing home drugs.

Drug distribution systems used by most nursing homes are inefficient and ineffective. An average home of 100 beds might have 850 different prescription bottles and 17,000 doses of medication on hand. Doctors are infrequent visitors to nursing homes. Nurses are few and overworked. All too often, the responsibility for administering medications falls to aides and orderlies with little experience or training.

Not surprisingly, 20 to 40 percent of nursing home drugs are administered in error.

Other serious consequences include: the theft and misuse of nursing home drugs; high incidence of adverse reactions; some disturbing evidence of drug addiction; and lack of adequate controls in the regulation of drug experimentation.

Perhaps most disturbing is the ample evidence that nursing home patients are tranquilized to keep them quiet and to make them easier to take care of. Tragically, recent research suggests that those most likely to be tranquilized sometimes may have the best chance for effective rehabilitation.

Kickbacks are widespread. A kickback is the practice whereby pharmacists are forced to pay a certain percentage of the price of nursing home prescription drugs back to the nursing home operator for the privilege of providing those services.

The atmosphere for abuse is particularly inviting when reimbursement systems under Federal and State programs allow the nursing home to act as the "middle man" between the pharmacy (which supplies the drugs) and the source of payment (private patient, Medicare, or Medicaid).

Kickbacks can be in the form of cash, long-term credit arrangements, and gifts of trading stamps, color televisions, cars, boats, or prepaid vacations. Additionally, the pharmacist may be required to "rent" space in the nursing home, to furnish other supplies free of charge, or to place nursing home employees on his payroll.

The average kickback is 25 percent of total prescription charges; over 60 percent of 4,400 pharmacists surveyed in California reported that they had either been approached for a kickback or had a positive belief that kickbacks were widespread; these same pharmacists projected \$10 million in lost accounts for failure to agree to kickback proposals.

In order to lower costs to meet kickback demands, pharmacists admitted numerous questionable, if not illegal, practices such as: billing welfare for nonexistent prescriptions, supplying outdated drugs or drugs of questionable value, billing for refills not dispensed, supplying generic drugs while billing for brand names, and supplying stolen drugs which they have purchased.

Congressional action in 1972 to make kickbacks illegal has had little effect. HEW has yet to announce regulations to implement this law.

MAJOR POINTS OF INTRODUCTORY REPORT

(Issued November 19, 1974)

Medicaid now pays about 50 percent of the Nation's more than \$7.5 billion nursing home bill, and Medicare pays another 3 percent. Thus, about \$1 of every \$2 in nursing home revenues is publicly financed.*

There are now more nursing home beds (1.2 million) in the United States today than general and surgical hospital beds (1 million).

In 1972, for the first time, Medicaid expenditures for nursing home care exceeded payments for surgical and general hospitals: 34 percent to 31 percent.

Medicaid is essential for growing numbers of elderly, particularly since Medicare nursing home benefits have dropped sharply since 1969. Average Social Security benefits for a retired couple now amount to \$310 a month compared to the average nursing home cost of \$600. Medicaid (a welfare program) must be called upon to make up the difference.

The growth of the industry has been impressive. Between 1960 and 1970, nursing home facilities increased by 140 percent, beds by 232 percent, patients by 210 percent, employees by 405 percent, and expenditures for care by 465 percent. Measured from 1960 through 1973, expenditures increased almost 1,400 percent.

Despite the heavy Federal commitment to long-term care, a coherent policy on goals and methods has yet to be shaped. Thousands of seniors go without the care they need. Others are in facilities inappropriate to their needs. Perhaps most unfortunate,

*The Committee's Introductory Report, as released on November 19, 1974, incorporating the latest statistics from HEW reported that total revenues for the nursing home industry in 1972 were \$3.2 billion and \$3.7 billion for 1973. Subsequent to publication of this report the Social Security Administration released new estimates for 1974. Total expenditures are estimated at \$7.5 billion. This change reflects spending for the Intermediate Care program, which until recently was a cash grant program to old age assistance recipients. With its change to a vendor payments program such expenses are properly countable as nursing home expenditures. Consequently, changes were made in this report.

institutionalization could have been postponed or prevented for thousands of current nursing home residents if viable home health care and supportive services existed. Although such alternative forms of care may be more desirable from the standpoint of elderly patients—as well as substantially less expensive—the Department of HEW has given only token support for such programs.

Despite the sizable commitment in Federal funds, HEW has been reluctant to issue forthright standards to provide patients with minimum protection. Congress in 1972 mandated the merger of Medicare and Medicaid standards, with the retention of the highest standard in every case. However, HEW then watered down the prior standards. Most leading authorities concluded at subcommittee hearings that the new standards are so vague as to defy enforcement.

There is no direct Federal enforcement of these and previous Federal standards. Enforcement is left almost entirely to the States. A few do a good job, but most do not. In fact, the enforcement system has been characterized as scandalous, ineffective, and, in some cases, almost nonexistent.

The President's program for "nursing home reform" has had only minimal effect since it was first announced in 1971 and actions in 1974 fall far short of a serious effort to regulate the industry.

The victims of Federal policy failures have been Americans who are desperately in need of help. The average age of nursing home patients is 82; 95 percent are over 65 and 70 percent are over 70; only 10 percent are married; almost 50 percent have no direct relationship with a close relative. Most can expect to be in a nursing home over 2 years. And most will die in the nursing home. These patients generally have four or more chronic or crippling disabilities.

Most national health insurance proposals largely ignore the long-term care needs of older Americans. Immediate action is required by the Congress and executive branch to improve past policies and programs which have been piecemeal, inappropriate, and short lived.

MAJOR POINTS OF SUPPORTING PAPER NO. 1 (Issued December 17, 1974)

"THE LITANY OF NURSING HOME ABUSES AND AN EXAMINATION OF THE ROOTS OF CONTROVERSY"

The subcommittee's Supporting Paper No. 1 reveals the following were the most important nursing home abuses:

- Negligence leading to death and injury;
- Unsanitary conditions;
- Poor food or poor preparation;

- Hazards to life or limb;
- Lack of dental care, eye care or podiatry;
- Misappropriation and theft;
- Inadequate control of drugs;
- Reprisals against those who complain;
- Assault on human dignity; and
- Profiteering and "cheating the system."

The inevitable conclusion is that such abuses are far from "isolated instances." They are widespread. Estimates of the number of substandard homes (that is, those in violation of one or more standards causing a life-threatening situation) vary from 30 to 80 percent. The subcommittee estimates at least 50 percent are substandard with one or more life-threatening conditions.

These problems have their roots in contemporary attitudes toward the aging and aged. As Senator Frank E. Moss, chairman of the Subcommittee on Long-Term Care, has said:

It is hell to be old in this country. The pressures of living in the age of materialism have produced a youth cult in America. Most of us are afraid of getting old. This is because we have made old age in this country a wasteland. It is T. S. Eliot's rats walking on broken glass. It's the nowhere in between this life and the great beyond. It is being robbed of your eyesight, your mobility, and even your human dignity.

Such problems also have their roots in the attitudes of the elderly toward institutionalization. Nursing home placement often is a bitter confirmation of the fears of a lifetime. Seniors fear change and uncertainty; they fear poor care and abuses; loss of health and mobility; and loss of liberty and human dignity. They also fear exhausting their savings and "going on welfare." To the average older American, nursing homes have become almost synonymous with death and protracted suffering before death.

However, these arguments cannot be used to excuse nursing home owners or operators or to condone poor care. Those closest to the action rightly must bear the greatest portion of responsibility.

To deal with the litany of abuses, action must be taken immediately by the Congress and the executive to: (1) Develop a national policy with respect to long-term care; (2) provide financial incentives in favor of good care; (3) involve physicians in the care of nursing home patients; (4) provide for the training of nursing home personnel; (5) promulgate effective standards; and (6) enforce such standards.

MAJOR POINTS OF FORTHCOMING SUPPORTING PAPERS

Supporting Paper No. 3

“DOCTORS IN NURSING HOMES: THE SHUNNED RESPONSIBILITY”

Physicians have, to a large degree, abdicated the responsibility for personal attention to nursing home patients. One of the reasons for their lack of concern is inadequate training at schools of medicine. Another is the negative attitude toward care of the chronically ill in this Nation. The subcommittee's May 1974 questionnaire to the 101 U.S. schools of medicine indicates a serious lack of emphasis on geriatrics and long-term care:

Eighty-seven percent of the schools indicated that geriatrics was not now a specialty and that they were not contemplating making it one; 74 percent of the schools had no program by which students, interns, or residents could fulfill requirements by working in nursing homes; and 53 percent stated they had no contact at all with the elderly in nursing homes.

Supporting Paper No. 4

“NURSES IN NURSING HOMES: THE HEAVY BURDEN (THE RELIANCE ON UNTRAINED AND UNLICENSED PERSONNEL)”

Of the 700,000 registered nurses in this Nation, only 35,000 are found in nursing homes, and much of their time is devoted to administrative duties. From 80 to 90 percent of the care is provided by over 215,000 aides and orderlies, some few of them well trained, but most literally hired off the streets. Most are grossly overworked and paid at or near the minimum wage. With such working conditions, it is understandable that their turnover is 75 percent a year.

One reason for the small number of registered nurses in nursing homes is that present staffing standards are unrealistic. The present Federal standard calls for one registered nurse coverage only on the day shift, 40 hours a week, regardless of the size of the nursing home. By comparison, Connecticut requires one registered nurse for each 30 patients on the day shift, one for every 45 in the afternoon; and one for each 60 in the evening.

Supporting Paper No. 5

“THE CONTINUING CHRONICLE OF NURSING HOME FIRES”

In 1971, there were 4,800 nursing home fires; 38 persons were killed in multiple death fires and some 500 more in single death fires. An estimated \$3.5 million loss was directly attributable to

nursing home fires. Fires in August-September of 1974 have claimed 13 lives.

Nursing home patients are especially vulnerable to fires. Many are under sedation or bound with restraints. Physical infirmities and confusion often cause resistance to rescue.

There is reason to believe the number of nursing homes failing to meet fire safety standards is actually increasing.

In 1971, the General Accounting Office reported that 50 percent of U.S. nursing homes were deficient in regard to fire safety. A January 1974 study of the U.S. Office of Nursing Home Affairs said that 59 percent of skilled nursing facilities are substandard with serious, life-threatening deficiencies. The same study indicates that in excess of 60 percent of intermediate facilities do not comply with existing standards. The requirements are on the books, but they are not heeded.

Supporting Paper No. 6

"WHAT CAN BE DONE IN NURSING HOMES: POSITIVE ASPECTS IN LONG-TERM CARE"

It is unjust to condemn the entire nursing home industry. There are many fine nursing homes in the United States. A growing number of administrators are insisting upon positive approaches to therapy and rehabilitation, innovations in physical structure of the physical plant; employee sensitivity training and cooperative agreements with local schools of nursing; and even self-government and other activities for the patients.

"Ombudsmen" programs have been established by Presidential direction and are making some headway. In some States, the nursing home industry has launched an effort to upgrade its facilities by establishing directories, rating systems, and a "peer review" mechanism. These efforts offer the prospect of improving nursing home conditions if conducted in a vigorous and effective manner. In Chicago, nursing homes have a "cool line" telephone number for relatives, visitors, or patients who have complaints.

Supporting Paper No. 7

"THE ROLE OF NURSING HOMES IN CARING FOR DISCHARGED MENTAL PATIENTS"

Thousands of elderly patients have been transferred from State mental institutions to nursing homes. The number of aged in State mental hospitals decreased 40 percent between 1969 and 1973 according to subcommittee data, dropping from 133,264 to 81,912. This trend is caused partially by progressive thinking intended to reduce patient populations in large impersonal institutions. Another powerful reason, however, may be cost and the desire to substitute Federal for State dollars. It costs the States an average

of \$800 per patient per month to care for mental patients in State hospitals while these same individuals can be placed in boarding homes at substantially reduced cost. Charges of "wholesale dumping" of patients have been made in several States. Acute problems have been reported, most notably in California, Illinois, and New York.

Supporting Paper No. 8

"ACCESS TO NURSING HOMES BY U.S. MINORITIES"

Only 4 percent of the 1 million nursing home patients in the United States are members of minority groups, even though their health needs are proportionately greater. Part of the problem is caused by cost obstacles or lack of information about Medicaid. Discrimination is the greatest obstacle to greater utilization by blacks. But discrimination need not be overt; often relatives are made to feel that their parent or grandparent would not be made comfortable. In the case of Asian-Americans and Spanish-speaking Americans, language barriers often cause insurmountable difficulties. Cultural and other problems, including rural isolation, cause problems to American Indians.

Supporting Paper No. 9

"PROFITS AND THE NURSING HOME: INCENTIVES IN FAVOR OF POOR CARE"

Profits by nursing homes have occasioned serious and persistent controversy. Nursing home administrators say that Medicaid reimbursement rates are low and that they can hardly become the basis for profiteering. Critics say that the economics of nursing home operation, supported in such large measure by public funds, should be examined more closely and publicly than they now are.

A subcommittee survey made in 1973-74, indicates that the 106 publicly held corporations controlled 18 percent of the industry's beds and accounted for one-third of the industry's \$3.2 billion in revenue (as of 1972.) Between 1969 and 1972 these corporations experienced the following growth:

- 122.6 percent in total assets;
- 149.5 percent in gross revenues; and
- 116 percent in average net income.

One recent HEW study, however, shows marginal rates of return in a sample of 228 nursing homes. Thus, the issue is far from settled. But a joint study—conducted by the General Accounting Office and the subcommittee—suggest significant increases in revenues, and profits for individual operators as well.

Two final documents will be issued as part of this study: A compendium of statements by the industry and administration spokesmen, and a final report by the Subcommittee on Long-Term Care.

NURSING HOME CARE IN THE UNITED STATES: FAILURE IN PUBLIC POLICY

SUPPORTING PAPER NO. 2

DRUGS IN NURSING HOMES: MISUSE, HIGH COSTS, AND KICKBACKS*

—Ordered to be printed

Mr. Moss, from the Special Committee on Aging,
submitted the following

REPORT

INTRODUCTION

Older Americans in nursing homes have a drug bill of about \$300 million a year, or about \$300 each.¹

And most of that cost is paid by Federal funds.

The average nursing home patient receives about 4.2 different drugs a day,² although more recent studies put the number at seven.³ (Some persons have been found to receive as many as 18 different drugs in 24 hours, and in one case the General Accounting Office

*As explained in "About this Report," a series of documents, all under the general heading of *Nursing Home Care in the United States: Failure in Public Policy*, is being issued by the Subcommittee on Long-Term Care, U.S. Senate Special Committee on Aging. An Introductory Report was issued on Nov. 19, 1974. A series of supporting papers will be issued approximately at monthly intervals.

¹ See industry statistics, Appendix 7, p. 315. These statistics indicate \$300 a year per patient for nursing home drugs. Assuming there are 1 million patients today, total drug costs would equal \$300 million per year. For confirmation, see *Modern Nursing Home*, June 1972, p. 23; see also: "Prescription Drug Data Summary—1972," U.S. Department of Health, Education, and Welfare, Social Security Administration, Office of Research and Statistics, DHEW publication No. (SSA) 73-11 900, p. 11.

² See source of industry statistics cited in footnote 1. See also: Introductory Report, part 1; and "The Resident-Patient Profile," a comparison of health related facility residents and nursing home patients in "mixed" long-term care institutions in New York State, New York State Department of Health, 1971.

³ Brady, Edward S., et al., *Drugs and the Elderly*, a series of papers published by the Ethel Percy Andrus Gerontology Center, University of Southern California, 1973; paper by Ronald C. Kayne and Alan Cheung, "An Application of Clinical Pharmacy in Extended Care Facilities," pp. 65-69; see also "A Prospective Study of Drug Preparation and Administration in Extended Care Facilities," by Alan Cheung, Ron Kayne, and Margaret M. McCarron, unpublished study in subcommittee files.

documented that one patient had received 33 different drugs during a 9-month period.)⁴

Why such high costs? Why so many medications?

The Subcommittee on Long-Term Care of the U.S. Senate Special Committee on Aging has received extensive testimony on those questions.

It has ordered studies to pinpoint questionable practices related to drug administration in long-term care institutions.

Subcommittee members and staff have studied extensive literature related to the many phases of medication in such facilities.

Part of the subcommittee concern is based upon the realization that elderly nursing home patients are highly dependent upon those who care for them, and they usually have multiple ailments and, therefore, may require varying medications. Many of their illnesses are of long duration; but they may nonetheless change, even if old medication patterns do not. Finally, the patient—especially if regarded as troublesome—may be heavily tranquilized.

These considerations have weighed heavily in subcommittee deliberations on the quality of care received in nursing homes. They are explored further in this Supporting Paper.

In short, an ugly pattern of prescription drug misuse, with harsh consequences to patients, exists in many nursing homes of the United States.

Part of the fault lies at the door of the Federal and State officials, who have yet to launch a coordinated attack on the problem.

Part of the fault lies in poor or inadequate staffing and practices within nursing homes.

Part of the fault lies with drug companies and pharmacists themselves, who have taken little notice of the special effect of drugs on the elderly.

Part of the blame must be directed at the medical community which has not yet given serious attention to medication problems affecting geriatric patients.

And part of the fault must be laid at the door of the American public which, by remaining apathetic or unaware, allows such practices to continue.

⁴ "Inquiry Into Alleged Improper Practices in Providing Nursing Home Care, Medical Services, and Prescribed Drugs to Old-Age Assistance Recipients in the Cleveland, Ohio, Area", report to the Subcommittee on Long-Term Care by the General Accounting Office, March 1967, p. 52.

PART 1

THE ELDERLY AND DRUGS

Older Americans constitute 10 percent of the population, but receive over 25 percent of the prescriptions written in this Nation (as compared to only one-fifth in 1965).⁵ The average senior citizen (95 percent of whom are not in institutions) spends about \$87 a year for drugs, but as has already been indicated, the cost for those in nursing homes is about \$300 a year.⁶ In all, the Nation's 1 million nursing home patients spent \$300 million for drugs in 1972, constituting almost 10 percent of U.S. total nursing home expenditures.⁷

One reason for the higher institutional cost is that nursing home patients—whose average age is 82⁸—have three or more chronic conditions.

Seventy percent of the drugs now on the market were unavailable 20 years ago.⁹ These new drugs are in part responsible for lengthening the life span. While the elderly take large numbers of drugs little notice is taken of the fact that they assimilate and tolerate drugs differently from younger Americans.

An article in the National Council on the Aging's magazine, *Perspective on Aging*, said recently:

By virtue of the natural aging process, the elderly are less physically tolerant of most drugs than younger persons, especially tranquilizers and other psychoactive drugs among those most frequently prescribed. They are less capable of metabolizing most drugs, more susceptible to direct, side, and interaction effects, and may require smaller dosages.¹⁰

The opposite side of the coin was also discussed:

There are strong indications that younger people, including many who are now middle-aged, are more tolerant and more conditioned to the use of drugs than the elderly. . . . As this population ages, it is highly likely that they will use

⁵ Page 53, book cited in footnote 3, paper by Dr. Bertram B. Moss, "Effective Drug Administration as Viewed by a Physician/Administrator."
⁶ *Developments in Aging: 1972 and January-March 1973*, report by the Special Committee on Aging, Washington, D.C., May 10, 1973, p. XVIII.

⁷ See chart prepared by the Social Security Administration, reprinted in "Barriers to Health Care for Older Americans," hearings by the Subcommittee on Health of the Elderly, Part 8, Washington, D.C., March 12, 1974, pp. 678-683.

⁸ See Introductory Report, Part 1, p. 16.

⁹ Wynne, Dr. Ronald D., and Heller, Frank, "Drug Overuse Among the Elderly: A Growing Problem," *Perspective on Aging*, National Council on the Aging, vol. II, No. 2, March-April 1973, p. 15-18.

¹⁰ Page 15, source cited in footnote 9.

even greater amounts of drugs than the present elderly. Obviously, if the existing overuse of drugs by the elderly is to be stemmed, and if even greater future overuse is to be prevented, something must be done.¹¹

In order to document the kind, number, and dollar amount of drugs furnished to nursing home patients, in February of 1971, Senator Frank E. Moss, chairman of the Subcommittee on Long-Term Care, asked the General Accounting Office (GAO) to undertake an audit.¹² GAO chose three States: Illinois, New Jersey, and Ohio. Their statistics cover payments by Medicaid for 4 months of the year: January, April, July, and October.

These statistics confirm the rough figures supplied to the committee by the industry.¹³ A chart with GAO's findings appears on page 247.

The total cost for drugs in the 4-month period was \$2,761,680. Central nervous system drugs (including tranquilizers, sedatives, and analgesics) accounted for 37 percent of the total (or \$990,418). Miscellaneous unclassified drugs were second with roughly 11 percent (or \$308,435). Anti-infective agents with 9 percent (or \$237,366) were third, followed by gastrointestinal drugs with about 8 percent (or \$220,124).

Tranquilizers alone amounted to \$524,381, which is 53 percent of all central nervous system drug costs and 19 percent of the cost of all drugs. The two strongest tranquilizers, Mellaril and Thorazine, accounted for 52 percent of all tranquilizers purchased—or 10 percent of total drugs.

In short, tranquilizers constitute almost 20 percent of total drugs in the GAO sample, confirming industry estimates. Projecting this percentage nationally on the Nation's \$300 million yearly drug bill would indicate that the annual cost for tranquilizers in American nursing homes is \$60 million.

¹¹ Page 15, source cited in footnote 9.

¹² *Drugs Provided to Elderly Persons in Nursing Homes Under the Medicaid Program*, report to the subcommittee by the U.S. General Accounting Office, January 5, 1972, reprinted in the *Congressional Record*, April 27, 1972, pp. S 6855-60.

¹³ See industry statistics, Appendix 7, p. 315.

MEDICAID DRUG PROGRAM—ILLINOIS, NEW JERSEY, AND OHIO: NUMBER OF PRESCRIPTIONS AND AMOUNT PAID IN JANUARY, APRIL, JULY, AND OCTOBER 1970, FOR DRUGS FOR RECIPIENTS OF OLD-AGE ASSISTANCE IN NURSING HOMES

Category	Number	Amount
Antihistamine drugs	15,758	\$50,532.43
Antiinfective agents	41,834	237,366.48
Antineoplastic agents	62	264.23
Autonomic drugs	25,115	96,751.10
Blood derivatives	7,812	17,996.62
Blood formation and coagulation	59,723	185,955.30
Cardiovascular drugs	204,382	990,419.00
Central nervous system drugs ¹	1,490	4,006.80
Diagnostic agents	49,416	192,448.36
Electrolytic, caloric, and water balance	894	5,754.83
Enzymes	7,524	17,758.56
Expectorants and cough preparations	6,211	19,948.22
Eye, ear, nose and throat preparations	64,514	220,124.05
Gastrointestinal drugs		
Gold compounds		
Heavy metal antagonists	30,282	139,550.16
Hormones and synthetic substitutes		
Local anesthetics	13	18.28
Oxytocics		
Radioactive agents	3,816	10,919.19
Serums, toxoids and vaccines	12,030	47,438.26
Skin and mucous membrane preparations	14,027	81,229.65
Spasmolytic agents	45,369	132,735.40
Vitamins	287	1,958.28
Unclassified therapeutic agents	67,264	308,435.06
Other unclassified drugs ²		
Total	657,822	2,761,680.26

¹ This category, which includes tranquilizers, represents about 35 percent (Illinois), 39 percent (New Jersey), and 36 percent (Ohio) of all amounts paid for drugs on behalf of nursing home patients.

² Includes drugs purchased under national formularies such as the National Formulary and U.S. Pharmacopeia; compounded prescriptions; specifically approved drugs; medical supplies (cotton, gauze, syringes) and other drugs which we could not classify.

Drugs Paid for by Medicaid in Three States—Illinois, New Jersey, and Ohio in January, April, July, and October

MOST DESCRIBED DRUGS BY DOLLAR AMOUNT

1. Mellaril (T)-----	\$138,882.03	7. Sparine (T)-----	\$27,565.27
2. Thorazine (T)-----	132,302.31	8. Darvon (A)-----	24,631.20
3. Darvon compound (A)-----	121,560.66	9. Stealazine (T)-----	23,128.75
4. Librium (T)-----	46,866.53	10. Doriden (S)-----	21,128.75
5. Valium (T)-----	36,817.24	11. Chloral hydrates (S)-	19,464.10
6. Indocin (A)-----	34,589.52	12. Nembutal (S)-----	13,955.25

MOST PRESCRIBED DRUGS BY NUMBER OF PRESCRIPTIONS

1. Thorazine (T)-----	23,126	7. Librium (T)-----	7,259
2. Darvon Compound (A)-----	21,436	8. Aspirin and bufferin (A)-	6,875
3. Mellaril (T)-----	17,977	9. Nembutal (S)-----	6,133
4. Phenobarbital (S)-----	9,663	10. Valium (T)-----	5,308
5. Chloral hydrates (S)-----	8,264	11. Darvon (A)-----	4,661
6. Diorden (S)-----	7,802	12. Indocin (A)-----	4,477

Key: T=Tranquilizer.
A=Analgesic.
S=Sedative.

I. HOW DO DRUGS GET INTO NURSING HOMES?

Most Americans associate the initiation of medications with an examination by their physician, who directs a specific course of therapy and prescribes the drugs most helpful to their needs. But doctors

are infrequent visitors to nursing homes, and it is, therefore, common practice in nursing homes today for nurses to call the patient's physician, who then prescribes drugs over the telephone (see Supporting Paper No. 3). This practice has been severely criticized, but it remains the most common method of authorizing drugs for nursing home patients.

Once drugs are authorized, how are they distributed in nursing homes? First, some homes, like hospitals, have their own pharmacists who oversee drug utilization. Others employ consultant pharmacists, who visit the home periodically to supervise drug distribution, provide training, and check patients for bad side effects of drugs.

Some homes employ unit dose distribution systems where each individual's dose is separately packaged in cellophane or plastic and labeled with content, strength, and the patient's name. A 24-hour supply is delivered to the nursing home by the pharmacist in a metal cabinet. Each patient has his own drawer in the cabinet which is divided in five sections to correspond with the home's medication hours. In delivering the chart of medications the pharmacist picks up the one to be filed for the next day.

Unfortunately, the methods of drug distribution just mentioned are the exception and not the rule. In most U.S. nursing homes, 30-day supplies of patient medications are stored in a drug closet (generally one per floor). Each patient may have from 4 to 10 different prescription bottles which are opened daily to remove the required dose. These individual doses are placed in small cups identified with cards bearing the patient's name. Thereafter, a typical medication tray with the medications of perhaps 20 patients is taken to bedside. Each patient is then given the pills in the small paper cup identified by the card bearing his name. Understandably, this system has been criticized as inefficient. For example, Richard Berman, president of the American Society of Consultant Pharmacists, told the subcommittee in 1971:

Documented time studies suggest that a 120-bed extended care or skilled facility with three 40-bed medication stations expends approximately 30 nursing hours per day pouring, administering, charting, ordering, and auditing medication.¹⁴

Another witness described a typical home of 100 patients. He said that 500 to 600 individual prescriptions would be required at any one time for the residents. He added:

You know the standard procedure: Doctors prescribe the drugs needed by each patient and pharmacists reach into bulk containers of tablets or capsules and measure out a specific quantity, label each bottle, note the charge, and possibly deliver it to the nursing center. Once there, these hundreds of bottles cause a major storage and distribution problem. Each time a nurse prepares medications, she must reach into practically every bottle, doling out the right dose, making sure that each patient gets the medication his doctor ordered.¹⁵

¹⁴ "Trends in Long-Term Care", part 17, hearings by the Subcommittee on Long-Term Care, U.S. Senate Special Committee on Aging, Washington, D.C., October 14, 1971, p. 1798.

¹⁵ Page 1801, part 17, hearings cited in footnote 14.

He also described an Indianapolis nursing center where :

The average number of doses per patient per day exceeded 14. Also, in that same facility, records of discontinued medications documented the fact that in a 9-month period from September 1970 to June 1971, *there accumulated more than 850 different prescription bottles containing over 17,000 doses of medicine, not counting narcotics.*¹⁶ (Emphasis added.)

His testimony referred to a New York center where the nursing staff, "observing strict professional techniques of drug preparation," spent an average of nearly 1 minute per dose for an average of nine doses per day per patient.

The witness added :

Ours and other studies corroborate the evidence that multiple-dose prescription dispensing for the nursing center patient is dangerous, inefficient, and counterproductive to the efforts of conscientious pharmacy and nursing personnel who are trying to upgrade the quality of care for the convalescent patient.¹⁷

It should be obvious from the above that proper drug distribution is complicated and difficult in the best of circumstances even with trained personnel. It should be clear that the responsibility for dispensing medications should be in the hands of one who is trained, licensed, and fully cognizant of the possible adverse effects of medications and capable of taking action to meet such problems.

Unfortunately, all too often the management of drugs is left to untrained aides and orderlies, often hired literally off the street, in the words of one aide, seldom knowing the difference between "an aspirin and a mothball."¹⁸ For example, Bill Recktenwald, chief investigator of the Better Government Association of Chicago, Ill., testified that he had applied for a job as a janitor and within minutes he was hired as a nurse with the key to the medications closet and narcotics cabinet on his belt. He said :

The only thing I would say, Mr. Chairman, when I was working in homes, the persons distributing drugs were not trained in the distribution of them, and I myself was placed in charge of distributing drugs to 37 patients, and I had no training, and in fact, when I had applied for the job, I indicated I had 6 years as a janitor.

I saw bottles of drugs being passed by bottle from one patient to another, using the nurses' ideas if the pills looked alike, to borrow some from one to the other.¹⁹

In addition, he told the subcommittee that he confirmed that a skid row hotel served as a contact point for recruiting nursing home orderlies. The operator of the hotel "received a finders fee for sending these people out to the nursing home and one part of the deal was that they had to stay sober for 30 days before they got their first check."^{19a}

¹⁶ Page 1801, part 17, hearings cited in footnote 14.

¹⁷ Page 1801, part 17, hearings cited in footnote 14.

¹⁸ Page 2128, part 19A, hearings cited in footnote 14.

¹⁹ Page 1456, part 15, hearings cited in footnote 14.

^{19a} Page 1032, part 12, hearings cited in footnote 14.

Similarly, Dan Henry, a nursing home orderly, testified:

My impression was that they would hire anyone off the streets who would come and could stand the conditions and would accept the wages they offered.

I was given absolutely no training whatsoever in the passing of medication; however, I did this on a regular basis. Nurse's aides would also pass medications, and they did not have training in the effects of medications. All the nurses, nurse's aides, and orderlies had access to the narcotics cabinet. It was very common when there were drugs left over from a patient who had left or had died to re-use these drugs.²⁰

Given the defects inherent in traditional drug distribution systems (as described above), the consequences to the nursing home patient can be severe.

II. CONSEQUENCES OF POORLY CONTROLLED DRUG DISTRIBUTION

Faced with the widespread use of an inefficient and poorly controlled system of drug distribution, the infirm elderly are subjected to a wide variety of drug abuses.

A. ERRORS IN MEDICATION

Providing the right drug to the right patient at the right time can do much for the nursing home patient's well-being. But the task is far from easy, and the likelihood of error is high. Mistakes can occur in many ways:

- (1) The wrong drug.
- (2) The wrong dose.
- (3) Wrong patient.
- (4) Wrong route.
- (5) Missed dose.
- (6) Wrong time (2 or more hours before or after scheduled time).

Evidence of errors in medication goes back many years. The subcommittee's 1965 hearings are replete with references to medications commonly being administered by untrained individuals without physician's orders. For example, one witness said:

A frequent violation is medication being administered by untrained persons without physician's signed order. I have been in homes where I have found patients in drug stupors. The medical chart indicates the doctor hasn't been around for 4 or 5 months and hasn't ordered any medication or changed it in a long time.²¹

There are also references to poor recordkeeping where it is impossible to tell if a medication was ordered by a physician and if it was administered.²² There are numerous examples of drug error, waste and inefficiency. One witness, Dr. Roginsky, along with other doctors

²⁰ Page 2278, part 19B, hearings cited in footnote 14.

²¹ "Conditions and Problems in the Nation's Nursing Homes", part 3, hearings by the Subcommittee on Long-Term Care, Los Angeles, Calif., Feb. 17, 1965, p. 243.

²² Page 41, part 1, hearings cited in footnote 21.

in New York, voluntarily set up a review team to improve medical conditions in several homes. He found some disturbing practices in his 1965 study :

The doctor would come in, write the prescription downstairs and spend 10 minutes to see 10 patients.

I am sorry to say this, but frequently they would enter the nursing home and write prescriptions—in duplicate—without ever seeing the patients. . . .

Patients receiving a drug for arthritis which is well known for its toxic effects had not once in a period of 3 to 6 months . . . had a blood count or a urine analysis to determine whether there was any toxic effect of this particular drug.

As you read in my statement, patients were receiving three to six different drugs without rhyme or reason.²³

With close medical supervision, Dr. Roginsky and his team were able to reduce the volume of drugs supplied to the affected facilities by 25 percent.²⁴

Faced with the mounting complaints about nursing home pharmaceutical practices, the subcommittee asked the U.S. General Accounting Office to make an investigation.

In 1966, the GAO conducted an audit of California nursing homes and found sizable amounts of drugs were being administered in error.²⁵ In 1967, GAO reported that the State of Ohio paid for large quantities of drugs which often were never received by the patient.²⁶ GAO said it was hindered by poor recordkeeping, making it impossible to tell how widespread such practices were.

In 1970, GAO returned to California for a followup study which they entitled, "Continuing Problems in Providing Nursing Home Care and Prescribed Drugs Under the Medicaid Program in California."²⁷ The results indicated stark failures in drug administration.

A review of 1 month's medical records of 106 medical patients at 14 nursing homes showed that 311 doses were administered in quantities in excess of those prescribed and 1,210 prescribed doses were not administered.

GAO auditors found the same abuses in 1966, when they looked at nursing home care provided to California welfare recipients.

Auditors . . . made random selection of 36 welfare patients, 3 in each of the 12 nursing homes visited, and compared the nurses' records of medications and treatment for about a 3-month period with the doctors' orders for the patients.

In 11 homes they found that the records indicated that 51 medications involving 1,208 dosages were not administered at the frequency ordered by the doctors—76 more dosages were administered than the order ordered by the doctors for the time periods involved, and 1,132 dosages ordered by the doctors were not recorded as having been administered to the patients.²⁸

²³ Page 545, part 5, hearings cited in footnote 21.

²⁴ Page 545, part 5, hearings cited in footnote 21.

²⁵ "Examination into Alleged Improper Practices in Providing Nursing Home Care and Controlling Payments for Prescribed Drugs for Welfare Recipients in the State of California," U.S. General Accounting Office, August 1966.

²⁶ See source cited in footnote 4.

²⁷ U.S. General Accounting Office, August 26, 1970.

²⁸ See source cited in footnote 25.

Having found the same practices detailed in 1966 continuing in 1970, GAO auditors stated:

Actions taken by HEW and the State to correct the previously reported problems were generally ineffective.²⁹

The GAO conclusion was reached despite nursing home administrators' assertions that: (1) Medical charts were in error, and therefore medications had actually been correctly distributed, and (2) actual conditions of patients were taken into consideration, and at times they did not need the medications that were ordered.

In 1970, the Nader Task Force on Nursing Home Problems also issued a report which said:

... Government statistics suggest widespread carelessness in the handling of drugs in nursing homes—drugs are administered incorrectly or not at all, drugs prescribed by physicians are allowed to continue too long, too many drugs are prescribed, or drugs are administered that have not been prescribed by a physician. Even more widespread is the practice of keeping patients under sedation to reduce the demands on the nursing staff.³⁰

Since the Nader report was issued in 1970 there has been increasing concern about the distribution of drugs in nursing homes. More recent studies by schools of pharmacy have documented significant medication errors in nursing homes. In 1973, Dr. Allen M. K. Cheung, assistant professor of clinical pharmacy at the University of Southern California, documented a 21.83 percent rate of error in a statistically selected sample of four California nursing homes.³¹

Dr. Cheung's still continuing study notes that even when nurses knew the pharmacists would be looking over their shoulder, one out of every five doses resulted in a medication error. A total of 2,505 doses were given with 547 errors. Fully one-half of the errors were missed medications. The lowest error rate, 13.98 percent, occurred in the only facility which had registered nurses on duty around the clock.

While the U.S.C. study is surely the most significant of its kind, other studies have documented even higher rates of error. The study of Professor Fred M. Eckel, University of North Carolina School of Pharmacy, is notable. He found a 69 percent rate of error and later a 50 percent rate of error in the same sample. Most of the errors in his study were in the "wrong time" category; the largest part of the remainder were missed doses.³²

After evaluating studies by Cheung, Eckel, and others, Dr. Allan Kratz, president of the American Society of Consultant Pharmacists, testified that "the rate of errors for medications administered in long-term care facilities is from 20 to 50 percent." He charged further that 60 percent of the patients in nursing homes received inadequate pharmaceutical services.³³

²⁹ Page 1, report cited in footnote 27.

³⁰ "Nursing Home for the Aged: The Agony of One Million Americans," Nader Task Force on Nursing Homes, 1970, pp. 191-97.

³¹ Page 67, book cited in footnote 3.

³² Crawley, Henry K. III; Eckel, Fred M.; and McLeod, Don C.; "Comparison of a Traditional and Unit Dose Drug Distribution System in a Nursing Home," *Drug Intelligence and Clinical Pharmacy*, vol. 5, June 1971, pp. 166-71.

³³ Page 2800, part 22, hearings cited in footnote 14.

OTHER EVIDENCE OF THE LACK OF CONTROLS AND DRUG ERRORS

Further support for the premise that nursing home drugs are almost totally without controls is provided by a 1971 HEW study of 75 nursing homes. The study attempted to measure the quality of nursing home care received by U.S. nursing home patients. Since the administration of drugs is the primary therapy in such homes, the study inevitably concentrated on their use. Equally inevitable, perhaps, were the findings of errors in medication. The study reported:

- More than 30 percent of the patients had no recorded admission data, no transfer abstract, no diagnosis, nor initial treatment orders—even though many of them were on digitalis and other potentially dangerous drugs.
- 73 percent had no recorded admission history.
- 66 percent had not been given, at admission, physical examinations and of the physicals that were recorded, less than a third covered more than three of ten body systems.
- 37 percent of the patients taking cardiovascular drugs (digitalis or diuretics, or both) had not had their blood pressure taken in over a year; and for 25 percent of these there was no diagnosis of heart disease on the chart.
- 35 percent of the patients on tranquilizers had not had their blood pressure recorded in more than a year. Some were taking two and often three tranquilizers concurrently.
- Most of the patients reviewed were on one to four different drugs; and many were taking from seven to twelve drugs; some were on both uppers and downers at the same time.
- A third of the patients being treated for diabetes mellitus had no diagnosis of diabetes on their charts; and over 10 percent of those receiving insulin or oral hypoglycemic agents were not on diabetic diets; and a large number of these had not had a fasting blood/sugar test in more than a year.
- Revised treatment or medication orders had been written in the past 30 days for only 18 percent of the patients.
- 40 percent had not been seen by a physician for over three months.³⁴

Connecticut, which in many ways has led the way in improving nursing home care, was the site of a Subcommittee on Long-Term Care hearing in 1970.³⁵ Even there, however, State health Commissioner Franklin M. Foote said he was concerned about findings by a State survey team which showed, among other things, that medication practices often suffer from lack of information. Dr. Foote said essential tests were not done in about 40 percent of the patients. He added:

We learned that 35 percent of nursing home patients taking drugs which might lower the blood pressure markedly had not had a blood pressure determination recorded during

³⁴ "Implications of Medical Review in Long-Term Care Facilities," presented in the conference, "The Nursing Home: Critical Issues in a National Policy," sponsored jointly by Duke University Center for the Study of Aging and the National Retired Teachers Association-American Association of Retired Persons, October 30–November 2, 1971, by Carl I. Flath, consultant to the Department of Health, Education, and Welfare's Medical Services Administration.

³⁵ Pages 317–25, part 3, hearings cited in footnote 14.

the past year. We found patients getting digitalis who had no record of any heart abnormality and patients getting insulin who had no record of the diagnosis of diabetes.³⁶

In the same study, one-fourth of the patients receiving digitalis had no diagnosis of heart disease on their charts. More than a third of those taking insulin for diabetes mellitus had no diagnosis of diabetes on their charts.

FURTHER EXAMPLES FROM DIRECT TESTIMONY

Considerable attention will be given in this Supporting Paper and others to hearings conducted by the Subcommittee on Long-Term Care in Chicago and in Minneapolis.³⁷ In each case, extensive local investigation had preceded actual testimony. In each case, sworn testimony was taken.

Much of that testimony dealt with harsh, and at times, outrageous realities which have also been reported in media exposés elsewhere in the United States. (See Supporting Paper No. 1 for more on the role of such journalistic inquiries.)

Statements provided by nursing home employees, relatives and others are quoted here at some length to provide the details of medication error which statistical studies cannot:

- From one patient's relative, Mrs. Loretta Brown:

On another occasion I had been visiting my cousins when a person who worked at the nursing home came into the room and told Nancy to take her medicine. Nancy knew that she did not take medicine at that hour and told the woman so. Nancy was alert and knew what medicines she was supposed to get. I couldn't help wondering how many times this happens at this home and what happens to the patient who is too confused to know what is going on.³⁸

- From licensed practical nurse Kay Schallberg:

There were two floors at this building and I worked the 2nd floor. On my shift, an aide would work the 1st floor and had the key for the medications. This aide would set up the medications and pass them, and then would set up the medications for the morning shift. She had no Nursing Supervisor over her at that time. She also had no training and knew nothing about the reactions of the drugs she was administering. Often times when I would come on there was a Registered Nurse by the name of Mrs. . . . who would tell me about overdosages or medicines that had not been prescribed that she had given to various patients. She told me to watch them. She never charted any of this information however. This nurse would also deliberately increase the dosage of a sedative much higher than the prescription in order to quiet down patients, but then she would put on the chart that she had administered the required dosage. She would take sedatives from the prescriptions of other patients in order to do this. One time on the afternoon

³⁶ Page 269, part 3, hearings cited in footnote 14.

³⁷ Parts 19A and 19B, hearings cited in footnote 14.

³⁸ Page 2239, part 19B, hearings cited in footnote 14.

shift before I came on, apparently a new aide who had no experience and did not know the floor at all was just given the medications to distribute. She, not knowing what to do exactly, went through room by room just passing out the medications as she went, and when she was through she was out of medications but there was still one room left. Therefore, when I came on I was told to keep an eye on all the patients in all the rooms in case there were any reactions to mixed up drugs that night. None of this was ever put on the charts.³⁹

- On the question of patients missing their medication, nurse's aide Lorraine Kippels testified with respect to a patient that jumped out of a third story window to her death:

Mrs. . . . had been on that floor for a number of days when one day when we came on work, we overheard a nurse, Mrs. Corry, say that Mrs. . . . was a diabetic. We were very surprised because no one had ever told us that she was diabetic. We had no cards, no orders, and no medications for her as a diabetic. As it turned out, she was one of the worst diabetics that they had in the whole building, but they never told us about it. Yet we were the ones who were supposed to be taking care of her. We looked at her medication charts and there were no medications ordered for her.⁴⁰

- Orderly Robert Shypulski testified:

There is one incident that I would like to bring out, because I was called as a witness to it. There was an LPN named Mrs. Bruckner who worked from 7 am to 3:30 pm. One day Mrs. De Mars noticed that there were three trays of medications that had been dumped into a wastebasket. Mrs. Bruckner had dumped them in the wastebasket. Mrs. De Mars called me as a witness. They put all the medication in a bag and called Mrs. O'Connell [the head nurse]. The next day Mrs. Bruckner told Mrs. O'Connell that she had not passed the medications because she did not feel that she should chase after all the patients. She didn't feel there was any sense in it. Mrs. O'Connell thought that was a good excuse. Some people pass out medications and just put them on the food trays. The kitchen reports that the medications come back to the kitchen.⁴¹

- Nurse's aide Glayds Danielson stated:

There is a constant problem with the giving out of medicines. There is an aide who has no nursing training who occasionally gives insulin injections. On one occasion she gave one diabetic patient an injection of insulin in the morning and did not mark it up in the day book. Later that morning an L.P.N. gave her another injection, and I had to feed her sweets all day long.

Medications are often set up by aides, only occasionally by R.N.'s. They make mistakes often. They mix up the pills or

³⁹ Pages 2334-35, part 19B, hearings cited in footnote 14.

⁴⁰ Page 2301, part 19B, hearings cited in footnote 14.

⁴¹ Page 2341, part 19B, hearings cited in footnote 14.

leave some out, and the aides do not check to be sure the pills are taken. Many times my sister has found pills of my mother's on the floor at night.⁴²

In summary, the flow of drugs through most of America's 23,000 nursing homes is almost totally without controls; it is haphazard, inefficient, costly, and, most of all, dangerous to the patients who must trust others for their protection.

The foregoing facts demonstrate the frightening conclusion that 20 to 40 percent of the drugs administered in U.S. nursing homes are administered in error. Unfortunately, medication error is only part of the problem.

B. THEFT AND MISUSE

The poorly controlled drug distribution system in nursing homes provides an open and tempting opportunity for numerous abuses. The subcommittee has documented several examples of the following illegal practices:

- Use of medications of discharged patients.
- Use of medications of dead patients.
- Theft of drugs for personal use or gain.
- Theft or borrowing from one patient's supply to serve another patient.

As previously described, it is difficult enough to administer drugs accurately to patients from their own clearly marked supplies. When medications are borrowed, or obtained from supplies saved from discharged or dead patients, the possibilities for medication error multiply. There is the added danger of medications decomposing and becoming ineffectual or dangerous if kept too long.

Keeping the unused drugs of patients who have left the nursing home also provides ample opportunity for monetary gain. Nursing home owners can agree to return unused supplies to the pharmacist for mutual profit. Examples of this practice have been reported to the subcommittee.⁴³ This available "pool" of unused medications can be used to provide doses to patients who are then charged for the drug, even though the nursing home paid for nothing. It also affords the home a ready supply of sleeping pills and tranquilizers which they could administer to patients without a prescription.

There are some who are sympathetic to the reuse of drugs. Their argument is generally structured in terms of preventing waste and inefficiency. Several studies have indicated that such drug waste can amount to as much as 15 percent of the nursing homes total drug bill.⁴⁴

In two separate studies, pharmacists John Rawlings and Donald R. Mathieson have found the drug waste due to death, transfer, release,

⁴² Page 2242, part 19B, hearings cited in footnote 14.

⁴³ See, for example, the statement of orderly Marotz, p. 2318, part 19B, hearings cited in footnote 14: "Several times drugs and medicines paid for by the patients are used for other patients. It is a common practice to give employees pills from the patients' supply. If I want a Darvon all I have to do is ask one of the nurses and she will take one from one of the patient's bottles."

See also; from the same hearings, part 19A, pp. 2127-28; and part 19B, pp. 2248, 2268, 2278, 2293.

⁴⁴ Mathieson, Donald R., and Rawlings, John L. "Evaluation of a Unit Dose System in Nursing Homes as Implemented by a Community Pharmacy." *American Journal of Hospital Pharmacy*, vol. 28, April 1971, pp. 254-59.

or change in medication to cost \$3.55 per patient per month and \$2.74 per patient per month.⁴⁵

If 15 percent of the Nation's total drug bill were being wasted by the statutory requirement that it not be reused, the cost would be \$45 million. Testimony before the subcommittee estimated this loss more conservatively at \$12 to \$15 million.⁴⁶

What these figures illustrate is the inefficiency of the traditional distribution system, *but they cannot, and should not*, be used to justify the accumulation of a private pool of pharmaceuticals from which nursing home personnel can prescribe on their own initiative.

Drug theft in nursing homes has primarily two serious results: (1) The cost of nursing home care increases (and the American tax dollar must pay more for Medicaid and Medicare), and (2) the potential supply of drugs to illicit markets is greatly increased.

The U.S. Bureau of Narcotics and Dangerous Drugs estimates that 90 percent of the dangerous drugs in the illicit market are diverted, intentionally, or unintentionally, from licensed sources.⁴⁷ Opportunities for diversion appear to be endless and nursing homes can provide an inviting target.

While theft of narcotics is not unheard of in nursing homes, the primary targets for theft are amphetamines and barbiturates:

With the development of the drug culture in our society, drug control problems have shifted from the narcotics and medications with high alcoholic content to the amphetamines and other stimulants, and to both the barbiturates and non-barbiturate sedatives. To a lesser degree, tranquilizers and the newer synthetic analgesics are now sought by those who experiment with and use drugs.⁴⁸

Congress passed, in 1965, the Federal Drug Abuse Control Amendments (known as the Harris Law)⁴⁹ in an attempt to curb the illicit distribution of amphetamines and barbiturates. Commenting on this law, the July 1966 edition of *Nursing Home* magazine reported its concern about possible diversion of nursing home drugs:

The immediate effect will result in more drugstore break-ins and more addicts seeking loosely controlled outlets, such as nursing homes for their source of supply.⁵⁰

Medicare and Medicaid regulations⁵¹ require that narcotics, barbiturates, amphetamines, and other dangerous drugs be kept under "double" lock in nursing homes. In other words, these drugs must be kept in a separately locked, securely fastened box or drawer within the medications cabinet (or room) which is also locked. Unfortunately, this regulation is often ignored and poorly enforced. In far

⁴⁵ See source cited in footnote 44. See also "Unit-Dose Packaging Spurs Optimum Therapy in 'Project ECE'", by John L. Rawlings and Donald R. Mathieson, *Pharmacy Times*, vol. No. 36, October 1970, pp. 50-56.

⁴⁶ Page 1801, part 17, hearings cited in footnote 14.

⁴⁷ "Efforts to Prevent Dangerous Drugs From Illicitly Reaching the Public," U.S. General Accounting Office, April 17, 1972, p. 1.

⁴⁸ See appendix, p. 6, p. 313.

⁴⁹ Drug Abuse Control Amendments of 1965. See appendix 6, p. 312 for details of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

⁵⁰ *Nursing Homes*, July 1966, p. 30.

⁵¹ See p. 274 for more details.

too many homes, access to medications and the narcotics cabinet is readily available to unlicensed, untrained, and sometimes teenaged personnel.

Once again, the full flavor of abuse (this time, of drug theft and misuse) can best be provided by testimony and sworn statements. Here are some examples:

- One nurse, Mrs. Kay M. Schällberg, reported open access to narcotics, and flagrant examples of employee theft:

I was the only nurse on at night, and all the staff at this home had keys to the medicine room and to the narcotics cabinet. The medications room was never locked. All the aides had keys to this room. They never kept count of the narcotics in this home. They would borrow one narcotic prescription to replace another, and then they would never replace the one they borrowed from. Contrary to what law requires, this home did not destroy medications that belonged to patients who died. They kept them in a special cabinet.

There were aides who stole medications and food at this home. Two of these aides worked on my shift. One of them had an invalid husband at home who took a lot of drugs. I actually saw them take food and medications to put in their cars at night to take home. I reported this to Mrs. Bartley but she said to let it go this time. The second time I saw it happen an aide and I went out and asked if we could look through their car; they refused to let me. One of these aides was fired, the other still works there. They both had keys to the medications room and to the narcotics cabinet and they just helped themselves to what they needed.⁵²

- From another nurse, Mrs. Nancy Fox:

Phenobarbital is not kept under double lock. Old medications from patients who had died remain for months in the medicine closet. Phenobarbital is put, by an untrained aide before I get there on my workdays, on the tray of Mrs. . . . and she takes it herself without supervision. It has been found to return to the kitchen on her trav, and on the floor, because she has an uncontrollable arm, shaking most of the time. The medicine closet is located in the kitchen, right next to the mop and broom closet. The medicine trav is always dirty and covered with dust when I get to it, as it is kept on top of the ice box. There are often spilled medicines stuck to it.⁵³

- Theft in one Minnesota home caused some employees to leave their jobs. From orderly Robert Shypulski:

For as long as I can remember there have been medications missing. Very recently there has been missing a large amount of liquid chloral hydrate. Staff people have quit because of the mess in the medications room. They do not want to be responsible for all the things that are missing.⁵⁴

⁵² Pages 2334-35, part 19B, hearings cited in footnote 14.

⁵³ Page 2261, part 19B, hearings cited in footnote 14.

⁵⁴ Page 2340, part 19B, hearings cited in footnote 14.

- Mrs. Lola Finney, a nurse's aide from the same home stated :

What was supposed to happen as far as narcotics were concerned, was that the nurses were supposed to come upstairs and set up the narcotics and barbituates. Then we were supposed to pass them out. Of course no one could really check any of the aides in case they wanted to pocket some of the narcotics. We didn't get that kind of supervision. We also had the key to the narcotics cabinet all the time. It would have been very easy to steal narcotics. If you wanted to steal narcotics you wouldn't go to the narcotics cabinet. It was much easier to slip them into your pocket instead of giving them to the patient, and then tell the nurse that the patient took them. Mrs. O'Connell [the head nurse] at times would ask me to open up the narcotics cabinet and set them up when the nurse wasn't available. Anybody who had a key to the Medications Room had access to the narcotics cabinet and a lot of people had keys to that room. There were a number of times when narcotics were missing. One day we were informed that a whole bottle of Seconal tablets was missing on the 2nd floor.⁵⁵

- About the same home, Mrs. Lorraine Kippels, also a nurse's aide, explained the procedure for "borrowing" medications :

I was also told by Mrs. O'Connell [the head nurse] if I ran out of medications that she had some in her office. I have gone down to her office, she has opened the drawer and given me medications out of her desk drawer. There were medications from patients that had expired or had left the home. There were also salves from other patients in this drawer. We were also told if we had to borrow medications, to borrow from the welfare patients.⁵⁶

As these examples illustrate, a poorly controlled system of drug distribution in a nursing home can provide numerous opportunities for theft and misuse of drugs. As long as this kind of haphazard approach is permitted, and as long as untrained aides and orderlies are given the responsibility for passing medications, these abuses will continue.

C. THE HIGH INCIDENCE OF ADVERSE DRUG REACTIONS

A few years ago, Dr. Margaret Mead sounded a warning in testimony before a Senate subcommittee :

We should be thinking about the tremendous health hazards of mixtures of drugs, of drugs that are administered in ignorance of the idiosyncrasies of the patient, of drugs that are administered in ignorance of the foods that are incompatible with them.⁵⁷

This admonition has become all the more important in recent years. More and more physicians and pharmacists are turning their atten-

⁵⁵ Page 2254, part 19B, hearings cited in footnote 14.

⁵⁶ Page 2127, part 19A, hearings cited in footnote 14.

⁵⁷ "Competitive Problems in the Drug Industry," part 13, hearings by the Monopoly Subcommittee of the Select Committee on Small Business, 1969.

tion to the topic of adverse drug reactions. There is growing recognition of undesirable and toxic drug reactions that can occur, especially among the elderly, because of their reduced metabolic activity, altered central nervous system response, and reduced elimination of the drugs.

For these reasons, what should be a standard dose of medication for a middle-aged adult, might well be an overdose in an older person. Moreover, scientists have documented greater variability in response to drugs taken by the elderly. Results are not always as predictable in seniors. Similarly, the number and frequency of interactions and side effects for most drugs increase sharply with age. Edward S. Brady, associate dean, school of pharmacy, University of Southern California, wrote:

The usual action of certain drugs may be influenced by chronic disease status of older people. Hence, usual dosages might not be appropriate to this age group. For instance, in cases of impaired kidney function, the patient might not be able to excrete drugs from his system as rapidly as he should. Or, certain enzyme systems of the older person's body, affected by the slowdowns of aging, can greatly influence the results of drugs.⁵⁸

All of these problems are amplified when patients receive two or more drugs. The medical and pharmaceutical community is just beginning to learn that two drugs taken at the same time may nullify each other or produce harsh or unexpected results. In some cases, one drug will potentiate another (they interact with each other), so that the effect of the total is greater than the sum of the independent effects of either of the two substances taken individually.

Obviously, the more drugs taken at the same time the higher the chances of an adverse reaction. A patient taking five different drugs has a 5 percent chance of an adverse drug reaction. The odds increase to 45 percent when 20 drugs are taken.⁵⁹

Accordingly, nursing homes are the most likely place for adverse drug reactions. The patients have an average age of 82 and take from five to seven different drugs each day, some taken two and three times a day.⁶⁰ Some patients take 20 or more drugs in the course of a month. Often, these drugs are taken for long periods of time. Finally, nursing homes have comparatively few licensed nurses (80,000) out of their over 500,000 employees. Unlicensed personnel, aides and orderlies, are for the most part untrained and unable to identify adverse reactions or side effects.

There are some examples of common drug interactions:

- A most common interaction occurs between digitalis (a heart stimulant) and various kinds of diuretics (drugs increasing the output of urine). These drugs are commonly used in combination to treat congestive heart failure, a disease commonly present in the elderly. Many diuretics cause loss of potassium, increasing the toxic effect of digitalis on the heart. The usual result

⁵⁸ News release of University of Southern California, June 1, 1973.

⁵⁹ "Rx for Drug Safety," by David W. Hacker, *National Observer*, September 22, 1978, pp. 1 and 20.

⁶⁰ See source cited in footnote 3.

of this interaction would be heart rhythm irregularities which could result in death.⁶¹

- Warfarin (a blood thinner) interacts with aspirin. Aspirin acts to potentiate the anticoagulant action of warfarin. The clinical result of this interaction would be hemorrhage due to enhanced warfarin action.⁶²
- Furazolidone (an antibiotic) can be nullified by Benzedrine (an amphetamine or "upper") or various foods containing tyramine such as aged cheese, beer, or chicken livers.⁶³
- Aspirin can interact with alcohol leading to severe intestinal bleeding.⁶⁴
- Kanamycin and methicillin (two antibiotics) given simultaneously inactivate each other.⁶⁵
- Bisulfite, a preservative used to protect phenylephrine (an anti-histamine and decongestant) will slowly inactivate penicillin (an antibiotic).⁶⁶
- Tranquilizers potentiate sedatives and analgesics (sleeping pills and pain killers).⁶⁷
- Antacids (i.e., Maalox) can sufficiently lower the rate of phenobarbital absorption.⁶⁸
- Laxatives speed passage of drugs through the gastrointestinal tract reducing the amount of the drug which is absorbed.⁶⁹

A detailed—and poignant—illustration of drug interaction is provided by Paul Lofholm, assistant clinical professor of pharmacy at the University of California, San Francisco:

It is my experience, particularly in the nursing home area, that constipation is a problem not only because of the aging process, but also because the patient may be constantly bombarded by a number of constipating drugs. Here is a patient who fits a typical description: he is initially diagnosed as senile so is put on phenothiazine (tranquilizer) like Mellaril. A second drug, such as Elavil, is then added to his regimen perhaps because of depression. The patient has a little stomach problem, so donatal is added to take care of his stomach. In the meantime, drug-induced Parkinsonism occurs because of the administration of Thorazine or Stealazine or Permatil, or Prolixin. This necessitates the use of an anti-Parkinson drug, such as Artance. Also, antacids which can be constipating are concurrently administered because of GI (general intestinal) problems; and finally iron salts or various minerals may be prescribed which are also binding. Now let's examine the patients whole regimen. He is taking perhaps five or six or seven drugs which all have in common either a mineral effect or anticholinergic effect (an atropine-like side effect of constipation). Therefore, it is no wonder that the patient has difficulty, not because of his age, but also because

⁶¹ Letter from Frank J. Ascione, director, drug interactions evaluation program, American Pharmaceutical Association, to Val J. Halamandaris, August 28, 1974.

⁶² See letter cited in footnote 61.

⁶³ *Evaluations of Drug Interactions—1975*, American Pharmaceutical Association, 1975, p. 12.

⁶⁴ Pages 13-14 of book cited in footnote 63.

⁶⁵ *AMA Drug Evaluations 1971*, American Medical Association, Chicago, 1971, p. XIX.

⁶⁶ Page XIX, book cited in footnote 63.

⁶⁷ Page XIX, book cited in footnote 63.

⁶⁸ Page XIX, book cited in footnote 63.

⁶⁹ Page XIX, book cited in footnote 63.

of the pharmacologic paralysis that occurs in the lower gut. Now, the central question is: does the patient need all of these drugs? Is there any way we can reduce the number of drugs to minimize particular side effects? ⁷⁰

The dangers inherent are all the more apparent after a quick look at the classes of drugs most commonly received by nursing home patients and their possible effects. The following excerpts are taken from the American Medical Association Drug Evaluation Guide. As indicated, adverse reactions may be as mild as a headache or nausea, or as serious as convulsions and death.

DIURETICS (EXAMPLES: DIURIL, OSMOTROL, LASIX)

These drugs are used to reduce the volume of extracellular fluid in order to eliminate edema (excessive accumulation of fluids) or prevent its developing. Adverse reaction may be either mild or dangerous: from headaches and nausea to dehydration and convulsions.⁷¹

SEDATIVES (EXAMPLES: SECONAL, NEMBTAL, CHLORAL HYDRATES)

When administered by day, and in small doses, sedatives may reduce emotional tension; in larger doses they induce sleep. Patients taking these drugs may show signs of lethargy. Prolonged use can lead to addiction, which the AMA drug guide notes "is more destructive to personality than narcotic dependence." Overdoses can result in death. Other drugs taken at the same time will increase the potency of sedatives, among these are alcohol, antihistamines and other central nervous system depressants.⁷²

ANTI-ANXIETY AGENTS (EXAMPLES: VALIUM, LIBRIUM, MILTOWN)

These drugs are used to suppress less severe manifestations of anxiety and tension. Adverse effects may include dizziness, impaired memory and judgment. Some patients evidence paradoxical reactions; rather than becoming quiet, the disturbed patient becomes more violent. Addiction may result from the prolonged use of such agents and withdrawal symptoms may be severe (delirium and convulsions) when the drugs are terminated.⁷³

ANTI-PSYCHOTIC AGENTS (EXAMPLES: THORAZINE, MELLARIL, SPARINE)

These drugs are useful in the treatment of acute and chronic psychosis. Ethical practice limits their use to relieve symptoms of mental illness or to alleviate delirium in individuals when anti-anxiety agents have failed.

⁷⁰ Page 12, book cited in footnote 3.

⁷¹ Page 43, book cited in footnote 65.

⁷² Page 215, book cited in footnote 65.

⁷³ Page 224, book cited in footnote 65.

Paradoxical reactions are not uncommon with these drugs and great care must be used in the dosage levels employed. These drugs may produce Parkinsonian syndrome (tremors, shuffling gait, excessive salivation, mask like faces); they may produce tardive dyskinesia, characterized by rhythmic movements of the tongue, jaw, and face which persist even after the drug is discontinued. These drugs should be given with great care to heart patients because they may cause arrhythmias of the heart (erratic heartbeat), myocardial infarction (a type of heart attack) and death.

The AMA guide notes that the elderly are particularly susceptible to the detrimental side effects of antipsychotic agents. Good medical practice requires that their use be strictly time-limited and episodic, and that they be used as an adjunct to getting at the cause of the patient's agitation.⁷⁴

Letters such as the following provide additional information:

DTEC, INC.,
MEMPHIS, TENN., *November 25, 1974.*

HON. FRANK E. MOSS,
Senate Office Building, Washington, D.C.

DEAR SENATOR MOSS: I must say that I heartily agree with your findings in nursing homes. We are a small group of physicians, clinical pharmacologists-pharmacists, and physiologists who have a small corporation, DTEC, Inc., which provides drug consultation services to nursing homes and hospitals in Tennessee. We nearly always find greater than 50% of the people in nursing homes are taking drugs which potentially interact and are subsequently quite dangerous. The Tennessee Medicaid Division has endorsed our services and will reimburse any nursing home who desires to take advantage of our program. We feel that much can be accomplished in this area to eliminate at least one bad problem, that of adverse drug effects and drug interactions.

May we offer you a sincere congratulations on a job well done with your straight forward presentation of the problems.

Sincerely,

DR. JAMES H. COLEMAN.

The following table provides additional details:⁷⁵

⁷⁴ Page 232, book cited in footnote 65.

⁷⁵ Page 49-50, book cited in footnote 3.

DRUGS WHICH INFLUENCE THE BEHAVIOR IN THE ELDERLY: PROMISES, PITFALLS, AND PERSPECTIVES

(By Eric Pfeiffer, M.D. *)

Type of Drug	Useful in	Adverse effects
A. Antidepressants imipramine (Tofranil) desipramine (Norpramin, Pertofrane) doxepin (Sinequan) amitriptyline (Elavil) nortriptyline (Aventyl)	Depression and depression with anxiety	delirium psychosis hypotension cardia arrhythmia dry mouth agitation mania
B. Major Tranquilizers chlorpromazine (Thorazine) thioridazine (Mellaril) haloperidol (Haldol)	paranoia agitation	drowsiness delirium hypotension Parkinson like syndromes
C. Minor Tranquilizers/Sedatives chlordiazepoxide (Librium) diazepam (Valium) meprobamate (Equanil, Miltown)	anxiety reaction transient situational reaction	delirium equilibrium disturbance habituation addiction withdrawal
D. Hypnotics chloral hydrate (Noctic) barbituates ethchlorvynol (Placidyl) methyprylon (Noludar) flurazepam (Dalmane) methaqualone (Quaalude)	anxiety reaction transient situational reaction other sleep disturbances	delirium habituation addiction withdrawal suicidal tool
E. Stimulants and/or adjuncts methylphenidate (Ritalin) amphetamines		hyperstimulation habituation addiction
F. Lithium Salts lithium carbonate (Eskalith)	mania	lithium toxicity
G. Useful perphenazine amitriptyline (Triavil)		
H. "Supportive Medication" Placebo	hypochondriasis	none

*Professor of Psychiatry, Duke University School of Medicine.

In short, drugs have the potential for harm as well as for good. Their use needs to be carefully controlled and managed. The elderly, and particularly those in nursing homes, present special problems. Because of the large number of different drugs taken over protracted

periods of time and the lack of personnel trained to deal with untoward effects, thousands of patients in long-term institutions are prime candidates for adverse reactions.

The full effect of this problem has yet to be determined in nursing homes but hospital studies provide this lesson: Despite strict hospital controls and the presence of trained personnel, 15 to 30 percent of patients have one or more drug reactions during hospitalization. Drug misadventures cause a total of 30,000 deaths annually, and the cost of drug induced hospitalization approximates \$3 billion a year.⁷⁶

D. DRUG ADDICTION AMONG NURSING HOME PATIENTS

Most nursing home patients receive drugs over a protracted period of time, sometimes months and years. If a patient is taking narcotics, sedatives, antidepressants, or tranquilizers, there is a good possibility of his developing addiction. The more technical name for addiction is psychic or physical dependence on drugs. Such "dependence" or "addiction" is characterized by withdrawal symptoms (when the drug is taken away) which can be moderate to severe. In some cases, removal from a drug can cause delirium and convulsions.

There are occasional references in the subcommittee's hearings to the problem of drug addiction among the elderly in nursing homes. E. C. Morris, executive director, Planned Action for Community Elderly, Des Moines, Iowa, testified:

If I could have my files here and show you documented files—giving you as one example a man who was 94 years old, whose wife was 92. These two people were in our local hospital, under Medicare. . . . Now, I am a former administrator of Medicare in the Public Health Service. I know a little something about it. The lady passed away 3 days after I was appointed by the courts as their guardian conservator.

We removed the gentleman; put him in a nursing home, and in 4 months' time this man's drug bill went from \$20 to \$104—\$104 a month for drugs.

We put him in another local nursing home—and for 3 weeks this man had to be held in restraint for drug removal. Today, I pay anywhere from \$16 to \$18 a month for his drugs.⁷⁷

There is no question that many of the drugs commonly administered in nursing homes have, at least, the potential of addiction as an adverse side effect (see chart on page 264). One doctor, who is also the executive director of a nursing home, has written:

Many of these elderly people are dependant, if not truly addicted, on the medications that they are taking; this is easily verified by observing the patient when the doctor suggests discontinuing medications.

. . . We inform the elderly applicant prior to their arrival at the home that . . . we want to see how these old people fare without the ingestion of their multitudinous drugs. . . . *This*

⁷⁶ Page 1, book cited in footnote 3.

⁷⁷ "Evaluation of Administration on Aging and Conduct of White House Conference on Aging", part 4, joint hearings by the Special Committee on Aging and the Senate Committee on Labor and Public Welfare, Washington, D.C., March 31, 1971, p. 246.

is one of the few available opportunities we have for really "drying" them out. I think that the popularity of our institution is really due in part to just that fact. (Emphasis added.) Our clients really do seem to flourish. . . . I think that's why we are one of the few homes for the aged which actually does graduate some of its residents back to society after they have been "dried out" for several months, or perhaps a year.⁷⁸

While the suspicion lingers that addiction among elderly nursing home patients is more frequent than anyone would care to imagine (because of the huge volume of drugs with addictive potential taken by nursing home patients for protracted periods of time), there is little hard evidence. Without doubt, the problem of addiction to drugs among nursing home patients needs much more attention than it is receiving today.

Perhaps part of the reason this question has not been brought into sharper focus is the attitude of some professionals. The Nader Task Force report stated:

One California physician, when told of an elderly lady's addiction to a painkiller Percodan replied: "She is an old lady, let her enjoy it."⁷⁹

Examples of addiction in the elderly raise serious moral and ethical questions which should be faced head on and should not be swept under the rug of complacency.

E. DRUG EXPERIMENTS IN NURSING HOMES

In the normal course of developing new drugs, some experimentation with human beings is required. It is not uncommon for this type of experimentation to take place in nursing homes.

The nursing home atmosphere provides many advantages for this type of experimentation. Some of the advantages include:

(1) The afflictions and infirmities which drugs are supposed to cure or treat abound in such facilities.

(2) Patients tend to be long-term so that results can be carefully monitored.

(3) Experimental variables can be more easily controlled.

Testing of investigational drugs in nursing homes should not necessarily be discouraged (especially if such testing will lead significant advances in understanding the effects of drugs on the elderly). However, experimentation in nursing homes should be permitted only under the strictest of controls. Nursing home residents are powerless and must look to others for their protection. Many cannot make their own decisions and in fact, a third or more of today's million nursing home patients have no relatives to assist them. More importantly, drug companies and others are aware of poorly controlled system of drug distribution in nursing homes. This atmosphere is inviting to drug manufacturers, who are anxious to complete tests for new drugs with a minimum of interference or delay.

The subcommittee has great misgivings about the absence of existing safeguards with respect to investigations generally and specifically

⁷⁸ Page 54, book cited in footnote 3.

⁷⁹ Page 191, report cited in footnote 30.

in nursing homes. There are some 6,000 so-called investigational drugs being tested today.⁸⁰ Under the Food and Drug Administration's (FDA) rules, a company is free to begin tests in humans subject to FDA veto, 30 days after notifying the agency of its intention. In practice, the FDA permits clinical testing to begin in humans after only 2 weeks of animal studies—and before those animal studies have been evaluated.

These facts and others came to light in a September 1973 report by the General Accounting Office which charged that the FDA had failed in its efforts to protect patients in whom medications were being tested for safety and effectiveness. Senator Abraham Ribicoff who released the report, charged that pharmaceutical companies had failed to establish safe testing procedures and had resisted FDA regulation.⁸¹

The GAO provided startling examples where several pharmaceutical companies had failed to notify the FDA after learning that people were exposed to drugs which caused adverse reactions in animals. Time lags in giving FDA crucial data ranged from 1 month to a year and a half. In one case, Ayerst Laboratories waited 19 months between the completion of a British study showing possible cancer in mice given its experimental drug Pronetholol and submission of the study to the FDA. In another case, GAO charged that the company had refused to inform the doctors conducting the tests in humans, of tests showing cancerous tumors in animals. Ayerst also disregarded three FDA orders to halt testing of its experimental drug, Practolol. In yet another case, E. R. Squibb and Sons halted tests on 324 patients receiving Cinanserin (once described by a Squibb executive as a drug looking for a condition to treat), after liver tumors developed in long-term tests with rats, but Squibb refused to undertake patient follow-up.⁸²

The GAO study has relevance in the nursing home context as well. The subcommittee has received several complaints charging improper controls. Most of these involved the question of "informed consent": Was the patient capable of understanding the situation and did he knowingly give permission?

One case received by the subcommittee involved the drug "Anavar" (developed by G. D. Searle and Co.) in which the patient's informed consent was established by an "X" on the consent statement.⁸³

Ralph Nader and his Task Force on Nursing Homes investigated the case in some detail. Testifying before the subcommittee in December of 1970 they said:

Drug companies frequently carry out experimental drug research on nursing home patients. One woman's report of an experiment involving her mother is a striking example of the opportunities for abuse that can occur. The case is unusual only in that the family of the patient made exhaustive inquiries following her death and found that no one—the Government, the attending physician, or the home—was adequately protecting the patient.

⁸⁰ "Ribicoff Hits FDA Laxity in Human Testing of Drug Safety," *Washington Post*, September 24, 1973, p. 48; see also "Lax Control Seen in Drug Testing," *New York Times*, September 23, 1973, p. 20.

⁸¹ See articles cited in footnote 80.

⁸² See articles cited in footnote 80.

⁸³ In subcommittee files.

Unknown to the family (the daughter had expressly told the attending physician not to allow her mother to be given experimental drugs), the nursing home and attending physician approved the patient, among others, for the experiment. The patient's "consent" was gained; she marked an X on a consent statement.

After taking the drug for about 6 months, the patient became critically ill. Medical diagnosis never confirmed the cause of the illness; no move was made to find out whether the experimental drug had caused or contributed to the illness; the drug continued to be given.

Two months later, the woman died. Both the home and the coroner who filled out the death certificate refused to tell the family exactly how or why the woman died. The home has refused to release the woman's medical records to her family.

The family did obtain a record of the drugs given the patient and discovered that she was taking an experimental drug. When they demanded to know why they had not been consulted, the home produced a "consent" document marked with the patient's X. The patient had been judged senile by her doctor who recommended that she live in an institution. Nonetheless, the home maintained and the FDA concurred, that the "consent" of a person medically diagnosed as senile was sufficient.

The family further discovered that the woman's doctor believed the drug was given as already approved and not as an experimental drug. He, therefore, made no attempt to see whether the drug was having ill effects on the patient. In this case, according to the daughter, certain allergies and an edema condition made it possible that the drug could have been highly dangerous for her mother.⁸⁴

The Anavar example points out clearly the need for the FDA to exercise particular vigilance in the case of drug experimentation with nursing home patients. The FDA should require a strict standard of consent where the infirm elderly are involved and pharmaceutical companies should be held accountable for the well being of these patients.

F. THE "CHEMICAL STRAIGHT JACKET"

Perhaps the most common and most devastating consequence of present inefficient drug distribution systems is the overuse of tranquilizers. Tranquilizers go by many names. Those most commonly used in nursing homes are called psychotropic drugs or antipsychotic agents; sometimes they go by their chemical name, phenothiazines, or butyrophenones. Their proper use is to modify psychotic symptoms (mental illness) for purposes of decreasing aggressive or overactive behavior.

The report of the Nader Task Force on Nursing Homes charged that tranquilizers were given to patients largely for staff convenience. They testified:

⁸⁴ Page 892, part II, hearings cited in footnote 14.

In perhaps 50 percent of the letters we received there was mention of patients being put under sedation for no other reason than to simply keep them quiet and out of trouble.⁸⁵

This charge should not be surprising in view of claims made by manufacturers on behalf of such products. For example, Sandoz Pharmaceuticals, in their advertisements for the tranquilizer Mellaril, claims that the "far-reaching" effects of this drug will benefit the staff who will "find their work load greatly lightened as patient demands are replaced by a spirit of self-help and self-interest."⁸⁶

In 1970, Nelson Cruikshank, president of the National Council of Senior Citizens, called upon Congress to investigate the "dangerous use of tranquilizer drugs on elderly nursing home patients simply to pacify them." He said:

Excessive use of tranquilizers can quickly reduce an ambulatory patient to a zombie, confining the patient to a chair or bed, causing the patient's muscles to atrophy from inaction and causing general health to deteriorate quickly.

Conscientious doctors may use tranquilizer drugs in a carefully administered program to help genuinely disturbed patients. However, it appears that many doctors, who are less than conscientious, give blanket instructions to nursing home staffs for the use of tranquilizer drugs on patients who do not need them.⁸⁷

In response, Senator Moss asked for a full investigation of the use of tranquilizers in nursing homes. He requested an audit by the U.S. General Accounting Office (described previously)⁸⁸ which was released at the subcommittee's September 1971 hearing in Chicago, Ill.

This audit confirmed beyond any doubt that enormous amounts of tranquilizers flow into U.S. nursing homes each year. Painkillers, tranquilizers, and sedatives accounted for almost 40 percent or \$120 million of the Nation's \$300 million nursing home drug bill. Tranquilizers themselves made up almost 20 percent of these drugs for a total of \$60 million a year. It is worth restating that 10 percent of the total nursing home drug bill (or \$30 million a year) goes to pay for the two strongest tranquilizers available, Thorazine and Mellaril.

Expressed in different terms, \$60 million spent for nursing home tranquilizers each year works out to an average of \$60 per patient per year for tranquilizers. There are certainly many legitimate uses of tranquilizers, but the sheer volume that has been documented creates at least the inference that some are given without proper controls.⁸⁹

William R. Hutton, executive director of the National Council of Senior Citizens, testifying at the Chicago hearing, charged that the overuse of tranquilizers is more fact than inference, and provided several examples:

It is the firm belief of the National Council of Senior Citizens, based on letters and phone calls from members and the public, that the unwarranted use of tranquilizer drugs in

⁸⁵ Page 883 of hearings cited in footnote 14.

⁸⁶ Advertisement reprinted at p. 277 *supra*.

⁸⁷ *The Machinist*, December 3, 1970, p. 2.

⁸⁸ See *Congressional Record*, September 13, 1971, p. S14170, for details on chronology.

⁸⁹ Press release from Senator Frank E. Moss, April 26, 1972.

nursing homes is far more widespread than has been generally realized.

Below are some recent complaints to the National Council of Senior Citizens headquarters regarding abuse of tranquilizer drugs in nursing homes across the United States.

—Mrs. J., Syosset, N.Y.—My brother—he's 63—had a stroke that paralyzed an arm and leg. I looked after him a while and he was always bright and cheerful. Finally, he entered a nursing home and, whenever I go to see him, he's either sleeping or acts half-asleep. I suspect they give him drugs to make him sleep a lot.

—Mr. T., Kansas City, Mo.—My mother is in a nursing home because she broke her hip and needs special care. I realize it's hard for her to get around but she acts like she's half dead. She tells me the medicine they give her makes her that way.

—Mrs. L., Los Angeles, Calif.—I would like to do something to help my mother who is 73. She has arthritis and has had to go to a nursing home. Ever since she went there, she acts like she's doped and I am afraid they keep her that way because then she doesn't need so much looking after.

Positive treatment leading to rehabilitation and the patient's return to the mainstream of society should be the goal of the nursing home.

If the nursing home patient receives little or no positive remedial care but instead is kept in a comatose state with tranquilizer drugs, this makes the nursing home a warehouse for the dying.⁹⁰

At the same hearing, Senator Charles Percy pointed out that bed-bound patients bring the highest rate of reimbursement under the Illinois public assistance program. He explained the operation of the Illinois system to the British expert, Dr. Lionel Z. Cosin. In Illinois, each individual patient is assigned points on the basis of his disabilities. Each point is worth \$6; the more points the greater the monthly reimbursement to the nursing home. Patients left sitting in their own waste who become bellicose can be labeled "behavior problems" which is worth 8 points at \$6 a point or \$48 more per month to the operator. Behavior problems require daily injections of a tranquilizer such as Thorazine which is another 6 points or \$36 more per month. Patients taking large quantities of tranquilizers run a high risk of developing bedsores which are also worth 8 points or another \$48 more a month to the operator. Senator Percy concluded: ". . . There is an incentive to keep patients in bed rather than get them out and rehabilitate them."⁹¹

Dr. Cosin responded: "I can't agree with you more, Senator. I think there is a gross overuse of drugs. I think there is a failure on the part of internal medicine to identify problems which result in disturbed behavior in elderly patients." He continued, suggesting that with proper diet and environment, the disturbed patient can be calmed down. He noted the deterioration of patients exposed to tranquilizers adding: "In fact, I think there is a good case for giving tranquilizers to the staff and leaving patients alone."⁹²

⁹⁰ Pages 1424-25, part 15, hearings cited in footnote 14.

⁹¹ Page 1388, part 14, hearings cited in footnote 14.

⁹² Page 1388, part 14, hearings cited in footnote 14.

THE INDUSTRY RESPONSE

A stern rebuttal to the charges made at the Chicago hearing was provided by A. B. Magnus Jr., administrator of the Magnus Farm in Arlington Heights, Ill.

Mr. Magnus—writing in the March 1972 issue of *Nursing Homes*, the official publication of the American Nursing Home Association, said that it was “astounding” that such assertions could be made on “hearsay” evidence.

He argued:

The use of tranquilizers as “chemical straitjackets” to make more money for the owners could not occur for two principal reasons. The first is that the practice would be counterproductive, i.e., it would actually increase operating costs; and second it would involve the participation of too many licensed professionals. Unauthorized use of tranquilizers, and all ethical drugs is a criminal act. Adequate legal safeguards exist.⁹³

He also questioned whether “people representing at least five licensed health care professions would be party to a conspiracy or remain silent in the face of such an obvious situation as an institution full of drugged or semiconscious patients.”⁹⁴

Still the question remains: Are tranquilizers being administered indiscriminately, to make it easier on the staff?

The data assembled by the subcommittee suggests the answer is affirmative. Given the shortcomings in control of nursing home drugs and the fact that unlicensed and untrained personnel have wide access to nursing home drugs, it could hardly be otherwise. The present system of drug distribution provides a ready supply of all drugs, tranquilizers in particular, which are paid for by the Government. Nursing personnel are not adverse to borrowing drugs from one patient for another. Neither physicians nor registered nurses are present in sufficient numbers to prevent this practice.

In order to accumulate more precise data on this question, the subcommittee structured its November 1971 hearings in Minnesota with the aid of the Minneapolis Age and Opportunity Center (M.A.O.).

The hearings was based on over 50 sworn affidavits from nursing home personnel, prepared by the legal staff of M.A.O. The subcommittee hearings proved conclusively that unlicensed aides and orderlies have ready access to the medications and narcotics in many nursing homes. Nursing home personnel in their testimony, reported indiscriminate tranquilization of patients to keep them quiet. The following are examples taken from evidence presented to the subcommittee:

- From nurse's aide Barbara Lace:

There is a heavy use of tranquilizers on our floor. We had a discussion about this once and I got kind of angry and told the nurse. There have been times when they woke the patients in

⁹³ “Are Tranquilizers Used as Chemical Straitjackets?” *Nursing Homes*, March 1972, pp. 24–28.

⁹⁴ See article cited in footnote 93.

order to give them tranquilizers so that the patients would stay out of their hair. By keeping the patients drugged up, they are being turned into vegetables. Many of these patients are having psychological problems that are not being treated. They are medicated so that we don't have to deal with them.⁹⁵

- From licensed practical nurse Kay Schallberg:

This nurse would also deliberately increase the dosage of a sedative much higher than the prescription in order to quiet down patients, but then she would put on the chart that she had administered the required dosage. She would take sedatives from the prescriptions of other patients in order to do this.⁹⁶

- From orderly Robert Shypulski:

Tranquilizers are used for everything. X was great for using tranquilizers. If you moved a muscle you got it. You could have dropped some of these people off of the building and they wouldn't have blinked their eyes. It doesn't phase them anymore. We either posey (restrain) them or let them walk.⁹⁷

- In presenting this information to the subcommittee, Mrs. Daphne Krause, executive director of M.A.O., told of her 6-year investigation of nursing homes in Minnesota, testifying, from her experience, that indiscriminate tranquilization was common practice. She said:

For the beleaguered nurse's aide, tranquilizers are a happy solution. If patients are sedated, they cause the staff few problems. The administrator is happy, too, because bedbound patients bring the highest rate of reimbursement.⁹⁸

The specter of unlicensed aides and orderlies prescribing tranquilizers on their own initiative is nothing short of hair-raising. Unfortunately, existing Federal regulations implicitly, if not directly, sanction the practice. Present Federal standards no longer restrict drug distribution in nursing homes to licensed personnel, as was the Medicare-Medicaid standard until January 1974. The decision to allow unlicensed personnel to set up and pass medications was made by HEW as part of their unification of Medicare and Medicaid standards, and was made in the face of strong protest by the subcommittee and despite seeming agreement by one administration spokesman.

At the subcommittee's October 1973 hearings, HEW Assistant Secretary Charles Edwards seemed convinced, possibly because of subcommittee insistence, on the use of licensed personnel. He said:

Furthermore, nursing personnel less qualified than a registered nurse are not capable of recognizing many sudden, subtle, potentially dangerous changes, that can take place in an ill patient, nor are they prepared to exercise the judgment necessary to respond appropriately in any number of patient crises.⁹⁹

⁹⁵ Page 2309, part 19B, hearings cited in footnote 14.

⁹⁶ Page 2335, part 19B, hearings cited in footnote 14.

⁹⁷ Statement by orderly Robert A. Shypulski to Associate Counsel, Val J. Halamandaris.

⁹⁸ Page 2096, part 19A, hearings cited in footnote 14.

⁹⁹ Pages 2721-22, part 22, hearings cited in footnote 14.

The Assistant Secretary's reference to adverse reactions is particularly appropriate in the context of tranquilizers which are powerful drugs with dangerous side effects. Many experts have emphasized the seriousness of some of these side effects which include: (1) a predisposition to accidents, (2) apathy, (3) confusion, (4) drooling of the mouth, and (5) difficulty in swallowing.¹⁰⁰

Dr. Victor Kassel, told the subcommittee that the combination of the tranquilizer and encephalopathy (brain disease or damage) eventuates in pseudo-bulbar palsey, followed by aspiration pneumonia and sudden death.¹⁰¹

Other writers have indicated the magnitude of the problem; some 16 percent of the patients in a study on one State hospital geriatric ward had side effects from tranquilizers. The study concludes that at least 20 percent of all admissions to geriatric wards "are precipitated by the adverse effects of psychoactive drugs (tranquilizers)."¹⁰²

Another study lists the following as common side effects from psychotropic drugs:

(1) **Akathisia:** This disorder is more common in the middle aged population and tends to onset days to months following the initiation of phenothiazine therapy, with women predominating over men in many series. It is characterized by continuous agitation or restless activity of the face and extremities with inability to sit or be still. It may closely simulate the picture of early Huntington's Chorea. Frequently the features of buccolingual dyskinesia may be associated with the generalized restlessness.

(2) **Buccolingual dyskinesia:** This has frequently been referred to as the classical form of phenothiazine dyskinesia. Features include chewing and mouthing movements, lip smacking, licking of the lips, increased blinking and grimacing, and continuous aimless movements of the tongue. Here, too, a more elderly population is affected, but the symptoms tend to onset or be aggravated following cessation of phenothiazine therapy.

(3) **Dystonia:** This group of patients has several distinctive features, including relatively young age and rapidity of onset of dyskinesia early in the course of drug therapy. Males predominate. The movements consist of various attitudes of tongue-face-neck posturing, including retrocollis and torticollis. Tonic or clonic twitching of shoulder girdle muscles may be noted. Prolonged tonic contraction of the involved muscles produces a variety of bizarre clinical pictures.

(4) **Pseudo Parkinsonism:** The most readily recognized of the syndromes, this is characterized by rigidity, resting tremor, loss of associated movements, mask-like faces, increased salivation, seborrhea, and a shuffling, festinating gait. The older patient is more vulnerable, and organic brain disease of diverse etiology may be predisposing. A majority of patients given phenothiazines will exhibit this syndrome to a variable degree, the symptoms usually making their appearance within a few weeks of therapy.

¹⁰⁰ "The Nurse's Role in the Administration of Medications in the Nursing Home Setting," paper presented by Sister Erika Bunke at the annual convocation of the American College of Nursing Home Administrators, Ellenville, N.Y., November 15, 1972.

¹⁰¹ Utah Report on the White House Conference on Aging, Utah State Division on Aging, May 1971, p. 8.

¹⁰² Fann, William E., and Maddox, George L., *Drug Issues in Geropsychiatry* (18 Contributors in a Conference on Psychopharmacology and the Management of the Elderly Patient, Center for the Study of Aging and Human Development, Duke University, June 1973), p. 19.

(5) **Choreoathetosis:** A more distinct choreiform or athetoid movement disorder has been reported in a minority of patients.¹⁰³

The AMA drug evaluation guide suggests great caution in the use of the most powerful and most used tranquilizers, Thorazine, Mellaril, Sparine, and other so-called antipsychotics. It warns of several severe side effects, and notes that it is important to recognize these side-effects because "acute encephalitis, meningitis, tetanus and other neurological disorders have been diagnosed erroneously," and patients have been treated for these conditions when, in fact, they have been suffering from tranquilizer side effects.¹⁰⁴ These warnings cast even greater doubts on the wisdom of funneling \$60 million in tranquilizers through the Nation's 23,000 nursing homes yearly.

But the great tragedy in the use of tranquilizers is that the most active and aggressive patients are the most likely to receive tranquilizers and yet, it is these patients who may have the best chance for rehabilitation. Elaine Brody and Morton H. Kleban of the Philadelphia Geriatrics Center in a study of mentally impaired elderly patients have written:

In an institutional setting, there is a tendency on the part of the staff to expect conformity and cooperation. The "well adjusted" people are usually those who meet those standards. Aggressive, managerial individuals elicit negative reactions from others and therefore tend to be regarded as maladjusted, "difficult," and inflexible.

Our data suggest very clearly that within this aggressive behavior is a force for self-improvement.¹⁰⁵

III. WHO IS RESPONSIBLE?

The responsibility for poorly controlled drug distribution must be shared by many. Each of the following play a part:

- (1) Federal policymakers who set and enforce national standards.
- (2) State officials who enforce Federal and State standards.
- (3) Pharmaceutical companies who manufacture the drugs.
- (4) Physicians who authorize the prescriptions.
- (5) Pharmacists who supply the drugs to the nursing home.
- (6) Nursing home administrators who supervise their employees.
- (7) Nurses who supervise drug distribution and sometimes administer them.
- (8) Aides and orderlies who all too often have the primary responsibility for drug distribution.

The errors and abuses described in this Supporting Paper are possible because nursing homes are isolated from the mainstream of society and the existing health care continuum.

A. THE EROSION OF FEDERAL STANDARDS

Medicare and Medicaid have been in operation for close to 7 years, and the Federal Government has gradually abrogated its responsi-

¹⁰³ Page 29, book cited in footnote 102, quoting J. Gordon Burch, M.D.

¹⁰⁴ Page 232, reference cited in footnote 65.

¹⁰⁵ "Report on Individual Treatment of the Mentally Impaired Aged, September 1967--September 1970", Philadelphia Geriatrics Center, February 1972.

bility for enforcing its standards. In the case of prescription drug practices, the States have been given greater and greater option to pharmacy regulations as they see fit.

What are the standards for nursing homes participating in either Medicare or Medicaid?

The existing standards are far from comprehensive but following are a few of the major requirements:¹⁰⁶

- Nursing homes that do not have their own pharmacists must secure the services of a consultant pharmacist. He is to provide training; to monitor drug administrations on a sample basis, to watch for possible adverse reactions and to help prevent waste and inefficiency.
- An emergency medication kit must be kept readily available.
- All medications administered to patients must be ordered in writing by the patient's physician. Oral orders must be given only to a licensed nurse, immediately reduced to writing, signed by the nurse and countersigned by the physician within 48 hours.
- The charge nurse and the prescribing physician together must review monthly each patient's medication.
- Narcotics, barbiturates, amphetamines and other dangerous drugs must be kept in separately locked securely fastened boxes or drawers within locked medicine cabinets.
- Each facility must comply with all Federal and State laws relating to narcotics and other drugs subject to the Drug Abuse Control Act of 1965.

With all of the abuses and errors described in this chapter one would assume that efforts to raise Federal standards would be underway. Just the opposite is true.

H.R. 1 (Public Law 92-603) in 1972 requested the unification of Medicare and Medicaid standards with the retention of the higher standard in every case.¹⁰⁷ Unfortunately, in the process HEW deleted the following important provisions:

- That all medication be administered by licensed medical or nursing personnel.
- That medication errors and drug reactions be immediately reported to the patient's physician and entry be made in the patient's clinical record.
- That up to date medical reference texts and sources of information be provided.
- That the label of each patient's individual medication container clearly indicate the patient's full name, physician's name, prescription number, name and strength of drug, date of issue, expiration date of all time dated drugs, and name and address and telephone number of the pharmacy issuing the drug.
- That medication of each patient be kept and stored in their originally received containers and that transferring between containers be forbidden.

¹⁰⁶ *Federal Register*, January 17, 1974, volume No. 39, No. 12, part 3.

¹⁰⁷ See Introductory Report, Part 4; see also *Developments in Aging: 1973 and January-March 1974* report by the Senate Special Committee on Aging, Washington, D.C., May 13, 1974, pp. 50-79.

- That medications having an expiration date be removed from usage and properly disposed of after such date.¹⁰⁸

Commenting in the magazine *Hospital Formulary Management*, George F. Archambault called the standards a "giant step backwards." He added, "We expect unpleasant case histories will emerge if the proposed conditions are adopted as written." The new standards were adopted as written on January 17, 1974.¹⁰⁹

B. STATE ENFORCEMENT OFFICIALS

As noted in Part 4 of the Introductory Report, enforcement of standards by the States has been both inadequate and haphazard.

State enforcement officials are required by law to enforce both their own standards and Federal Medicare and Medicaid standards. As noted in Part 4 of the Introductory Report, the enforcement of Federal standards has been less than satisfactory. The same is true with respect to State enforcement. All too often inspections are few and far between, States have inadequate number or poorly trained inspectors. Sometimes advance notice is given. All too often, responsibility for the enforcement of standards is fragmented between several State agencies and jurisdictions.

C. THE RESPONSIBILITY OF PHARMACEUTICAL COMPANIES

Pharmaceutical companies can be faulted first because of the limited research in geriatric pharmacology and psychopharmacology and to some extent for their advertising techniques.¹¹⁰

Drug companies tend to view the elderly as having the same strength and qualities of adult Americans. They seem to be oblivious to the fact that older Americans have: (a) Reduced metabolic activity necessitating lower doses; (b) an altered response of the central nervous system so that confusion is often associated with sedation; (c) a reduced rate of elimination which means that drugs are often retained in the body leading to overdoses; (d) impairment in the homeostatic mechanism; (e) greater variability in response to drugs than younger Americans.¹¹¹

At the same time, drug advertisements stress the social control potential of many drugs, thus appealing to the management needs and wishes of professionals rather than to the therapeutic needs of the elderly.¹¹² For example, an ad for the powerful tranquilizer, Mellaril, cites benefits for "the patient, the family, and to the staff." For the patient it suggests, "Mellaril can help reduce emotional distress and restore order—especially during that 'settling-in' period."

(See advertisement reprinted on opposite page.)

William R. Hutton, executive director of the National Council of Senior Citizens protested against similar ads for the tranquilizer

¹⁰⁸ Page 70, report cited in footnote 107.

¹⁰⁹ Editorial featured in September 1973 edition, p. 46.

¹¹⁰ "Improved Packaging and Dispensing Systems Could Reduce Medication Errors, Manufacturers and Pharmacists Agree," *Modern Nursing Home*, June 1972, pp. 23-24.

¹¹¹ See reference cited in footnote 100.

¹¹² See reference cited in footnote 9.

Why Mellaril is especially suited to the nursing-home patient



the patient

When behavior problems such as mental confusion, agitation, anxiety and insomnia disrupt the daily routine of the nursing home, administration of Mellaril can help reduce emotional distress and restore order - especially during the "settling in" period. More important, Mellaril achieves this with notably less extrapyramidal side effects and other serious untoward reactions than are sometimes encountered with other tranquilizing

agents. In difficult-to-manage patients, the most obvious changes include a calmer, more cooperative attitude, friendlier relations with fellow patients, increased interest in surroundings and fewer demands for special attention.

the staff

as a rule, benefits from this far-reaching effect of Mellaril since they find their work load greatly lightened as patient demands are replaced by a spirit of self-help and self-interest. In general, the overall nursing-home atmosphere remains relaxed and pleasant - a reflection of adjusted patients and efficient service. In most instances you will find that attending and visiting physicians are already aware of the advantages of Mellaril.



the family

usually develops a more positive attitude toward the nursing home since the noticeable improvement in the patient's condition tends to justify the family's decision to avail themselves of your services. Also, typically, visits are more cheerful, pleasurable meetings for both the family and patient.

INDICATIONS: Anxiety, tension and agitation in pediatric, adult, and geriatric patients. Psychomotor hyperactivity in psychotic patients.

CONTRAINDICATIONS: Severely depressed or comatose states; major degree of hypertensive or hypotensive heart disease; with or following recent use of MAO inhibitors.

PRECAUTIONS AND SIDE EFFECTS: From a clinical experience of more than ten million patients, it is apparent that Mellaril has a wide range of safety. Jaundice has not been observed. Drowsiness, dryness of the mouth, nasal stuffiness, skin disorders, nocturnal confusion, galactorrhea, amenorrhea, orthostatic hypotension, inability to ejaculate in the male, or pseudoparkinsonism may occur. Pigmentary retinopathy has been reported in doses in excess of 1600 mg. daily given over long periods of time. Leukopenia, agranulocytosis, photosensitization, and convulsive seizures are extremely rare, but are possible complications of all phenothiazine administration.

for moderate to severe anxiety

Mellaril
(thioridazine)



Valium at subcommittee hearings.¹¹³ Equally offensive are ads which promote drugs as the answer to anxieties occasioned by retirement.

(See advertisement reprinted, p. 282.)

One such ad says: "Since I retired I'm not sleeping. And I get tense during the day. My wife said, 'See the doctor.'—Tension and insomnia respond particularly well to SINEQUAN."

Even more serious are ads such as for Cerespan (papa verine HCL) which is promoted for angina pectoris (suffocating, painful contractions in the chest) and cerebral ischemia (deficiency in the supply of blood to the brain). The AMA drug evaluation guide comments that the drug is "useless in angina pectoris and of unproved value in cerebral ischemia" adding that this condition "might be worsened by the hypotension resulting from effective doses."¹¹⁴ Still the ad promises "benefits to all concerned" in relieving the symptoms of cerebral ischemia day and night for the patient; benefiting the staff by providing an "easier to manage patient" and benefiting the nursing home because a "less troublesome patient requires less nursing care."

(See advertisement reprinted, p. 283.)

D. PHYSICIANS

Supporting Paper No. 3 points out that only 13 of 104 U.S. medical schools has or was developing a program in which geriatrics is a specialty; that most medical schools provide little training in geriatrics or geriatric pharmacology and that physicians in general tend to avoid nursing homes feeling that their time is better spent with the younger members of society. Moreover, there are few continuing education programs in geriatrics for physicians and physicians cannot keep up with the literature on new drugs. This is significant in view of one study which found that 54 percent of physicians in all types of practice felt they had inadequate knowledge of drugs.¹¹⁵

E. PHARMACISTS

Medicare regulations for the last 7 years have required participating nursing homes to secure the services of a consultant pharmacist. Under the regulations, the pharmacist should work with the nursing home personnel to monitor drug administration, watch for adverse reactions, and provide training. In practice, this standard has never been enforced and very few pharmacists practice clinical pharmacy—that is, very few of them visit nursing homes to look at patients. Part of the problem is that the schools of pharmacy do not stress geriatric pharmacology or consulting pharmacy.¹¹⁶ In fact only 10 schools had such program on a regular basis.

As a result, the American Association of Consultant Pharmacists charges that 75 percent of U.S. nursing home patients do not receive adequate pharmaceutical services and drug controls.¹¹⁷

¹¹³ Page 1425, part 15, hearings cited in footnote 14.

¹¹⁴ Page 21, reference cited in footnote 65.

¹¹⁵ See reference cited in footnote 59.

¹¹⁶ Subcommittee questionnaire to 74 colleges of pharmacy, results reported in April 12, 1972, news release of American Society of Consultant Pharmacists.

¹¹⁷ Page 963, part 11, hearings cited in footnote 14.

F. ADMINISTRATORS

Because of a 1967 amendment introduced by Senator Edward M. Kennedy,¹¹⁸ nursing home administrators working in homes participating in Medicare and Medicaid must meet minimum Federal licensure requirements. This law, in effect, required the nursing home administrator to be a professional and consolidated in him the overall responsibility for the quality of care offered by the facility.

It is the administrator who most often sets the home's staffing policies. This decision can be critical. Professor Cheung's study at the University of Southern California School of Pharmacy, reported that homes with the highest ratio of registered nurses reported the lowest rate of drug error.¹¹⁹

At the same time nursing home administrators have not been anxious to hire consultant pharmacists—even though it is required by law. A recent article in *Nursing Homes* concerning lax drug control procedures in nursing homes states:

We can't let the administrator off the hook. Very often he is concerned with rebates, discounts or "kickbacks" because he does not understand how to use his consultant pharmacist.¹²⁰

Inevitably, nursing home administrators reply that it is all a question of money. State reimbursement rates are too low, they contend, making it impossible for them to pay for consultant pharmacists, or for the nursing personnel they would like to have. Others simply view these "extra" personnel as unnecessary.

G. NURSES

Some 70 percent of the medications in use today in hospitals and nursing homes were developed within the past 20 years. At the same time, many of the registered and licensed practical nurses who work in nursing homes completed their education 10, 15, or perhaps 20 years ago. The obvious conclusion is that many of today's nurses are not adequately informed about the effects of many pharmaceutical products offered to the patients.

Like physicians, nurses suffer from the lack of continuing education programs in geriatrics and from the general lack of emphasis on geriatrics and geriatric pharmacology in schools of nursing. Of the 1,072 schools of nursing polled by the subcommittee, only 27 reported what the subcommittee staff considered an effective program offering geriatrics as a specialty; and only 135 reported any connection with or services to nursing homes.¹²¹

A fundamental problem, of course, is the inadequate Federal standard which requires only one registered nurse (RN) 8 hours a day in Medicare-Medicaid's 7,300 skilled nursing homes. In the 8,500 intermediate care facilities under Medicaid, only one LPN for 8 hours a day is required (plus 4 hours of consultation per week with an RN). During the afternoon and evening shifts, the Federal standard re-

¹¹⁸ Public Law 90-248, Section 235; see Introductory Report, part 4.

¹¹⁹ See references cited in footnote 3.

¹²⁰ *Modern Nursing Home*, May 1971, p. 19.

¹²¹ See Supporting Paper No. 4.

quires only one licensed practical nurse in charge of each shift. This compares poorly with many State standards. Connecticut, for example, requires an RN for every 30 patients on the morning shift, one for every 45 on the afternoon, and one for every 60 on the evening shift.

As the name "charge-nurse" indicates, these nurses must supervise their fellow employees. However, analysis indicates that the nurses spend an alarming 54 percent of their time on nonnursing duties including administrative and clerical work, ordering supplies, preparing forms, and answering the telephone.¹²²

H. AIDES AND ORDERLIES

As noted above, aides and orderlies provide 80 to 90 percent of the care in today's long-term care facilities. These individuals are paid the minimum wage and are grossly overworked. Most have no previous experience and no formal training.¹²³

In the words of Senator Moss:

What can we really expect from unlicensed personnel who are hired in many cases right off the street? Personnel who are given the most difficult job in the world to do and are then paid only the minimum wage? I am grateful that many of these aides and orderlies come to the nursing home not for the money but because of their concern for the infirm elderly. These individuals deserve our respect. They also deserve higher wages. Respect and higher wages are the two elements that make any occupation desirable. With a greater share of each, I am sure that the 75 percent turnover rate in unlicensed personnel would be markedly reduced.¹²⁴

Unlicensed personnel are often given full or partial responsibility for administering medications. They are commonly given access to medication closets and to narcotics cabinets within them. These personnel open prescription containers, set up medication trays, and then distribute the drugs to the patients. It goes without saying that they have little knowledge of drugs, their possible side effects and adverse reactions.

Until this year, Medicare and Medicaid regulations did not allow unlicensed personnel to administer medications (this requirement was often ignored). Unfortunately, new regulations have weakened this standard. As of January 17, 1974, unlicensed personnel *may* administer medications if they have completed State approved training courses.¹²⁵

¹²² "Is There a Nurse Shortage?", *Nursing Homes*, August 1970, p. 17.

¹²³ Reference cited in footnote 84 notes that only 89 percent of the nursing homes surveyed provided in-service training programs for their personnel. For additional examples relating to the access of unlicensed personnel to medications (including narcotics) and the setting up and passing of medications in violation of Federal standards see: part 19B, hearings cited in footnote 14: Bozych p. 2238; Danielson p. 2242; Dhar p. 2244; Elyford p. 2245; Finney p. 2246 who commented she was given a short course in passing drugs just in case of emergency and the emergency started at once; also pp. 2253-4 and p. 2229; Fox pp. 2258, 2262; Gardas p. 2268; Heininger, p. 2276; Henry p. 2102; Kippels pp. 2127, 2219, 2220, 2269; Kleppinger p. 2306; Lace p. 2309; Marots p. 2318; Meyer p. 2323; Schallberg p. 2334.

¹²⁴ "Is the Quality of Care Adequate in Nursing Homes?", by Sen. Moss, *Bedside Nurse*, September 1972, pp. 11-16.

¹²⁵ See reference cited in Footnote 106; see also *Federal Register*, October 3, 1974, volume 39, No. 193, part II.

SUMMARY

In short, the causes for poor drug distribution are many. Clearly, responsibility is not limited to any one group or profession.

The Ralph Nader study group, in 1971, charged "widespread carelessness in the handling of drugs in nursing homes—drugs are administered incorrectly or not at all; drugs prescribed by physicians are allowed to continue too long, or too many drugs are prescribed, or drugs are administered that have not been prescribed by a physician."¹²⁶

This evaluation is likely to stand for some time to come unless strenuous efforts are made to deal with root causes.

A positive, and challenging, statement on the requisites for such reform was recently offered by Edward S. Brady, associate dean of the school of pharmacy at the University of Southern California:

Remedying the problem related to drug use by the elderly is not difficult if a few principles are taken to heart and a few simple practices are faithfully employed. For while the ultimate responsibility for medication rests with the physician, every person in health care service has a responsibility toward each patient's drug therapy. Physicians must be certain that their prescribing is rational and that their medication orders are obeyed. Nurses must follow a rational and logical system of drug administration, yet remain alert and sensitive to symptoms in the patient which may be induced by drugs. The pharmacists must observe the total utilization of drugs by the patient and question improper combinations and overutilization. All must have access to record systems which are complete, accurate and current. And the administrators of extended care facilities must see to it that their health workers have the time, facilities, and motivation to properly fulfill these functions.¹²⁷

¹²⁶ Page 191, reference cited in footnote 80.

¹²⁷ Pages 3 and 4, book cited in footnote 3.

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PART 2

NURSING HOME DRUG KICKBACKS: DISCOUNTS OR EXTORTION

In 1968, a report by the attorney general of California charged that it was common practice in that State for nursing homes to require pharmacists to pay back a certain percentage of the price of nursing home prescription drugs for the privilege of providing such services. The amount of the kickbacks ranged from 25 to 40 percent of the total price of the prescription drugs delivered to the nursing homes.¹²⁸

Nursing homes in California responded to the charge, saying that kickbacks did not exist, and further if they did exist to any extent, it was the pharmacist and not the nursing home operator who was responsible. Some nursing home operators did admit that they had received discounts based on the large quantities of drugs they purchased.¹²⁹

As a result of the California Attorney General's report, a State law prohibiting kickbacks was enacted.¹³⁰ However the charges against nursing homes continued. In 1970, representatives of the American Pharmaceutical Association charged flatly that kickbacks must be given in order to secure a nursing home account.¹³¹

In 1971, the subcommittee received a letter from an accountant who serves a chain of nursing homes in Illinois. This accountant implored the subcommittee to do something about kickbacks and provided the following assertions:

1. The pharmacies which supply these nursing homes have agreed to a "kickback" to the home which averages out between 25-30 percent on all prescription drugs delivered to the home.
2. A 50 percent across the board "kickback" is given by the pharmacies on all welfare prescriptions (prescriptions paid for in part by a third party).¹³²

The subcommittee began its preliminary investigation, which to some degree confirmed the charges of the accountant. The subcommittee also found that HEW had recognized the possibility for this kind of abuse in Illinois. The HEW audit agency noted in a recent audit of Illinois that the State's reimbursement formula for drugs could lead to high profits. Illinois will pay pharmacies their average

¹²⁸ "Report on the Medi-Cal Program by the California Department of Justice," Charles A. O'Brien, Chief Deputy Attorney General and Herbert Davis, Deputy Attorney General, reprinted in "Cost and Delivery of Services to Older Americans," Part 3, hearings by the Senate Committee on Aging, Los Angeles, Calif., October 18, 1968, pp. 811-836.

¹²⁹ The President of the California Association of Nursing Homes, at the time of their denial of the Attorney General's charges of rampant kickbacks between nursing homes and pharmacists, was Donald W. Gormley who later served as treasurer of the American Nursing Home Association. As reported in the *Los Angeles Times*, July 22, 1971, Mr. Gormley was indicted for fraud in "submitting false claims under the name of five dummy corporations. Legitimate fees were increased 25 percent as they passed through the skeleton corporation it is alleged," wrote the *Times*. See also *Modern Nursing Home*, May 1972, p. 79, which reports that Mr. Gormley was convicted of conspiracy and grand theft.

¹³⁰ Sections 650, 651 and 652 of the California Business and Professional Code, also section 1765 of title 16 of the California Administrative Code promulgated by the State Board of Pharmacy.

¹³¹ "Washington Pressures Nursing Home Industry Attempts to Shape Federal Health Programs," by Judith Robinson, *National Journal*, vol. 2, No. 27, July 4, 1970, p. 1421.

¹³² Letter in subcommittee files.

wholesale costs plus a profit of 30 percent, plus a constant factor of \$1.35 per prescription. This formula explained the possibility of a 50 percent kickback, but a wider study was needed.

In cooperation with the American Pharmaceutical Association, the subcommittee fashioned a questionnaire which was sent to every pharmacist in the State of California and to 200 more throughout the Nation. In the questionnaire the word "kickback" was defined as:

The practice whereby pharmacists are forced to pay a certain percentage of the price of nursing home prescription drugs, back to the nursing home operator for the privilege of providing those services.¹³³

The questionnaire was sent "blind," that is, no one needed to identify himself although many pharmacists took advantage of the opportunity to air their grievances. Some signed their names and some did not.

California was selected because of its long history with drug kickbacks and to test the effectiveness of the intervening State law prohibiting the practice. (Concurrently, the subcommittee continued its kickback investigation in Illinois with the aid of the American College of Apothecaries.)

In all, the questionnaire was sent to 4,400 pharmacists; 40 percent, or 1,792, were returned to the committee.

Of the 1,792 responses received, 326 or 18 percent stated they had never attempted to serve a nursing home.

Another 18 percent, 328, indicated that they had attempted to deal with nursing homes but were not approached for a kickback and did not believe the practice was widespread.

Some 383 pharmacists or 21 percent indicated they had tried to serve a nursing home, had not been approached for a kickback but had a positive belief that they were widespread.

The remaining 755 or 42 percent of the pharmacists indicated that they served nursing homes and that they had been approached for a kickback. Of these, 700 indicated that kickbacks were increasing, 51 indicated they were decreasing and 251 felt they were about the same.

In other words, 63 percent of all pharmacists responding indicated an actual experience or a positive belief that kickbacks were widespread.

Pharmacists projected \$10,363,000 in lost accounts from refusing to go along with kickbacks in 1971.

The average kickback was 25 percent, although some were larger. Postmarks identifying the State of Illinois among the 200 outside California, indicated generally higher kickbacks, but few as high as 50 percent.

But the pharmacists from all parts of the country did not limit their response to the questionnaire. Many provided the committee with written comments and with actual names of pharmacists and nursing home operators. In some cases they made incredible admissions relating to their participation in forced profitsharing, allegedly to secure and maintain a nursing home account.

¹³³ Report of the subcommittee's questionnaire detailed in speech by Senator Frank E. Moss before the American Society of Consultant Pharmacists, Chicago, Ill., October 1, 1972.

These admissions were made despite the fact that these practices are in violation of California law.

A few pharmacists accepted primary or joint responsibility for kickbacks. The following comments are typical: "The ethical pharmacists are not usually approached for a percentage kickback, most are prearranged by both sides." "In order to testify I would have to name the most important members of our association. Sorry, I'm too small now." "Not being a member of our profession, I would not expect you to know how we operate. It is not the nursing home that instigates the kickback but the hungry-for-business members of our own group. They are the ones who offer the nursing home the 'deal'."

Most of the replies the committee received are on the other side of the ledger. They charged that nursing home operators, driven by inadequate Medicaid reimbursement rates were resorting to any and all methods to pick up a few extra dollars. For their part the pharmacists recognized little difference between discounts, collection fees, and rebates. A few were willing to recognize discounts of 10 percent, or less, given for quantity purchasing or to have nursing home accounts paid within 30 days. But these discounts were recognized only if voluntarily given and if such discounts could be given without inflating the costs of drugs to private paying patients or to Medicare and Medicaid. From the pharmacist's point of view, a voluntary discount rarely happens. One pharmacist wrote: "I'm afraid to testify. My biggest account is a nursing home. If I lost this business, who will sustain me?"

Another said: "I own part of a nursing home and do not get any prescriptions from them, as I wouldn't kickback to them."

Still another commented: "In one pharmacy we served about 12 nursing homes. We were required to pay 25 percent to the operator of several of the homes and lost the business of three of them when we attempted to cut the kickback to 20 percent. The volume loss was in the vicinity of \$5,000 a year."

One pharmacist noted: "Your effort is too late. Now many homes are owned by corporations that also own pharmacies and medical supply houses. No kickbacks as such are needed, they make it all in the pharmacy."

Pharmacists wrote that kickbacks can be cash, i.e., 25 percent of total prescription charges or a flat \$5,000 a year. They can be in the form of long-term credit arrangements, or in some cases, unpaid bills to pharmacists. They can be in the form of rental of space in the nursing home—\$1,000 a month for a closet, for example—or they can be in the form of a pharmacy bill to an individual patient in the nursing home where the home keeps 25 percent of the total bill as a "collection fee."

With some pharmacists the kickback is supplying drugs, vitamins, and supplies at no charge, or merchandise offered to employees at no charge, or personal cosmetics and pharmacy needs of nursing home personnel delivered to the nursing home and charged to the home.¹³⁴

¹³⁴ The subcommittee received ample evidence of kickbacks between nursing homes and other suppliers which are beyond the scope of this chapter but two examples are provided. "In regard to physical therapists: my sister-in-law is one, she bills the home for services at \$20 an hour, she is allowed to keep \$10 an hour. The home gets the difference. Again with respect to physical therapy: It is not uncommon for the facility to demand 15 to 50 percent, and in some cases more, for the 'privilege' of providing needed medical care to 'their' patients."

Another pharmacist wrote: I tried to get a pharmacy in a medical building and the doctors wanted [on top of rent] \$100 per doctor for the lease plus a percentage."

Other pharmacies pay the salary of certain nursing home employees who are ostensibly working for the pharmacy. Still others noted that outright gifts of large quantities of green stamps, new cars, color televisions, boats, desks and prepaid vacations to Hawaii or Europe are made. Some are required to advertise in the home's brochure at ten times normal prices.

Some nursing homes have opened their own pharmacy and offer shares in the corporation to other nursing homes if they agree to use this new pharmacy.

Examples of each of these abuses are provided below; they are quoted from replies the subcommittee received to its questionnaire.

CASH

Another means of kickback is accomplished by just sending over to the owners (physician-owner's love this one) 20-25 percent of previous month's gross or a present fee in cold cash every month. Just put eight \$50 bills or whatever in an envelope and hand deliver it to him or them.

CREDIT

One such method to which I have been personally subjected in at least a couple of instances involved very strong pressure to grant excessive credit in amounts never allowed anyone else. In each case, the operator folded, leaving me stuck with an uncollectable bill of one to two thousand dollars each time.

You might not consider this to be a "kickback." I do, for its origins, cause and effect were precisely the same as in the more formal instances you might have in mind.

RENTING SPACE

Both places wanted me to *rent* a complete room in ECF plus supplying their own personal needs. This (at that time) was about \$1,100-\$1,200/month with an estimated percent to volume of about 20-25 percent. The pharmacy had the "*contract*" was renting a linen closet for \$700/month for "storage." The home owner also wanted me to explore with him the setting up of a company to supply these homes (he had two and one in the planning stage) since if the supply costs were high they would do better since they were on a cost plus percentage with the health agencies.

FURNISHING SUPPLIES

I was requested to supply the nursing home with such things as mineral oil, aspirin, gauze pads, tape, etc., free of charge. These were things that the nursing home was being paid to supply in the daily rates set by the State.

I was also requested to mail out prescriptions for drugs that were not used but instead I was asked to supply things that the nursing home was supposed to supply. These were to

be charged to welfare. Example: Make out a prescription for antibiotic and charge to welfare but instead send to the patient a posey belt restraint.

HIRING EMPLOYEES OSTENSIBLY WORKING FOR THE PHARMACY

Kickback demands are in various forms, not necessarily cash rebates. Two examples are: The supplying of certain drugs, vitamins, and supplies at NO CHARGE to the ECF. Paying the monthly salary of a full time employee whose sole duty is to tell the pharmacy whether the patient is a MEDICAL, MEDICARE, or private patient in the ECF, thus ostensibly working as an employee of the pharmacy, but in reality working for the ECF.

GIFTS OF TRADING STAMPS

Kickbacks in this area are more subtle. For example, green stamps, advertising in facilities' promotional brochures at 10 times the normal prices.

GIFTS OF COLOR TELEVISIONS AND BOATS

I have no real proof of kickbacks on a specific situation as far as cash is concerned—however, I do know that on the Xmas of one year, color TV's were delivered and paid for by one of the stores—also, the following year a boat was given—also, massive amounts of trading stamps are sent to the facility.

PREPAID VACATIONS

In this area the "kickback" is in the form of personal gratitude such as prepaid trips to Hawaii, Japan, a new desk, free use of a ski cabin, beach house, or other valuable usage.

ADVERTISING

Because of my refusal to "buy advertising space" in their monthly nursing home newsletter (a three-page affair) priced at \$124 per month (my rebate computed at 10 percent of medical charges and 15 percent of private patient charges), I was dropped as the pharmacy to provide services. Whether I buy advertising space or slip them the money in cash under the table, it is still graft and I certainly hope you are able to stem this horrible practice. I wrestled with my conscience as to whether I should suffer the \$15,000 a year loss or whether I should "make up the difference" on charges for any new prescription for the private patients that would be reimbursed under extended care Medicare funds. You would be absolutely amazed at the amount of Government money is being sopped up by these "extra billings."

AUTOMOBILE LEASING

Another approach is that of auto leasing for the home's administrator. Maybe given him as a fringe benefit of his job by the owners. All kinds of things can be worked out by the leasing company whereby it is almost completely tax deductible. Most pharmacies have delivery cars; usually small and compact cars with low monthly leasing fees. Now, new Mark III leases for \$225/month and a VW delivery car for \$50 monthly. The leasing agency writes up any kind of lease it wishes; it can lease the Mark III to the rest home owners for \$75 per month and charge the pharmacy \$200 per month for the VW. Everybody is happy, IRS cares not because somebody is going to write off the car as expense anyway, no cash has been lifted from the pharmacy so no books have to be juggled, and you get the business.

PURCHASING STOCK OR SHARES IN THE FACILITY

Owners of nursing homes in our area have joined forces and opened pharmacies which only service nursing homes. They then offer interest in their pharmacy to other nursing home operators if they will use the pharmacy.

One nursing home in our area approached drugstores in our area as to amount of kickback they would give to get the drug business. It was given to one drugstore. This went on for some time. Then the manager (a circuit judge) asked the drugstore supplying drugs to nursing home to buy stock in said nursing home for the business. This he wouldn't do and business was taken away and given to a drugstore that did. The amount of stock in corporation was \$5,000.

Many pharmacists wrote of their serious concern about the conflict of interest presented where the ownership of the pharmacy and the nursing home overlap. One side of the argument is the ability to manipulate prescriptions to bilk the Government and the other relates to the ability to cover up mistakes:

Another reason I have never pursued nursing home accounts is because they are always having drug problems as most of them are operating without pharmaceutical assistance and often request drugs to cover up for some they have borrowed from another patient. They have a number of reasons for requesting drugs early and an investigation will show that many laws are being violated daily and I don't intend to practice in this manner.

Several pharmacists believe that inadequate nursing home rates encouraged nursing home operators to make a profit elsewhere. Many also felt that reimbursement formulas for welfare medications too low, stating that the necessity to pay kickbacks leads pharmacists to many shortcuts. As an illustration, one

pharmacist noted that a prescription might cost \$4.50 plus a fee of \$2.30. This was the most welfare would allow as a fee. Thus the total price of the prescription would be \$6.80 and with a 25 percent kickback of \$1.70, only 60 cents would be left over for profit, salary, rent, etc.

Accordingly, some of the pharmacists admitted:

- (1) Billing welfare for nonexistent prescriptions.
- (2) Supplying outdated drugs or drugs of questionable value.
- (3) Supplying stolen drugs which they have purchased or supplying discarded drugs (those belonging to dead or discharged patients).
- (4) Supplying drug samples which they have received free of charge.
- (5) Supplying generic drugs and charging the State for brand name drugs.
- (6) Dispensing less than the prescribed amount and billing for the full amount.
- (7) Raising the amount prescribed by the doctor (kiting) and billing for the same.
- (8) Billing for refills not dispensed.
- (9) Receiving payment from a patient and submitting invoice for payment.
- (10) Using a particular line of drugs because the manufacturer has a price list where every item is listed at a higher price than is actually charged. By using such products the pharmacist can charge the State more and make a higher profit.¹³⁵

The practices above are highly questionable and in most cases clearly illegal. There are many reasons for the prevalence of these practices but the primary cause is the reimbursement system for nursing home drugs.

How does this system work? Obviously, there are many variations among the 50 States but in general the practice works as follows. The pharmacist presents a bill (often unitemized) for prescriptions to the nursing home. The nursing home then bills each individual patient collecting from those who pay for their own drugs and sending the balance to the State welfare department or to Medicare for payment. Neither the welfare department nor the Medicare intermediaries examine the billings very carefully. Most are paid automatically. Upon receiving payment from these third party payers, the nursing home then reimburses the pharmacist (often keeping a prearranged percentage for "handling," etc.).

This policy of allowing the nursing home to act as the "middle man" between the pharmacy (which supplies the drugs) and the source of payment (private patient, Medicare or Medicaid) creates an inviting atmosphere for abuse. The shortcomings of this questionable policy are obvious:

- (1) Medicare, Medicaid, and the private patient have no idea what they are paying for. The bill does not come from the pharmacist, but from the nursing home, and it is often unitemized. Close scrutiny of a bill is extremely difficult, if not impossible.

¹³⁵ For instances of inflation of the cost of drugs furnished to nursing home patients: One pharmacist wrote: "I noticed that an item costing \$1.79 was priced \$7.95 to a patient in a convalescent hospital. So let's do something about it."

See also page 833, part 11 hearings cited in footnote 14; pages 2109, 2132 (part 19A of same hearings); pages 2248, 2294, 2314, 2322, part 19B, same hearings. An instance on page 2314, part 19B of same hearings, related to the fact that a patient's drug bill tripled for the same medication upon entering a nursing home.

(2) "Cozy" relationships between pharmacies and nursing homes are encouraged whereby both parties can benefit at the expense of the private patient and the public. With the taxpayers paying \$2 out of every \$3 that goes into nursing homes, the implications of a nursing home owning its own pharmacy are all the more serious.

(3) In the end, pharmacies and nursing homes find it easy to cover up mistakes and increase their profits.

After reviewing the results of this questionnaire, Senator Moss directed that a questionnaire be sent (the same form) to pharmacies in and around Chicago.¹³⁶ One hundred pharmacies were selected at random. In the case of the pharmacists in Chicago, their returned questionnaires indicated the same pattern. Some 27 percent of the returns indicated that they had not attempted to serve a nursing home; another 23 percent indicated that they had served nursing homes, but had not been approached for a kickback. The remaining 58 percent indicated that they had been approached for a kickback or had a positive belief they were widespread.

The Senator also directed that a similar questionnaire be sent to every administrator of a long-term care facility in California. The questionnaire had the following results: 2,050 questionnaires were sent; 30 percent or 619 were returned.

Of the 619 returns, only 20 nursing home operators indicated having an interest in a pharmacy; 60 percent (or 373) indicated that their nursing homes were served by more than one pharmacy; 78 percent (or 484) nursing home providers stated they had never offered or accepted a kickback; 67 percent (or 415) indicated they did not believe kickbacks were widespread.

For the most part, nursing home owners were much less free with their additional written comments. The comments that were received related to the definition of the word "kickback" and to the inadequate nursing home reimbursement rates.

Nursing home operators went to great pains to emphasize a difference between unearned "kickbacks" or other consideration and

¹³⁶ It is to be emphasized that 200 of the original questionnaires were sent to pharmacists around the Nation. Their replies (identified by postmarks) were much the same as those received from California. For example:

"Kickbacks to nursing homes and extended care facilities have been prevalent in the Tampa bay area as long as I have been in the drug business; 1958.

"The practice increased sharply with the introduction of Medicare and Medicaid.

"I believe very strongly that Medicare placed a big club in the hands of nursing homes by allowing the nursing home to bill for pharmaceutical services and pharmaceutical consulting fees, and not allowing the pharmacy nor the pharmacist to effect their own billing; as do other professionals in the medical field. This practice has increased the cost of medications tremendously to nursing home clientele, no matter who pays the bill.

"I believe the practice of kickback to be present in 95 percent of homes in St. Petersburg, Fla."

"Why is it that a drug store say in Chelsea . . . is able to go all the way (20 miles) thru traffic, etc., and service a nursing home in Newton, Mass., West Roxbury, Mass., etc?

"Why? Because he is a nice fellow? . . . Hell no . . . kickbacks are so prevalent that you would be amazed at the discounts given in cash under the table . . . tax free . . .

"The only way I am able to beat competition on nursing home Rx service without giving a 20 percent kickback . . . is by (1) delivering papers to patients, (2) show movies every week to patients, (3) inservice movies, (4) take urine samples to hospital lab.

"In my estimate (based on factual information) approximately 99 percent give kickbacks."

"We have a law in Arizona prohibiting a pharmacy from giving discounts or kickbacks, but half of the pharmacists in Arizona are doing it and no one is enforcing the regulation. I am presently working on it."

earned service discounts. They pointed out that in many cases, nursing homes bill all the patients in their homes and that they collect the money from their individual private paying patients. This saves the pharmacists the cost of billing and collecting from nursing home patients individually. It also allows the pharmacist to receive a lump sum payment which is paid by the nursing home on behalf of its patients.

If the pharmacy were troubled to collect from individual patients, presumably it would have to wait longer for its payment. In the case of Medicare and Medicaid, pharmacies often have to wait for months for final payment. The nursing homes feel they create a cash flow for the pharmacist and that they guarantee payment from individual private paying patients. For this service and because of the large quantities of drugs purchased, many nursing home operators believe they are entitled to a cut or discount.

The following comments are typical: "Everyone gets their cost except the nursing homes so they must accept discounts from the pharmacy." "Kickbacks are wrong in any field, however, I do not feel a discount for buying volume merchandise and providing book-keeping services for billing are wrong. Discounts are part of the American scene." "The common misconception is that a pharmacist should receive retail prices for, let's say, 400 prescriptions delivered to the nursing home and which the nursing home collects for the pharmacy, guaranteeing payment. An arrangement involving a fee for nursing home services should be recognized as legitimate. Some pharmacists want full retail for a "wholesale" account and don't care who pays. Nursing homes in most cases bargain for better prices and pass at least part of the savings on in terms of reduced costs, or as discounts taken, etc., to their patients, private and Medicare."

Clearly, the results of the two questionnaires indicate two differing points of view. On the one hand, pharmacists indicate they are forced to pay a kickback as a precondition of obtaining a nursing home account; on the other hand, nursing homes claim they are legitimate discounts justified by their quantity buying or because of "billing services" performed for the pharmacist. The line between "kickbacks" and discounts is perhaps difficult to draw. However, there are several factors which should be considered.

- Is the arrangement between the parties disclosed?
- Is the "discount" voluntary given or is it mandatory?
- Is the "discount" a prerequisite of doing business with the nursing home?
- Is the amount (or percentage) of the discount nominal or excessive?

Although these distinctions remained unresolved, some conclusions can be drawn:

First—the profit in drugs supplied the nursing home is being shared. Pharmacists claim they are unwilling partners—that they are the victims of extortion. Nursing home operators allege that the discounts are voluntarily given by the pharmacists.

Second—the costs of drugs to private paying patients and to the taxpayer is being inflated. Pharmacists indicate that the pressure of kickbacks or discounts causes them to get as high a price for their drugs as they can, whether the party paying is the State, Federal Government, or the individual. One pharmacist wrote that an item which cost \$1.79 in the pharmacy was priced at \$7.95 to the nursing home patient. Subcommittee files reflect many such examples, including one in which the patient's drug bill tripled for the same medications upon entering a nursing home.

Third—because the practice of “kickbacks” is widespread, some pharmacists are resorting to unethical methods to lower their costs, such as charging the Government for nonexistent drugs, supplying generic drugs and charging for name brands, supplying old or ineffective drugs, supplying samples which they have received for free, and reusing discarded or supplying stolen drugs.

To put an end to these serious abuses and to resolve definitional distinctions, Senator Moss turned to the industry. Officers and members of the American Nursing Home Association met with Senator Moss and the subcommittee staff and pledged their best efforts toward preventing kickbacks. They offered to define the relationship between the nursing home and the pharmacist and to distinguish kickbacks from earned discounts. The Association in fact appointed a blue ribbon panel, promising the subcommittee a full report addressed to these objectives. Their efforts resulted in a 2½ page list of “suggested principles” in which the term “kickback” is not even mentioned. The essence of this document is one line: “The financial arrangement between the pharmacist and the nursing home should be fully disclosed.”¹³⁷

By contrast, spokesmen for the National Council on Health Care Services (NCHCS) gave the problem far greater attention in 1973. A press release from NCHCS says in part, “Nursing home ‘kickbacks or rebates’ pose a serious threat in the relationship with the pharmacy profession and in the optimum delivery of health care.” Mr. Berkley Bennett, executive vice president of NCHCS offered some definitions:

Rebate—Where a home takes back a dollar percentage of all drugs delivered. Certainly illegal for Medicare drugs when only reasonable costs are paid for, a bit unsavory when applied to Medicaid drugs, and hardly conscionable when an unreported profit is made on private patient drugs.

Kickback—Similar to rebate, only more so, usually with an “under the table” connotation.

Discount—If unearned, then in the same category as rebates and kickbacks.

Earned discount—When a nursing home is rendering a service for the pharmacist which he would normally be required to perform, such as billing and collections, where the nursing home, like Bankamericard and similar bank credit cards, guarantees payments to the pharmacist for all drugs ordered; and where the pharmacist gives a nursing home a

¹³⁷ See December 8, 1972, letter to Senator Moss from Don Barry, president of the American Nursing Home Association, appendix 4, p. 309; and April 1973 ANHA position paper in Appendix 5, p. 310.

service or volume-discount, as most suppliers do for other goods and services, the National Council of Health Care Services believes that a discount can and should be offered by the pharmacist—in return for services rendered.

*On the other hand, if a nursing home demands a reduction in charges from the pharmacist without offering any compensatory advantages to the pharmacist, an unwarranted situation is occurring and should not be countenanced.*¹³⁸

H.R. 1: KICKBACKS MADE ILLEGAL

What does the law say with respect to kickbacks? Up until late 1972, there were no Federal requirements. But some States, such as Arizona and California, prohibited kickbacks. In November 1972, the President signed H.R. 1 (Public Law 92-603), whose section 242 provided penalties of a year in jail and a \$10,000 fine for soliciting, offering or accepting bribes or kickbacks.¹³⁹

It has been more than 2 years since Senator Moss revealed the widespread existence of kickbacks. And it has been more than 2 years since the law prohibiting kickbacks was entered on the books. Unhappily, HEW has never announced regulations to implement this law. Accordingly, States are given no instruction as to how to enforce the law and therefore must rely on their own definitions of fraud.

Not unsurprisingly, reports of kickbacks continue. For example, over half of the California pharmacists polled by the subcommittee in January 1974 indicated that kickbacks were widespread and that the intervening Federal statute had little effect. Senator Moss called for a "full-scale" investigation by the U.S. General Accounting Office, turning over the leads and other information received by the subcommittee.

Of equal interest is a report from Paul Allen, director, bureau of medical assistance, State of Michigan Department of Social Services. He relates the activities of Michigan's postpayment surveillance and investigation section, sometimes known as the "Medicaid Fraud Squad." The fraud squad documented a large number of kickbacks and other fraudulent schemes among nursing homes, pharmacists and other providers such as ambulance companies, doctors and dentists. The fraud squad recouped \$1,040,000 and avoided payment of an additional \$740,000 in Michigan last year.¹⁴⁰ Specifically with respect to pharmaceutical services they found:

- Inaccurate acquisition cost reporting for drugs.
- Prescription splitting (instead of billing for one 30-day supply as written, sending two 15-day supplies and collecting a fee for each).
- Generic substitution for brand name drugs (charging the higher proprietary fee).
- Several pharmaceutical providers were involved in "deals" in nursing homes.

¹³⁸ May 1973, press release from American Society of Consultant Pharmacists.

¹³⁹ Statute reprinted in Appendix 1, p. 297.

¹⁴⁰ September 16, 1974, letter to Val J. Halamandaris from Paul M. Allen, director, bureau of medical assistance, Michigan Department of Social Services.

The discovery of 50 cases of kickbacks and other abuses involving pharmacists and nursing home operators allowed the recovery of \$396,416.24 and prevented the fraudulent payment of another \$141,144.05 in Michigan last year. In short, more than one-half million in pharmacy related abuses was discovered in Michigan alone. If this same savings could be projected to the entire 50 States, an estimated savings of over \$15 million would result.¹⁴¹ This \$15 million figure is probably a low estimate because it is based only on illegal activities which were documented. Nevertheless, the figure still represents 5 percent of the Nation's \$300 million nursing home drug bill.

It is apparent that the law making kickbacks illegal must immediately be implemented and vigorously enforced by HEW. The alternative is to accept the rationalization of one nursing home operator who wrote: "Kickbacks are a way of life in this country; there is a little larceny in us all."

RECOMMENDATIONS

A. GENERAL

1. Nursing homes should take strong and immediate measures to improve the quality of medication distribution. This can be accomplished in several ways. First, by employing greater numbers of registered nurses; second, by greater personal supervision of drug distribution practices; third, by employing and cooperating with consultant pharmacists as required by Medicare-Medicaid regulations for skilled nursing facilities; and fourth, by adopting unit dose distribution systems.

2. The subcommittee concurs with the U.S. General Accounting Office findings that traditional drug distribution systems produce (1) a significant degree of medication errors, (2) staff inefficiency, and (3) medication loss; and in its recommendation that long-term care institutions adopt this system.¹⁴² However, as implied above, unit dose may not be the total answer to the drug distribution problems of each of America's 23,000 nursing homes. Accordingly, HEW should conduct a study of the safety and possible savings of unit dose and other system with an eye to upgrading existing regulations.

3. The regulation requiring skilled nursing homes to employ consultant pharmacists must be enforced by HEW and the States.

4. Only licensed personnel, registered nurses, and licensed practical nurses should be allowed to set up or pass medications in both skilled or intermediate care facilities. In lesser facilities such as personal care and boarding homes, States should require requisite minimum training for personnel given this important responsibility.

¹⁴¹ A projection based on the fact that Michigan has about 3.6 percent of the Nation's nursing home beds. When the ratio of Michigan's over one-half million saved is projected to the Nation as a whole the savings is about \$15 million.

¹⁴² "Study of Health Facilities Construction Costs," by the U.S. General Accounting Office, printed for the use of the Senate Committee on Labor and Public Welfare and the House Committee on Interstate and Foreign Commerce Committee, December 1972, pp. 363-370.

5. The deletions and omissions in the Medicare/Medicaid standards effected by the January 1974 regulations should be reinstated. HEW should enforce the existing regulations (405:1127) and conduct some "spot inspections" within the States to insure compliance; to insure that medications are not being given without physician's order and that there are stop orders in effect for all medications.

6. Doctors and nurses should place more emphasis on the proper recording of medications on the patients charts.

7. Nursing personnel who reuse medication or prescribe medications on their own initiative should face licensure revocation or censure hearings conducted by State agencies.

8. Nursing home administrators working with nurses and consultant pharmacists should make a concerted effort to reduced medication errors, to limit adverse reactions, and psychic or physical dependence.

9. The FDA should be more vigilant in its control of human experiments conducted in nursing homes; they should not be conducted unless individuals are competent and can give effective informed consent.

10. Pharmaceutical companies should conduct greater research in geriatric pharmacology and psychopharmacology, taking into consideration the changes that aging brings to body systems.

11. Advertisements for medication should be written in concise simple terms. The FDA and FTC should insure that they are truthful to the point where they reflect possible side effects and untoward reactions. The purpose should be informative, not income generative.

12. More literature should be written in simple terms for the purpose of informing health professionals who are hard pressed to keep up with the latest pharmaceutical developments.

B. RECOMMENDATIONS WITH RESPECT TO KICKBACKS

1. The nursing home should be eliminated as the "middleman" between the pharmacy and the source of payment (private patient, State welfare department, or Medicare intermediary).

2. The right of patients to choose their own pharmacy should be secured.

3. Pharmacists should be required to submit itemized bills in all cases (to the welfare department, Medicare and to the private paying patient).

4. Section 242 of Public Law 92-603 prohibiting kickbacks should be vigorously enforced. Long overdue regulations clearly distinguishing kickbacks from discounts should be immediately promulgated.

5. The patient's name, the medication price, the name of the drug, the size of dose, and the total drugs supplied should be printed on each prescription label.

6. The interest of professionals such as physicians and nursing home owners in pharmacies and vice versa should be disclosed to the State if not prohibited outright. State agencies should exercise special vigilance where interlocking ownership of nursing homes and pharmacies is present with greater frequency of audits and review to protect the public interest.

APPENDIXES

APPENDIX 1

PENALTIES FOR FRAUDULENT ACTS AND FALSE REPORTING UNDER MEDICARE AND MEDICAID—PUBLIC LAW 92-603, SECTION 242

SEC. 242. (a) Section 1872 of the Social Security Act is amended by striking out "208."

(b) Title XVIII of the Social Security Act is amended by adding at the end thereof (after the new section added by section 226(a) of this Act) the following new section:

"PENALTIES

"SEC. 187. (a) Whoever—

"(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this title,

"(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to any such benefit or payment,

"(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

"(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$10,000 or imprisoned for not more than one year, or both.

"(b) Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any—

"(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or

"(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services,

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$10,000 or imprisoned for not more than one year, or both.

“(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution or facility in order that such institution or facility may qualify (either upon initial certification or upon recertification) as a hospital, skilled nursing facility, or home health agency (as those terms are defined in section 1861), shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$2,000 or imprisoned for not more than 6 months, or both.”

(c) Title XIX of such Act is amended by adding after section 1908 the following new section:

“SEC. 1909. (a) Whoever—

“(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a State plan approved under this title,

“(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

“(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

“(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person.

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$10,000 or imprisoned for not more than one year, or both.

“(b) Whoever furnishes items or services to an individual for which payment is or may be made in whole or in part out of Federal funds under a State plan approved under this title and who solicits, offers, or receives any—

“(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or

“(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$10,000 or imprisoned for not more than one year, or both.

“(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution or facility in order that such institution or facility may qualify (either upon initial certification or upon recertification) as a hospital, skilled nursing home, intermediate care facility, or home health agency (as those terms are employed in this title) shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$2,000 or imprisoned for not more than 6 months, or both.”

(d) The provisions of amendments made by this section shall not be applicable to any acts, statements, or representations made or committed prior to the enactment of this Act.

APPENDIX 2

GENERAL DEFINITION OF DRUG CATEGORIES

Antihistamine Drugs—Products used to alleviate the symptoms of hayfever, allergy, and the common cold.

Anti-Infective Agents—Products used in the treatment of bacterial and viral diseases.

Antineoplastic Agents—Products used in the treatment of cancer.

Autonomic Drugs—Products whose primary effect is on the nervous system and includes drugs used to treat abnormalities in smooth muscle tone and certain abnormal eye conditions.

Blood Derivatives—Products used in blood replacement.

Blood Formulation and Coagulation—Products used to enhance formation of blood cell products and components, including the treatment of anemia and the treatment and prevention of blood clotting.

Cardiovascular Drugs—Products used to treat abnormal blood pressure, heart congestion, and cardiac insufficiency.

Central Nervous System Drugs—Products whose primary effect is on the brain and are used to excite, sedate, tranquilize, or relieve pain.

Diagnostic Agents—Products used to diagnose diseases and in laboratory analysis.

Electrolytic, Caloric, and Water Balance—Products used to restore water balance of body fluids. Also, products are used to help eliminate abnormal water retention in tissues.

Enzymes—Products derived from naturally occurring substances and generally used to expedite or retard a natural body process. Frequently, these products are also used to treat undesirable blood coagulation.

Expectorants and Cough Preparations—Products used to alleviate coughs and to break up excessive sputum.

Eye, Ear, Nose, and Throat Preparations—Anti-infectives, anti-inflammatories, and pain reducers used in treatment of eye, ear, nose, or throat disorders.

Gastrointestinal Drugs—Drugs used to treat hyper-acidity, diarrhea, nausea, and vomiting.

Gold Compounds—Products containing gold and generally used in treatment of rheumatoid arthritis.

Heavy Metal Antagonists—Products used primarily to treat certain types of poisoning.

Hormones and Synthetic Substitutes—Products used to treat hormonal deficiencies, inflammations, diabetes, and thyroid conditions.

Local Anesthetics—Preparations used for relieving pain on body surfaces, joints, and mucous membranes.

Oxytocics—Products used to control or induce uterine contractions.

Radioactive Agents—Radioactive products used most frequently as diagnostic agents or tracers.

Serums, Toxoids, and Vaccines—Naturally occurring substances generally used to treat or prevent infection and to treat certain types of poisoning.

Skin and Mucous Membrane Preparations—Products used to treat infections, inflammations, and itching of the skin.

Spasmolytic Agents—Products which act largely on smooth muscle tissue in treating asthma and occasionally in treating gastrointestinal disorders.

Vitamins—Products used to supplement body enzymes.

Unclassified Therapeutic Agents—Products of naturally occurring substances which are not classified elsewhere.

APPENDIX 3

IMPLICATIONS OF MEDICAL REVIEW IN LONG-TERM CARE FACILITIES*

More than 2,000 years ago, Cicero said, "The competent physician, before he attempts to give medicine to his patient, makes himself acquainted not only with the disease which he wishes to cure, but also with the habits and constitution of the sick man" . . . Is it possible that, through some divination, Cicero may have been foreseeing nursing homes of the twentieth century and the outrageous medical neglect and unconscionable human indignities that many of their patients would be called upon to endure? . . . Is it not possible too, that, however unwittingly, sponsors of a 1971 Federal regulation requiring medical review and audit of quality-of-care in nursing homes were somehow moved by the Judeo-Christian ethic that each of us *is* his brother's keeper and must not walk by on the other side in the face of his adversity? I like to think so!

Part 250.23 of the Code of Federal Regulations calling for "Periodic Medical Review and Medical Inspections in Skilled Nursing Homes and Mental Hospitals" became effective May 3, 1971. And, although its provisions are applicable specifically to persons eligible for nursing home and mental hospital care under Title XIX, an undeniable collateral byproduct of its implementation on behalf of Medicaid beneficiaries (who constitute the majority of patients in most of these facilities) can be its salutary influence in raising the over-all professional tone and improving patterns of care for all other patients in the same facilities, be they Medicare or private-pay.

This epic statute is the Federal regulation that really zeros in on the very fulcrum of quality nursing home care; i.e., the centrality and controlling importance of the proper fulfillment of physicians' moral, professional, ethical and legal duties and obligations once they accept patients, and undertake management of their medical care. Effectively implemented and rationally enforced, periodic medical review has more muscle and greater potentialities for putting an end to unresponsive, unsupervised, irresponsible, discontinuous, and indifferent kinds of nursing home care, and to the inappropriate placement of long-term patients—now too characteristic of altogether too many of our long-term care facilities in too many of our states.

For those of you who may wish to read the statute itself, Regulation 250.23 appeared in Volume 36, Number 32, February 17, 1971 issue of the Federal Register. *It* takes up three columns. Subsequently, I was engaged by the Medical Services Administration (Medicaid) of H.E.W. to write interpretations and guidelines for its implementation. *That* took up a hundred and twenty-five pages . . . Translation

*Presented at a conference: "The Nursing Home: Critical Issues in a National Policy"; sponsored jointly by the Duke University Center for the Study of Aging and Human Development, National Retired Teachers' Assn., and the American Assn. of Retired Persons; convened at the State Department Building, Washington, D.C., October 31–November 2, 1971 . . . Carl I. Flath, FACHA, FAPHA, Consultant, 7501 Democracy Blvd., Bethesda, Maryland.

of this Federal regulation into everyday language and real-life situations perhaps grants me a degree of poetic license to make some observations about its provisions, problems, and promises as applied to the goals of this conference.

That official codification of the kinds of institutional and professional attitudes and responses that must prevail in order to ensure that the right kinds of chronically ill, disabled and impaired aging patients are receiving the right kinds of care in the right kinds of places at the right points in time is long overdue, goes almost without saying. A welter of exposes already have proven the case; yet, seldom has the evidence been more convincingly documented than in the consolidated findings from two structured medical reviews of typical nursing home patients in a cross-section of facilities in two eastern university cities. Collectively, these reviews covered seventy-five nursing homes and a ten percent random sample of their 3,400 patients. The average patient was age 79, and had been receiving care (to use the word loosely) for two years. On the day of the reviews:

37% of the patients taking cardiovascular drugs (digitalis or diuretics or both) had not had a blood pressure in over a year; and for 25% of these there was no diagnosis of heart disease on the chart.

35% of the patients on phenothiazines had not had a blood pressure recorded in more than a year. Some were taking two and often three phenothiazine drugs concurrently.

Most of the patients reviewed were on one to four different drugs; and many were taking from seven to twelve drugs; some were on both psychotropic uppers and downers at the same time.

A third of the patients being treated for diabetes mellitus had no diagnosis of diabetes on their charts; and over 10% of those receiving insulin or oral hypoglycemic agents were not on diabetic diets; and a large number of these had not had a fasting blood/sugar test in more than a year.

Revised treatment or medication orders had been written in the past 30 days for only 18 percent of the patients.

40% had not been seen by a physician for over three months. In the full year preceding reviews:

- Only 6% of the patients had had follow-up physical examinations
- Only 28% had had follow-up urinalyses
- Only 20% had had follow-up hemoglobin/hematocrit tests.

8% of the patients had decubitus ulcers; and 15% were visibly unclean.

39% of the patients reviewed were inappropriately classified and placed.

No nursing-care plans existed with respect to diets and fluids for 19%; personal care for 23%; activities for 14%; and individual treatment needs for 18% of the patients.

In-service staff training programs were conducted by only 39% of the homes.

"Gang visits" of individual physicians on multiple patients in a paltry few minutes was not uncommon.

These findings are neither isolated nor atypical in terms of the rest of the country. However, what they do epitomize are the classically unacceptable conditions and practices from which periodic medical review was spawned and to which its corrective provisions are addressed.

Stated simply, the function and gut thrust of periodic medical review is to bring to a grinding halt uncaring attitudes and indifferent care that are tantamount to medical abandonment of nursing home patients—and to accomplish this by means of on-going professional audits to determine and document if the level of care being provided is indeed appropriate and necessary; and if so, to ascertain whether or not physician, nursing, personal, and social care and services are of acceptable quality, adequate in quantity, and sufficient in scope; and are being rendered in a timely manner under environmental conditions and organizational circumstances that promote the optimum physical wellbeing, emotional stability, functional health, and social welfare of patients.

Periodic medical review is not to be confused with nor does it replace mandatory utilization review required under both Title XVIII (Medicare) and XIX (Medicaid). Medical review is exclusively quality-of-care oriented and must be carried out on behalf of each and every Medicaid patient in skilled nursing homes or mental hospitals; whereas, utilization review has a level-of-care, cost-saving emphasis, and is applied on a sampling basis only. And, although it has been said that periodic medical review and utilization reviews are mutually exclusive, this is not entirely so, for to some degree, each can enhance the other's purposes and effectiveness. In the same vein, periodic medical review of patient care and services is only tangentially concerned with physical facility, staffing, and environmental factors that otherwise fall within the province of state licensure programs. In a manner of speaking: licensure inspections are intended to scrutinize the characteristics and condition of the nest; whereas medical reviews are intended to evaluate the quantity and quality of the eggs.

The three professional disciplines most affecting the physical, emotional, functional, and social wellbeing and progress of nursing home patients are physicians, nurses, and social workers. Appraisal of how well these professionals are responding separately and in relation to each other in providing care that is timely and conforms to acceptable standards and practices is the singular aim of patient-centered medical review.

To get a feel of how far along the road towards better nursing home care the universal implementation of periodic medical review can take us, here is the essence of some of its highlight provisions and requirements:

A. All State plans providing medical assistance for eligible patients in skilled nursing homes, and care in mental hospitals for medical assistance patients over age 64 must provide for on-sight evaluations of each and every such patient at least annually and more often as circumstances may require—conducted by medical review teams comprised of a physician team leader, one or more registered professional nurses, and a trained social work specialist¹—to ensure that each such

¹ Title XIX Single State Agencies are held fully responsible for the effective implementation and administration of periodic medical reviews whether carried out by its own medical review teams or by contract with State or County Health Departments, Medical Foundations, or Group Practice or Health Maintenance Organizations.

patient receives prior to, at the time of, or immediately following admission, a complete medical evaluation which includes a comprehensive medical history, a complete physical examination, recorded diagnoses, assay of his mental and physical functional capacity, a written prognosis, an explicit recommendation for admission or continued care in the facility; and, a written plan of care which includes orders for medications, treatments, restorative services, diet, activities, and plans for continuing care when the patient's condition improves to a point when his needs can be met in an alternative setting where care on a less continuous and active level than that provided in skilled nursing homes and hospitals for mental disease is available.

Comment:

Abstracts of a patient's course during a hospital stay, such as a perfunctory discharge summary or a sketchy transfer form, are no longer acceptable in satisfaction of this requirement.

Because nursing home patients usually have multiple chronic diseases and disabilities, and, because physicians tend to miss more diagnoses by not looking than by not knowing; and, because a patient's original physician does not always continue as the patient's attending in the nursing home—a complete work-up such as that just described is basic to setting the stage and professional climate for appropriate and adequate on-going care of these patients.

Dealing with multiple and often fluctuating chronic and degenerative problems that beset elderly patients in nursing homes calls for a vastly different clinical and attitudinal approach on the parts of physicians than treatment of a single disease or symptom in an acute short-term hospital. In long-term care, the aim is to preserve what can be preserved by practicing preventive geriatric medicine so disease or impairments already present won't worsen; and to improve what can be improved by practicing therapeutic, rehabilitative medicine of conventional kinds. But, if those dual goals are to be reached, attending physicians of nursing home patients must treat the whole person and not just his overt symptoms while permitting other aspects of his physician needs and psychological problems to go unattended.

B. Medical review teams must audit each patient's record to ensure that it is complete and current, and contains evidence of physicians' medical evaluation as described previously; follow-up medical evaluations as indicated by the patient's diagnosis and condition; a medical plan-of-care, and evidence that it is being followed; a nursing plan-of-care, and evidence that it is being followed; physician review and re-authentication of medication and treatment orders not less frequently than every thirty days; appropriate and timely physician progress notes; adequate nursing notes reflecting medication and treatments given and patient responses thereto; observations of significant clinical or behavioral changes in the patient; appropriate nursing and related notes reflecting significant aspects of the patient's physical, personal, and psychological functioning; physician orders and instructions respecting diagnostic tests, provision of paramedical services; and, the orderly and continuous recording of all of the foregoing and results therefrom.

Comment :

Maintenance of comprehensive, complete, and current medical records constitutes little more than the "bookkeeping" of patient-care; and, like the routine auditing of "bookkeeping" records of fiscal affairs, patient-care "bookkeeping" also must be subject to periodic audit. Most hospitals know this; most nursing homes have yet to learn it!

C. Medical review team members must carry out individualized patient evaluations at the bedside or elsewhere in the facility. This entails conversation with and professional observations of each and every patients; and, the correlation of bedside findings with related data in the medical record. Factors to be observed during such appraisals include: presence of decubitus ulcers; state of body cleanliness; the patient's nutritional and hydration status; evidence of training and encouragement in ambulation, self-help in personal care, social activities, etc.; evidence of humane, considerate, and attentive care and emotional support; patients' attitude to their present placement and care; patients' social and family problems and circumstances and the impact of these on the clinical and emotional status and progress of patients.

Comment :

This one-to-one communication and eyeballing of each patient prevents medical review from deteriorating into a mindless, mechanical, and relatively meaningless ritual—as is the case with too many official inspections of nursing homes by other agencies for other purposes.

D. Henceforth, attending physicians will be required to visit their nursing home patients not less often than every thirty days. On such visits they must re-evaluate the patient; write new and revalidate existing orders for medications, treatments, diagnostic tests, paramedical services, and instructions for nursing care and personal support services. Appropriate progress notes must be recorded accordingly.

Comment :

Historically, physicians have been casual and reluctant visitors in nursing homes. Common among excuses given for such disengagement are: caring for patients with long-term, chronic illnesses lacks the drama and satisfactions that go with treating and curing acute symptoms and disease; progress of patients is slow and often frustrating; only a few patients are involved; nursing home locations make visits inconvenient; and caring for public assistance and low-income older patients has a low, uncertain economic return in relation to the professional time and effort it is necessary to expend on them.

Nursing homes have lacked the same leverage as hospitals enjoy by virtue of the sanctions which they can employ to ensure responsible and responsive patient-care attentiveness, the maintenance of adequate medical records, etc., on parts of physicians who use the facilities. However, with the passage of HR-1, and with the possible introduction of other promising legislative amendments and regulations now under active discussion on Capitol Hill, there is every reason for hope that multitudes of our ailing aging patients now subject to the caprices of a relatively unregu-

lated, uncoordinated, and medically unsophisticated long-term-care industry may be able to look forward to brighter, more promising futures.

In the works or in the cards among influences and actions pointing to better days through better care in better long-term care facilities for afflicted oldsters are such necessary and well-intentioned expectancies as:

Nursing homes, in all probability, will be required to appoint and cloak with appropriate authority full-time or part-time non-vested-interest medical directors to serve as medical-staff equivalents in developing and enforcing medical care procedures and medical practice policies.

In all likelihood nursing homes will be required to develop and enforce medical-care procedures and medical practice policies, as the counterpart of hospital medical staff bylaws, rules and regulations, which are acceptable to voluntary accreditation programs, and to official certification and licensing agencies, and which must be provided for, signed by, and adhered to on the part of each and every physician utilizing a given facility's resources for care of his long-term patients.

In multi-facility areas, public policy and a means could very well be brought into play to encourage, if not indeed require, physicians to elect the use of and to seek privileges at a single nursing home, or a limited few long-term care facilities.

It should come as no surprise when official dictum requires that all licensed nursing homes and related care facilities be formally and officially affiliated with a single accredited general hospital; wherein, the affiliate hospital medical staff and the hospital's professional-care structures are programatically superimposed upon the affiliate long-term facility.

It is a foregone conclusion that a modified version of periodic medical review now covering Title XIX patients receiving care in skilled nursing homes and mental hospitals soon will be made applicable to Title XIX patients in intermediate nursing care and intermediate personal care facilities.

That periodic medical review as spelled out in Section 250.23 must perforce, and sooner than later, become applicable to patients receiving care in extended care facilities under Title XVIII seems hardly debatable.

At long-last the AMA and its component State and County Medical Societies have taken a quarter-turn in the direction of exhibiting what gives every appearance of being a serious interest in carrying out peer review of admissions to and quality-of-care audits in health-care facilities, including nursing homes, through Professional Service Review Organizations, Foundations for Medical Care and the like. This strikes many observers as a partial answer by organized medicine to a prolonged public clamor that has been saying to the medical community: "Don't just stand there—do something!"

As the current trickle towards capitation, prepayment group practices and Health Maintenance Organizations takes on the power and proportions of an irreversible flood; and as more and more public assistance and publicly assisted sectors of regional populations become enrolled in these programs, most of the pres-

ent difficulties experienced in controlling utilization and quality-of-care externally will vanish because of the operational modes of prepayment group practices internally.

However desperately needed they may be, the several hoped-for developments just cited lie somewhere in the future; hopefully, in the near future. So, for the time being, we must exploit fully the intent and substance of what is here and now—periodic medical review—the singular instrumentality that holds promise of having a more pronounced impact on raising standards of care in the nation's 14,000 or so nursing homes, and on improving the lot and functional health of their 800,000 or so patients than possible all other Federal regulations addressed to similar purposes enacted to date. Obviously, the effectiveness and widespread acceptance of periodic medical review among skilled nursing homes and mental hospitals will depend importantly on the spirit in which Title XIX Single State Agencies go about the task. If implementation is conducted within an attitudinal posture that views the promotion of adherence to its provisions as essentially an educational, consultative, and supportive undertaking in the public interest, the effort is likely to yield rewarding results; but, if it is thought of as just one more policing apparatus to be enforced, results are likely to fall short of expectations.

Criticism of and resistance to Regulation 250.23 where periodic medical review is already underway has been minimal. Adverse attitudes usually come down to two expressed concerns:

Are you trying to make-over nursing homes into junior hospitals?

Are you trying to force physicians' practices in nursing homes up to the standards expected of them in hospitals?

Assuredly, the answer to both of these questions must be an unqualified yes! It could not be otherwise—that is—if nursing homes intend to be accepted as respectable members, and respected neighbors within America's health-care community.

APPENDIX 4

LETTER FROM DON T. BARRY, PRESIDENT, AMERICAN NURSING HOME ASSOCIATION; TO SENATOR FRANK E. MOSS, DEC. 8, 1972

AMERICAN NURSING HOME ASSOCIATION,
Washington, D.C., December 8, 1972.

DEAR SENATOR MOSS: I would like to take this opportunity to report on the action which our Association has undertaken since your address for the American Society of Consultant Pharmacists in Chicago during their recent convention.

Immediately following our conversation with you and Mr. Val Halamandaris of your staff and your address at the ASCP convention, our Executive Board and Governing Council requested that the Association contact the other major groups who are involved in the area of provision of pharmacy services to nursing homes. This we have proceeded to do.

Meetings were scheduled with the Executive Secretary of the National Association of Retail Druggists, the Executive Director of the American Pharmaceutical Association and various consultant pharmacists to nursing homes.

In addition to meetings with the above mentioned groups individually, we have retained the services of Mr. Carl Lyons who is a licensed pharmacist and a member of the American Pharmaceutical Association to assist in the development, in cooperation with the American Pharmaceutical Association and the National Association of Retail Druggists, of a position paper on the relationship between pharmacists and nursing homes.

In addition he will assist in updating of our manual which we publish in cooperation with the American Pharmaceutical Association, The American Society of Hospital Pharmacists and Roche Laboratories, Division of Hoffman-La Roche Inc. We will seek the support of other groups in the formulation of the position paper which will be made available to you for your consideration and input.

We would hope that through such cooperation with the other involved groups and your office, and Mr. Halamandaris in particular, we can solve many of the recurring problems in this area.

Sincerely,

DON T. BARRY, *President.*

APPENDIX 5

RELATIONSHIP BETWEEN NURSING HOME FACILITIES AND PHARMACISTS: PHARMACEUTICAL SERVICES, APRIL 1973

[AMERICAN NURSING HOME ASSOCIATION]

SUGGESTED PRINCIPLES

PREAMBLE

Recent developments in the delivery of pharmaceutical services, and particularly the delivery of services within the nursing home, indicate that traditional concepts of the relationship between a nursing home and a pharmacist are unresponsive to present patient, pharmacist, facility or third party insurer needs.

Today pharmaceutical services encompass more than the provision of a specific drug to a nursing home patient.

Pharmaceutical services in a health care facility encompass the control of the use of drugs which is the sum total of knowledge, understanding, judgments, procedures, skills, controls, and ethics that assure the optional safety in the distribution and administration of medications by both the pharmacist and the facility's personnel.

The relationship between the nursing home and the pharmacists, therefore, must be built on the recognition of the broader aspects of these services. In the past, payment for pharmaceutical services has centered primarily on the drug product delivered to the patient. The payment in turn has been calculated and expressed in most instances as a percentage of the cost of the drug product.

The relationship between the nursing home facility and the pharmacist must incorporate three factors: (1) Pharmaceutical Services; (2) Drug Product; and (3) Facility Administrative Services. These three components are all necessary in the provision of pharmaceutical services and must be recognized from both an organizational and payment basis.

In the interest of better patient care and fiscal integrity, the following guidelines are recommended:

I. ORGANIZATION OF PHARMACEUTICAL SERVICES

Organization of pharmaceutical services refers to the relationships which exist between the pharmacist and the facility as they jointly provide these services to the patient. In the organization of pharmaceutical services, the location of the pharmacy department (within or outside the facility) is a major factor. Currently, the most common approach to providing service is through a community pharmacy. This service usually includes providing both the drug product and the related pharmaceutical service. If more than one pharmacy is providing the drug product (prescription) in the facility, the drug products and their use must be within the confines of the drug control

system and are the responsibility of the pharmacist providing the contractual pharmaceutical service and must be accurately defined in his scope of responsibilities.

When the facility and the pharmacist defines the scope of pharmaceutical service, they must include all aspects of drug control as defined by the various state and federal laws thereby promoting safe and effective drug therapy. Pharmaceutical services also encompass numerous activities such as the editing of the physicians original order, monitoring drug therapy and participating in the educational programs of the facility.

It is important to recognize that pharmaceutical services like other professional services, medical, nursing, dietary, etc., must be integrated into the total patient care program and is the responsibility of the facility. The scope of services delineated in the policies and procedures must be related to written agreement between the pharmacist and the facility. The services provided by the pharmacist should be defined in written policies and procedures.

Those facilities that provide an on-site pharmacy department may organize their pharmaceutical service in at least three ways. First, the pharmacy (fixtures, inventory and space) may remain in the ownership of the facility and the pharmacist (or pharmacists) who provides service may be employed by the facility. Second, the pharmacy may be owned by the facility while the pharmacist (or group of pharmacists) provides services based on a contractual agreement with the facility. Third, the facility may wish to rent space to a pharmacist (or group of pharmacists) who would purchase fixtures and inventory. In this latter case, the pharmacist rather than the facility operates the pharmacy department.

Recent innovations in drug distribution systems such as unit dose systems, might necessitate further refinement in the pharmacists scope of responsibilities and his related reimbursement, however, the principles outlined in this statement would still be applicable as to the relationship between the facility and the pharmacist.

A. *Pharmaceutical Services.*—The financial arrangement between the pharmacist and the Nursing Home should be fully disclosed.

B. *Drug Product.*—The fee for the drug product has been and is traditionally borne by the patient or third party payor. The financial arrangement between the Pharmacist and the Nursing Home should not increase the price of drugs to the patient or third party payor above the cost for comparable drug service in the community.

SUMMARY

The intent of these guiding principles is to promote a basic understanding of the relationship that should exist between pharmacists and long term care facilities.

It is the hope that through such an understanding, the quality of patient care and fiscal integrity of all involved may be assured at the highest possible level.

APPENDIX 6

ARTICLES FROM "MODERN NURSING HOME," APRIL 1971

MEDICATION PROCEDURES MUST CONFORM TO DRUG ABUSE LAW

(By Grover Bowles Jr.*)

The comprehensive Drug Abuse Prevention and Control Act of 1970 signed into law by President Nixon on Oct. 27, 1970, has been widely acclaimed in the lay press as the most significant drug legislation yet passed. Although it includes the controversial "no knock" provision, this complex law deals compassionately with first offenders and allocates funds for education and research in drug abuse, and for the treatment and rehabilitation of addicts. However, of more significance to nursing home pharmacists are the provisions tightening record-keeping and the stiff penalties for violations.

Title 2 of the act, dealing with control and enforcement, will be of special interest to pharmacists. This section establishes five schedules of controlled substances, sets forth definitions, spell out registration requirements, specifies which records and reports are required, and deals with violations and penalties.

The five schedules or categories of controlled substances are:

1. Drugs such as LSD and heroin which have no accepted medical use but have a high potential for abuse.
2. Drugs such as the opiates and other potent narcotics, including injectable methamphetamine, or "speed," which have accepted medical uses but also have high addiction potential.
3. Class B narcotics, amphetamines, some barbiturates, and other drugs with accepted medical uses with less potential for abuse than those substances in schedule 2.
4. Drugs with accepted medical uses but with low abuse potential such as meprobamate, phenobarbital and others.
5. Class X or exempt narcotics and other drugs with low abuse potential and limited dependence.

When dispensed to patients, drugs from schedules 2, 3 and 4 must bear a clear and concise warning that it is a crime to transfer the drug to any person other than the patient. The refill provisions, five times within six months for non-narcotic drugs, remain the same as set forth in the Drug Abuse Amendments of 1965.

Whether nursing homes will need to alter their record-keeping for drugs subject to control will depend upon the adequacy of current records. Invoices, prescriptions, requisitions and other records for non-narcotic controlled drugs may be maintained separately or together with other records as long as they are "readily retrievable from the ordinary business records of the registrant." Because of the number of drug products involved and the volume of activity, retrieval of

*Mr. Bowles is director of pharmacy, Baptist Memorial Hospital, Memphis, Tenn.

needed information from the business records of a busy nursing home records for control drugs may prove burdensome.

The effective date of the law is May 1, 1971, at which time a complete inventory of all controlled drugs must be taken. Thereafter, an inventory every two years will be required. As is now required, all invoices, prescriptions, requisitions and other documents related to the purchase, receipt and dispensing of controlled drugs must be kept for at least two years.

NEW TARGETS OF DRUG THIEVES ARE STIMULANTS AND SEDATIVES

(By Grover Bowles, Jr.)

Thefts of drugs from receiving and storage areas, usually those drugs with high abuse potential, unfortunately do occur. Such thefts may take place when dishonest employes work together or in collusion with family, friends or organized crime, and where money is the primary motive.

Good storage facilities, proper inventory control records, and well-planned security measures minimize the wholesale loss of drugs. However, the abuse and misappropriation of drugs by physicians, pharmacists, nurses, aides and other personnel who have easy access to drugs is much more difficult to detect and eradicate. This does not mean that nursing homes have drug addicts by the dozens among their employes, but drug dependency occurs with sufficient frequency among physicians, pharmacists and nurses to be considered an occupational hazard.

With the development of the drug culture in our society, drug control problems have shifted from the narcotics and medications with high alcoholic content to the amphetamines and other stimulants, and to both the barbiturates and nonbarbiturate sedatives. To a lesser degree, tranquilizers and the newer synthetic analgesics are now sought by those who experiment with and abuse drugs. The codeine-containing cough preparations are also widely abused, particularly among the lower income groups.

Positive control of all drugs, not just those with high abuse potential, is essential throughout the facility. The unit dose medication system offers maximum protection against illicit diversion of drugs in patient areas and eliminates the accumulation at the nursing unit of large quantities of drugs which then must be returned to the pharmacy. The use of physician order forms that provide copies of medication orders for the pharmacy minimizes the number of faked orders. Secure storage for all drugs is essential and only minimal supplies of drugs should be kept at nursing stations and treatment areas. The distribution of drug samples by pharmaceutical representatives and by direct mail should be discouraged if not prohibited.

The security force should be familiar with the procedures for receiving and moving drugs about the facility and should make spot checks periodically. Intrusion alarms and other devices should be used to safeguard the narcotics and major supply of drugs in the pharmacy and storage areas.

Security personnel should be on the lookout for discarded hypodermic syringes, empty cough sirup bottles, broken ampules, empty vials, and other medication containers in locker rooms, stairwells, rest-

rooms and other nonpatient areas. These are telltale signs of employe or visitor drug abuse.

Steps should also be taken to safeguard hypodermic syringes from theft, and procedures for the disposal of used syringes should be established and enforced.

APPENDIX 7

LETTER FROM F. J. McQUILLAN, ASSOCIATE DIRECTOR OF RESEARCH, TO SENATOR FRANK MOSS, TRANSMITTING: FACT SHEETS, PHARMACEUTICALS AND THE NURSING HOME MARKET; DATED SEPTEMBER 8, 1971

MODERN MEDICINE,
Minneapolis, Minn., September 8, 1971.

DEAR SENATOR MOSS: In response to a telephoned request from Mr. Val Halamandaris, Counsel for the Senate Committee on Aging, we are enclosing copies of estimated prescribing volume in nursing homes as computed about a year ago for use in presentations and a seminar in New York last October. This material in the "Fact Sheets Pharmaceuticals and the Nursing Home Market," was based on market data and a series of interviews across the country with administrators and medical directors of nursing homes.

We are also enclosing a copy of our mail survey of October–November 1969, "Nursing Homes, Patients, Attending Physicians, Drug Supplies, Treatment Categories," which may be helpful.

You may wish to obtain from the American Nursing Home Association in Washington, D.C., Suite 607, 1025 Connecticut Avenue NW., 20036, their recently published, "Nursing Home Fact Book, 1970–1971." It is quite detailed, including state figures in a number of tables.

We appreciate the opportunity to be of service.

Sincerely,

F. J. McQUILLAN,
Associate Director of Research.

[Enclosure]

FACT SHEETS

PHARMACEUTICALS AND THE NURSING HOME MARKET

U.S. nursing homes

THE MARKET, 1970

Licensed nursing home beds.....	900,000
Convalescent, long-term beds.....	250,000
Total	1,150,000

GROWTH

New beds a day, every day.....	300
New construction, new homes, average beds.....	112
Growth rate per year:	
Nursing homes (percent).....	15
General hospitals (percent).....	3.4

PATIENTS

Average age (years)	79
Average of diseases	3
Average of medications per day	4.2
Bedridden (percent)	50
Confused (percent)	40
Incontinent (percent)	33

TOTAL DRUG MARKET

\$25 per month per patient for 12 months	\$300
Number of patients	900,000
Total per year	\$270,000,000

R_x CATEGORIES OF A \$270 MILLION PER YEAR MARKET

	<i>Percent</i>
1. Vitamins and nutritional supplements	5
2. Cardiovascular drugs	10
3. Diuretics	10
4. Cold and cough preparations	5
5. Analgesics	10
6. Antibiotics	10
7. Tranquillizers and psychotherapeutic drugs	15
8. Sedatives and hypnotics	10
9. Urinary tract disinfectants	5
10. Other	20

DOLLAR EXPENDITURES BY MAJOR CATEGORIES

1. Vitamins and nutritional supplements	\$13,500,000
2. Cardiovascular drugs	27,000,000
3. Diuretics	27,000,000
4. Cold and cough preparations	13,500,000
5. Analgesics	27,000,000
6. Antibiotics	27,000,000
7. Tranquillizers and psychotherapeutic drugs	40,500,000
8. Sedatives and hypnotics	27,000,000
9. Urinary tract disinfectants	13,500,000
10. Other	40,500,000

NUMBER OF R_x FILLED PER DAY FOR RESIDENTS OF SKILLED NURSING HOMES

<i>Number of R_x:</i>	<i>Percent</i>
Less than 5	6.6
5 to 9	21.8
10 to 19	30.1
20 to 29	16.8
30 to 39	6.7
40 to 49	4.1
50 or more	8.6
Not reported	5.3
Total	100.0

Average number of R _x filled daily only for residents of skilled nursing homes	24
Average estimated proportion of prescriptions filled for skilled nursing home residents which involve brand name drugs (percent)	85

Source : from App.

40 percent of the retail pharmacists serving skilled nursing homes report that they dispense some medications in *unit-dose* package form.

UNIT DOSE DISPENSING

	<i>Percent</i>
Sometimes	40.3
Never	55.0
Not reported	4.7

MOST COMMON CLASSES OF OTC ETHICALS PURCHASED BY SKILLED NURSING HOMES

	<i>Percent</i>
Laxatives	64.1
Analgesics	42.5
Vitamins, tonics and hematinics.....	23.0
Antiacids and digestants.....	18.9
Dermatogicals and lotions.....	11.7
Cough/cold remedies.....	11.0
Alcohols, rubs, liniments, etc.....	9.3
Disinfectants	7.6
Oral antiseptics.....	4.2
First-aid items.....	3.8
Diabetic supplies and tests.....	3.4
Talcum powder.....	3.0

Source : App.

Who is involved in drug discussion?

Doctor treating patient in nursing home.

Nursing supervisor.

Consulting pharmacist.

How do you reach the \$270,000,000 nursing home pharmaceutical market?

In nursing homes official journal, American Nursing Home Association.

COVERAGE OF MARKET

	<i>Number</i>
Nursing homes (addressed to administrators).....	¹ 12,600
Approximate number of R.N.'s (percent).....	40
Convalescent homes over 100 beds.....	348
M.D.'s related to nursing homes.....	1,842
Nursing supervisors who requested magazine.....	4,000

¹ Reaching 8,000 R.N.s

