

July 1995

PRESCRIPTION DRUGS AND THE ELDERLY

Many Still Receive
Potentially Harmful Drugs
Despite Recent
Improvements



**Health, Education, and
Human Services Division**

B-259603

July 24, 1995

The Honorable Ron Wyden
House of Representatives

Dear Mr. Wyden:

A recent study concluded that, in 1987, nearly one of four noninstitutionalized elderly patients were taking prescription drugs that many experts regard as generally unsuitable for their age group because alternative drugs provide the same therapeutic benefit with fewer side effects.¹ According to gerontology experts, the percentage of elderly patients affected by the inappropriate use of prescription drugs would be even greater if other situations, such as potentially dangerous drug interactions or incorrect dosages, were taken into account. The inappropriate use of prescription drugs may cause unnecessary adverse drug reactions that may lead to subtle deterioration of function or precipitate medical crises resulting in hospitalization or death. They also contribute to higher medical costs borne in part by either Medicare or Medicaid. The Food and Drug Administration (FDA) estimates that the annual cost of hospitalizations due to inappropriate prescription drug use is \$20 billion.

Concerned that the inappropriate use of prescription drugs harms the health and quality of life of the elderly, you asked us to

- determine if the inappropriate use of prescription drugs among the elderly is widely viewed as a serious health problem;
- identify the ways prescription drugs are inappropriately used and why these situations occur;
- identify how physicians, pharmacists, and patients receive information on prescription drugs and how their knowledge of prescription drugs and drug therapies could be improved; and
- provide information on how emerging trends in health care delivery affect drug prescribing for the elderly.

To address these issues, we conducted a literature review and obtained documents from leading researchers in the fields of gerontology and elderly clinical pharmacology. We interviewed these individuals as well as representatives of FDA, the Health Care Financing Administration (HCFA),

¹Sharon M. Wilcox, David U. Himmelstein, and Steffie Woolhandler, "Inappropriate Drug Prescribing for the Community-Dwelling Elderly," *Journal of the American Medical Association*, Vol. 272, No. 4 (July 27, 1994), pp. 292-96.

state Medicaid programs, industry trade associations, senior citizen and consumer advocacy groups, and medical associations who are knowledgeable in the use of prescription drugs for the elderly. We analyzed data on prescription drug use from HCFA's 1992 Medicare Current Beneficiary Survey.² We conducted our study from October 1994 to May 1995 in accordance with generally accepted government auditing standards. (See app. I for details on our scope and methodology.)

Results in Brief

The inappropriate use of prescription drugs is a potential health problem that is particularly acute for the elderly. Not only do the elderly use more prescription drugs than any other age group, they are more likely to be taking several drugs at once, increasing the probability of adverse drug reactions. Furthermore, the elderly do not eliminate drugs from their systems as efficiently as younger patients because of decreased liver and kidney function.

Our analysis of 1992 data from the Medicare Current Beneficiary Survey found that about 17.5 percent of almost 30 million noninstitutionalized Medicare recipients 65 or older used at least one drug identified as generally unsuitable for elderly patients since safer alternative drugs exist. While still significant, this is an improvement over the almost 25 percent reported for 1987 data.

Inappropriate prescription drug use can result from the behavior not only of the physician but also of the pharmacist and patient. Such behavior includes physicians using outdated prescribing practices, particularly for elderly patients; pharmacists not performing drug utilization reviews; and patients not informing their physician and pharmacist about all the drugs they are taking. Any of these factors can increase the likelihood that an elderly person will use a drug that may impair his or her health.

Although the experts we interviewed agreed that the inappropriate use of prescription drugs remains a significant health problem, they identified several recent efforts that are helping to address this problem. Federal and state initiatives have encouraged the development and dissemination of detailed information on the effect of prescription drugs on the elderly. At the same time, the medical community has begun to emphasize the need to increase physicians' knowledge of geriatrics and elderly clinical pharmacology. The development of drug utilization review systems now permits prescriptions to be screened before they are filled to identify

²For a complete explanation of the Medicare Current Beneficiary Survey, see appendix II.

potential problems, such as adverse drug interactions or inappropriate dosage levels. Finally, patients increasingly have been seeking information about their drug therapies from several sources, including consumer advocacy groups, state agencies, and pharmaceutical companies.

Changes in the health care delivery system also have the potential to reduce the inappropriate use of prescription drugs. Managed care plans, whose enrollment has grown from 10 million in 1980 to almost 90 million in 1992, are now actively enrolling senior citizens. Through utilization controls such as a “gatekeeper,” managed care plans have the potential to improve the coordination of drug therapies for newly enrolled elderly patients. Furthermore, a growing number of employers and health plans now use pharmacy benefit management firms to administer their prescription drug benefit programs. From 1989 to 1993, the number of individuals covered by pharmacy benefit management firms increased from fewer than 60 million to 100 million. Through increased oversight and review, these firms have the potential to further reduce inappropriate prescription drug use.

Inappropriate Use of Prescription Drugs Is a Major Health Problem for the Elderly

The inappropriate use of prescription drugs is a problem that is particularly acute for the elderly. The elderly use more prescription drugs than any other age group and are more likely to be taking multiple prescription drugs, which increases the probability of adverse drug reactions. Furthermore, the elderly are more susceptible to adverse drug reactions because of the aging process. As a result, many experts believe that some drugs are generally inappropriate for the elderly because equally effective and safer alternative drugs exist. Additionally, other drugs though appropriate should be used at reduced dosage levels to accommodate elderly physiology.

Inappropriate Prescription Drug Use Is Widespread Among the Elderly

Based on 1987 data from the National Medical Expenditure Survey, a research study published in July 1994 concluded that almost 25 percent of the noninstitutionalized elderly 65 or older used prescription drugs at least once during the year that are generally considered unsuitable for their age group.³ The study used a list of 20 drugs, based on criteria published in 1991, that generally should not be used by elderly patients.⁴

³Wilcox, Himmelstein, and Woolhandler, pp. 292-96.

⁴Mark Beers, Joseph G. Ouslander, Irving Rollingher, and others, “Explicit Criteria for Determining Inappropriate Medication Use in Nursing Home Residents,” *Archives of Internal Medicine*, Vol. 151 (Sept. 1991), pp. 1825-32. A list of these 20 drugs is in appendix III.

A second study published in October 1994 reinforced the findings of the earlier study.⁵ In this study, the researchers interviewed a sample of community residents, 75 or older living in Santa Monica, California, during 1989 and 1990 about their use of prescription drugs, over-the-counter medications, and home remedies within the 4 weeks prior to the interview. The researchers used primarily the same criteria as the July 1994 study, but only looked at drug usage over a 1-month period rather than the entire year. This study concluded that 14 percent of those interviewed used at least one of the drugs generally identified as not suitable for elderly patients.

Several experts we interviewed expressed reservations about the appropriateness of using 1991 criteria to evaluate prescription drug use in years before the criteria were developed. However, these experts did not disagree with the criteria themselves. To determine if there was much change in prescribing patterns after 1991, we analyzed data from the Medicare Current Beneficiary Survey conducted by HCFA's Office of the Actuary to see what percentage of noninstitutionalized Medicare beneficiaries in 1992 used any of the 20 drugs.⁶ Our analysis showed that an estimated 17.5 percent of the almost 30 million senior citizens in the survey used at least one of these drugs in 1992.⁷ Although this represented an improvement over the 1987 data, more than one out of six elderly patients were still using prescription drugs generally considered unsuitable for their age group.

Many health care practitioners questioned whether the use of these drugs should always be characterized as inappropriate. They maintained that, under certain circumstances, their use would be perfectly acceptable. For example, if a patient was already using a particular drug and doing well, there would be little medical justification for switching to another drug. Still, none of these practitioners said that this rationale would account for the high percentage of elderly patients using drugs deemed inappropriate. All the experts we interviewed agreed that the inappropriate use of prescription drugs continues to be a significant health problem.

Several experts also pointed out that these research studies only looked at one type of the inappropriate use of prescription drugs. In their opinion,

⁵Andreas E. Stuck, Mark Beers, Andrea Steiner, and others, "Inappropriate Medication Use in Community-Residing Older Persons," *Archives of Internal Medicine*, Vol. 154 (Oct. 10, 1994), pp. 2195-2200.

⁶According to HCFA, this survey is representative of the Medicare population as a whole.

⁷For the details of this analysis and a discussion of the three studies, see appendix IV.

when other examples are considered such as potentially dangerous drug interactions or incorrect dosages, the percentage of senior citizens affected by the inappropriate use of prescription drugs would be even greater than the estimates provided in those studies.

The Elderly Are Particularly Vulnerable to Inappropriate Prescription Drug Use

The elderly are more likely than other segments of the population to be affected by the inappropriate use of prescription drugs. As a group, the elderly are more likely to suffer from more than one disease or chronic condition concurrently, which means that they may take several different drugs at one time. As the number of prescriptions increases, so does the potential for adverse drug reactions caused by drug interactions or drug-disease contraindications. The physiological changes of aging are a major reason drugs have the potential to cause problems in the elderly. Elderly patients often lack the ability to eliminate drugs from their systems as efficiently as younger patients do because of decreased liver and kidney function. In addition, they are more sensitive to the effects of drugs. Thus, they are not able to accommodate the normal adult dosage.

The inappropriate use of prescription drugs is a major cause of adverse drug reactions that, if severe enough, can result in hospitalization or death. Since the elderly are more vulnerable to the effects of the inappropriate prescription drug use, they are at greater risk from adverse drug reactions than other segments of the population. Studies indicate that about 3 percent of all hospital admissions are caused by adverse drug reactions.⁸ However, the percentage is much higher for the elderly. One study estimated the percentage of hospitalizations of elderly patients due to adverse drug reactions to be 17 percent, almost 6 times greater than for the general population.⁹ Applying an average unit cost to the proportion of hospital admissions that are drug-related, FDA estimates that hospitalizations due to inappropriate prescription drug use cost about \$20 billion annually.

Less severe adverse drug reactions may go unnoticed or be discounted by both health practitioners and the elderly as the normal effects of the aging process. However, these side effects, such as drowsiness, loss of coordination, and confusion, can result in falls or car accidents. A study

⁸Keith Beard, "Adverse Reactions as a Cause of Hospital Admission in the Aged," *Drugs & Aging*, Vol. 2, No. 4 (July/Aug. 1992), pp. 356-67.

⁹Nananda Col, James E. Fanale, and Penelope Kronholm, "The Role of Medication Noncompliance and Adverse Drug Reactions in Hospitalizations of the Elderly," *Archives of Internal Medicine*, Vol. 150, No. 4 (Apr. 1990), pp. 841-45.

estimated that 32,000 senior citizens annually suffer hip fractures as a result of falls caused by adverse drug reactions.¹⁰ Another study concluded that about 16,000 car accidents resulting in injuries each year can be attributed to adverse drug reactions experienced by elderly drivers.¹¹ Even if no serious bodily injury occurs, adverse drug reactions decrease the general quality of life for patients because of drug-induced mental impairment, loss of coordination, or addiction.

Many Factors Contribute to the Inappropriate Use of Prescription Drugs

The factors leading to the inappropriate use of prescription drugs are multifaceted and interconnected, according to experts we interviewed. These factors reflect the behavior of the physician, pharmacist, and patient, either collectively or individually. From the time a drug is prescribed to the point where the drug is taken, many possible events, often interconnected with each other, can lead to an adverse drug reaction or other serious results.

The inappropriate use of prescription drugs can take several different forms, ranging from potentially life-threatening drug-drug interactions to therapeutic duplication (using two or more similar drugs to treat the same problem), which yields little benefit at increased cost. Other examples of the inappropriate use of prescription drugs include

- drug-age contraindication,
- drug-allergy contraindication,
- drug-disease contraindication,
- incorrect drug dosage,
- incorrect duration of drug therapy, and
- less effective drug therapy.¹²

A physician, a pharmacist, or a patient may take or omit actions that can produce an adverse drug reaction. For example, a drug-drug interaction could be due to a physician not recognizing that a prescribed drug interacts badly with another prescribed medication or over-the-counter drug used by the patient. (See fig. 1.) The pharmacist may contribute to the situation by not detecting the negative interaction or by failing to determine which drugs the elderly patient is taking. The elderly patient

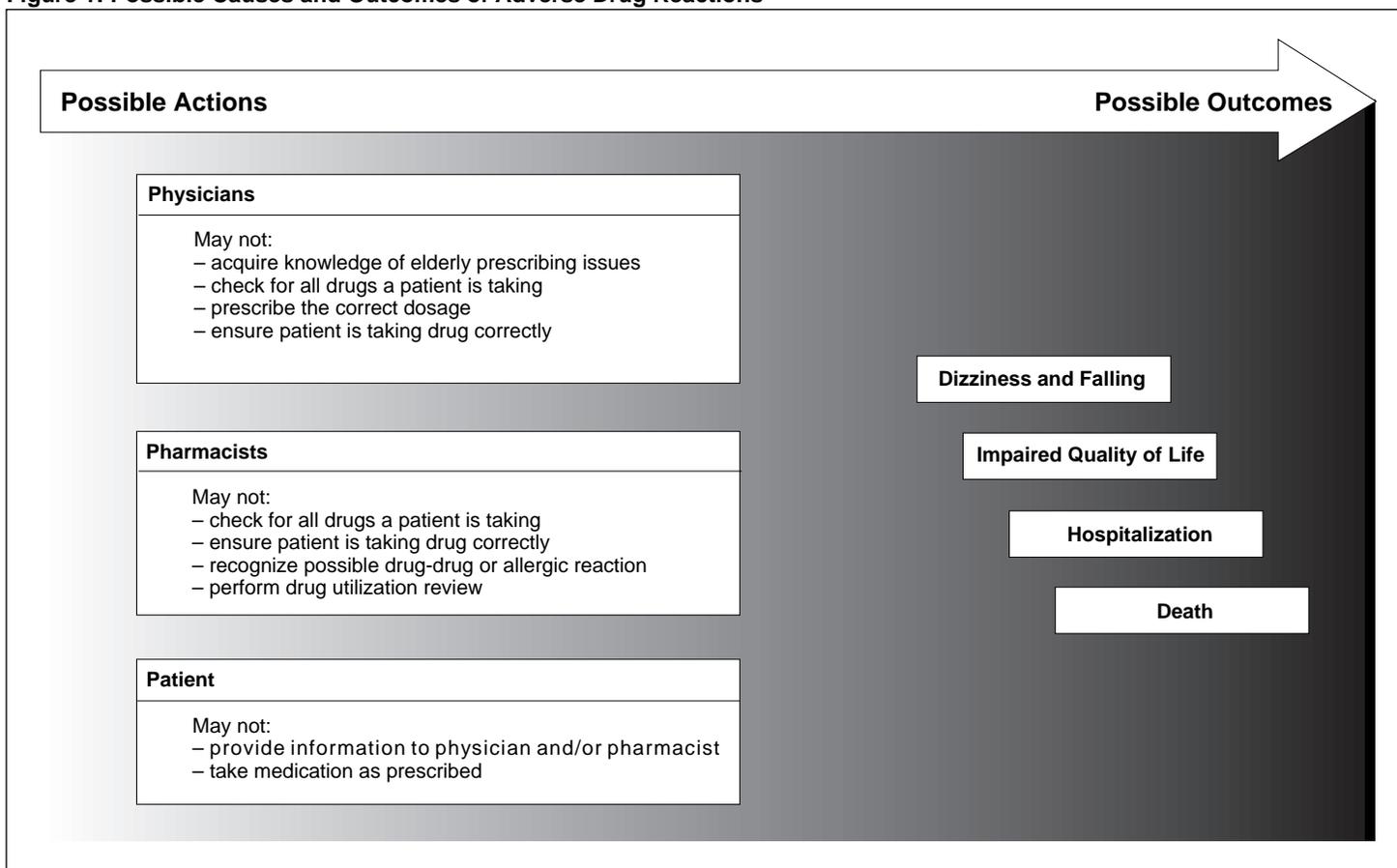
¹⁰Wayne A. Ray, Marie R. Griffin, William Schaffner, and others, "Psychotropic Drug Use and the Risk of Hip Fracture," *New England Journal of Medicine*, Vol. 316, No. 7 (Feb. 12, 1987), pp. 363-69.

¹¹Wayne A. Ray, Randy L. Fought, Michael D. Decker, "Psychoactive Drugs and the Risk of Injurious Motor Vehicle Crashes in Elderly Drivers," *American Journal of Epidemiology*, Vol. 136, No. 7 (Oct. 1, 1992), pp. 873-83.

¹²Definitions of these terms are in the glossary.

may not give the doctor and pharmacist a complete list of all the medications, including over-the-counter drugs, that he or she is taking. Thus, all three parties may contribute to a drug-drug interaction, with potentially serious consequences to the patient.

Figure 1: Possible Causes and Outcomes of Adverse Drug Reactions



Health care professionals noted that the overuse and underuse of drug therapies may also contribute to the inappropriate use of prescription drugs.¹³ Drug overuse occurs when a medication is prescribed but either no medication was needed or an alternative treatment approach existed. For example, changes in diet and lifestyle may be more appropriate than

¹³Jerry H. Gurwitz, "Suboptimal Medication Use in the Elderly: The Tip of the Iceberg," *Journal of the American Medical Association*, Vol. 272, No. 4 (July 27, 1994), pp. 316-17.

drug therapy. More controversial is the selection of drug therapy over counseling to treat psychological conditions such as anxiety or depression. Drug underuse occurs when an appropriate medication either is not prescribed or is underprescribed. For example, one study reported that patients with advanced cancer were at risk of receiving less than adequate pain medication.¹⁴

Better Information and Communication Can Help Prevent Inappropriate Drug Use

According to several experts we interviewed, lowering the elderly's risk of adverse drug reactions requires that more detailed information on the impact of drug therapies on the elderly be developed and disseminated to health practitioners. Furthermore, many health practitioners agreed that physicians, pharmacists, and patients should all participate in the drug therapy decision-making process. Increased communication between and among physicians, pharmacists, and patients is vital to ensuring that this process is effective.

FDA Has Improved Drug Guidelines for the Elderly

One difficulty in prescribing drugs for the elderly has been the lack of specific information on dosage levels established for the elderly through clinical tests. Recognizing the need for additional information on the effects of drugs on the elderly, FDA issued voluntary guidelines in 1989 governing the testing of new drugs intended for elderly patients. These guidelines call for the inclusion of elderly patients during the drug's testing process. The intent of these guidelines is to develop better information for both physicians and pharmacists on dosage standards for new drugs intended for elderly patients as well as to identify side effects that are more pronounced in the elderly than in the general population. FDA's Director of Drug Policy and Evaluation stated that he believed that pharmaceutical manufacturers have complied with these guidelines. However, several experts said that clinical trials performed under these guidelines are not representative of the elderly population as a whole. For example, they believe that elderly patients over 75 are underrepresented.¹⁵

Better Physician Education Can Improve Poor Prescribing Practices

The medical community has only recently started to emphasize the study of geriatrics and elderly clinical pharmacology. For example, board certification in geriatrics was offered for the first time in 1988. Recognizing

¹⁴Charles Cleeland, Rene Gonin, Alan K. Hatfield, and others, "Pain and Its Treatment in Outpatients With Metastatic Cancer," *New England Journal of Medicine*, Vol. 330, No. 9 (Mar. 3, 1994), pp. 592-96.

¹⁵Jerry Avorn, "Grant Watch—Medication Use and the Elderly: Current Status and Opportunities," *Health Affairs* (Spring 1995), pp. 276-86.

the aging of the population, most medical schools now offer courses in geriatrics, though only 12 schools require courses devoted solely to geriatrics. Experts we interviewed agreed that medical schools could improve how they train doctors in geriatrics. Moreover, several experts stressed the need to improve the quality of continuing education in geriatrics, because a large portion of the education doctors receive in medical school becomes outdated during their careers. Since medical schools have only recently introduced geriatric training in their curricula, many doctors in practice today have had little formal training in that area. Two experts also pointed out a similar need for an emphasis on geriatrics in the training of pharmacists, both in pharmacy school and through continuing education.

While preclinical training in pharmacology is routinely provided in medical school, several experts said that improvements are needed in the teaching of clinical pharmacology, which trains doctors in the use of drug therapies to treat disease. Doctors obtain their clinical pharmacology training during their residencies. Physicians' clinical knowledge of the unique aspects of elderly pharmacology depends on their exposure to elderly patients. Several experts believe that the real expertise in pharmacology rests with the pharmacists and that doctors need to use this expertise in deciding the most appropriate drug therapy to prescribe.

Drug Utilization Review Programs Offer Safeguards Against Inappropriate Use of Prescription Drugs

One strategy that is increasingly used to identify and minimize the inappropriate use of prescription drugs involves drug utilization reviews. Drug utilization reviews are intended to screen drug therapies for potential problems, such as drug-drug interactions, drug-disease contraindications, incorrect dosages, or improper duration of treatment. These reviews can be done either prospectively or retrospectively. Prospective drug utilization reviews are designed to detect potential problems before a prescription is filled by the pharmacist. Retrospective drug utilization reviews occur after the prescription is filled and are intended to detect prescribing patterns that indicate inappropriate or unnecessary medical treatment as well as fraud or abuse. The Omnibus Budget Reconciliation Act of 1990 requires all states to conduct ongoing retrospective reviews of Medicaid prescription drug claims and prospective reviews before each prescription is filled. Most states have expanded that requirement to mandate drug utilization review of all prescriptions. While several experts acknowledged the potential benefits of drug utilization review systems, two experts cautioned that these benefits have not been thoroughly documented to date.

A prospective drug utilization review system allows point-of-sale vendors such as pharmacies to check a prescription and a patient's history against a central database. This database can alert a pharmacist to possible drug-drug interactions or a drug-disease contraindication. Our study of prospective Medicaid drug utilization review systems in five states during fiscal year 1993 found that pharmacies' use of automated drug utilization review systems linked to statewide Medicaid databases provided a more thorough prospective review than a manual or localized system.¹⁶ This type of automated review can reduce the risk of inappropriate drug therapy and increase patient safety, though we recognized the need for these benefits to be demonstrated conclusively and recommended that HCFA take steps to do so. We also recommended that HCFA develop guidance for the development of these systems to ensure standard implementation of effective drug utilization review systems.

New York State's Elderly Pharmaceutical Insurance Coverage program provides prescription drug insurance coverage for low-income senior citizens not eligible for Medicaid. This program uses a retrospective drug utilization review system for its therapeutic drug monitoring program. This review system monitors each client's prescriptions, using data from prescription claims submitted for payment by pharmacies, to detect potential problems such as overutilization of a drug or a drug-drug interaction. Once a potential problem is detected, a program official notifies the prescribing physician. The alert is informational only and provides the doctor with a history of the patient's prescription drug usage, the suspected problem, its effect and severity, and recommendations for resolving the problem. No action is required, but the doctor is asked to respond. In one analysis conducted by program staff, 38.4 percent of the patients whose doctors received letters alerting them to a potential problem subsequently had their drug therapy changed.

The Massachusetts Medicaid program also uses its retrospective drug utilization review system to detect questionable prescribing practices affecting any of its recipients. For example, if a patient is prescribed a nonsteroidal anti-inflammatory drug commonly used to relieve the symptoms of arthritis, the system will monitor that patient for potential side effects of this type of medication, such as stomach or intestinal bleeding. If the patient later begins to take antiulcer medications, the system will issue an alert to the prescribing doctor that the usage of the

¹⁶Prescription Drugs: Automated Prospective Review Systems Offer Potential Benefits for Medicaid (GAO/AIMD-94-130, Aug. 5, 1994).

first drug may be the cause of the ulcers. This allows the doctor to evaluate the situation and, if warranted, alter the patient's drug therapy.

A retrospective drug utilization review system can also monitor patient compliance with a prescribed drug therapy. For example, a patient may discontinue his or her blood pressure medication when the symptoms disappear. Despite the lack of symptoms, the causes remain, leaving the patient still at risk. A retrospective drug utilization review can detect the patient's failure to refill a prescription and alert the patient's doctor to the situation for further action.

Improved Patient Counseling Can Reduce the Risk of Adverse Drug Reactions

One way to lower the potential of adverse drug reactions is to ensure that patients are counseled by either their doctor or pharmacist on the usage and characteristics of a prescription drug. Often, subtle side effects of drugs are ignored by patients and not reported back to the doctor or pharmacist. Unless alerted that the patient is experiencing side effects, a doctor would not be likely to change drug therapies. Counseling not only improves the information received by the patient but also that obtained from the patient. This improved communication between doctor or pharmacist and the patient may prompt a question that leads to the discovery of a drug-drug interaction or drug-allergy interaction.

Although effective counseling by doctors and pharmacists can help reduce the likelihood of an adverse drug reaction, two studies have found that many patients do not receive this counseling. A *Consumer Reports* study of 70,000 people published in 1995 found that about 26 percent had not been counseled by a physician about their drug therapies.¹⁷ A 1989 study by the American Association of Retired Persons (AARP) found that more than one out of three patients reported that they were not counseled by their doctors on their drug therapies.¹⁸ Time pressures on both doctors and pharmacists may also be an obstacle to effective counseling.

Recognizing the importance of counseling, the Omnibus Budget Reconciliation Act of 1990 mandated that pharmacists counsel Medicaid patients when they receive prescription drugs. A majority of states have expanded this requirement to include all patients. Officials of the American Pharmaceutical Association and the American Society of

¹⁷"How Is Your Doctor Treating You?," *Consumer Reports* (Feb. 1995), pp. 81-88.

¹⁸Mismedication and Its Impact on Older Americans, a statement of the American Association of Retired Persons presented by John Lione, M.D., before the U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Health (Sept. 20, 1994).

Consultant Pharmacists, two professional associations that represent pharmacists, stressed the importance of counseling but noted that the current system of compensation for pharmacists is based on dispensing drugs and lacks meaningful incentives for counseling. For example, a pharmacist may detect a potential problem with a prescription and, after consultation with the doctor and patient, cancel the prescription. If another drug is not substituted and no drug is dispensed, the pharmacist receives no reimbursement for the professional services rendered.

Patients Can Protect Themselves From Adverse Drug Reactions

Patients who seek information about their drug therapies can reduce their likelihood of experiencing adverse drug reactions. Besides requesting counseling from both the doctor and pharmacist, public advocacy groups urge individuals to develop their own knowledge of drugs. To achieve this objective, AARP encourages the development of package product inserts in large type that are easy for the elderly to read and understand. Public Citizen Health Research Group, a public advocacy group, has also published a consumer guidebook for prescription drugs. Moreover, pharmaceutical manufacturers have begun to make information available directly to consumers. Increased understanding of their drugs, dosage requirements, and possible side effects makes patients more likely to avoid the inappropriate use of drugs.

State and local agencies have developed several initiatives to alert consumers to the dangers of inappropriately using prescription drugs. For example, the Massachusetts Department of Public Health sponsors brown bag seminars at senior citizen or community centers. At these seminars, elderly patients are encouraged to bring in all their medicines for review by pharmacists. The goal is to inventory all the medications a senior citizen has and eliminate those that are for conditions no longer being treated or which have expired. The remaining drugs are cataloged in what is called a "medicine passport" that can be shown to doctors and pharmacists as new or additional drugs are prescribed. This record allows health practitioners to quickly review what other medications the person is taking and why.

Managed Care Has the Potential to Reduce the Inappropriate Use of Prescription Drugs

Recent changes in the health care delivery system have implications for the use of prescription drugs. The growing emphasis on controlling health care costs creates a strong incentive to reduce the inappropriate use of prescription drugs and the physical and financial costs associated with adverse drug reactions. Likewise, the increasing importance of cost

containment has helped spur the emergence of managed care as a major form of health care delivery. The number of people covered by managed care plans has increased dramatically from 10 million in 1980 to almost 90 million in 1992. Moreover, many managed care plans have recently initiated major marketing efforts to enroll elderly patients. Similarly, the number of people whose prescriptions are filled by pharmacy benefit management companies has also increased. While it is too early to understand the full impact these changes may have on reducing inappropriate drug use—in general, and among the elderly in particular—several experts we interviewed stated that these changes have the potential to improve the coordination of care and to increase the ability to detect inappropriate use of drugs. However, one expert cautioned that the achievement of these goals might be adversely affected by pressures to contain costs or increase profits.

Improved Coordination of Care Is a Goal of Managed Care

Many elderly patients are under the care of several specialists as well as their primary care physician. At times, these doctors may prescribe several drugs to treat various ailments. Unless these various drug therapies are coordinated, adverse drug reactions pose a serious risk. Experts in gerontology and elderly clinical pharmacology that we spoke to stated that the most effective way to deal with the inappropriate use of prescription drugs was to improve the coordination of care. Ideally, this role should fall to the patient's primary physician.

Proponents of managed care have stressed improved coordination of care as a major goal. Though there are several variations of managed care such as health maintenance organizations (HMO) or preferred provider organizations, a basic characteristic of managed care is control over utilization. Often, this is done through a gatekeeper. A gatekeeper is usually the patient's designated primary doctor who oversees the individual's care, referring the patient to specialists as needed. This allows one doctor to coordinate various treatments, including drug regimens. Several experts agreed that such coordination could help lower the risk of adverse drug reactions posed by inappropriate drug therapy or a patient receiving multiple prescriptions from different doctors. However, they cautioned that the improved coordination of care is dependent on the quality of patient care, which varies widely among managed care plans.

Managed care plans also have the potential to use formularies to reduce the inappropriate use of prescription drugs. A formulary lists the preferred drugs used to treat certain diseases or conditions. Typically, the formulary

is developed by a committee of doctors and pharmacists associated with the managed care plan, who seek to identify the most effective drug therapies at the lowest cost to the plan. For example, if two drug therapies are deemed equally effective, then the plan will recommend the less costly of the two as the preferred treatment. However, several experts expressed the concern that cost concerns rather than effectiveness may be the primary driving force in selecting which drugs to place on a managed care plan's formulary.

A managed care plan can change its formulary to reflect new drug therapies. This has an impact on the prescribing behavior of a plan's doctors who may have to seek an exception if they wish to prescribe a drug not designated by the plan's formulary. However, two experts said that few managed care plans have used their formularies to improve prescribing practices for elderly patients though the experts acknowledged this potential exists.

Another potential advantage of managed care is the data collected on patients. This gives managed care plans the information needed to monitor both the drug therapies patients receive and the prescribing patterns of physicians. One HMO we visited provided its doctors with periodic analyses of their drug-prescribing habits as compared with standards developed by the HMO. This comparison allows the HMO to identify doctors who may need additional training or counseling in prescribing drugs for their patients, particularly the elderly.

Increasing Number of People Obtain Prescriptions From Pharmacy Benefit Management Firms

Over the past few years, the number of people who receive their prescription drugs through pharmacy benefit management firms has increased dramatically from fewer than 60 million in 1989 to 100 million in 1993. Pharmacy benefit management firms manage prescription drug benefits on behalf of health plan sponsors, including self-insured employers, insurance companies, and managed care plans.

The initial attraction of pharmacy benefit management firms is their ability to reduce administrative costs and obtain discounts on prescriptions drugs through volume buying. However, these firms can also provide formulary management and drug utilization review services with the potential to reduce inappropriate drug use. For example, the drug utilization review done by one pharmacy benefit management firm, PCS Health Systems, generated almost 25 million alerts in 1994. Of these alerts, 25 percent dealt with drug-age contraindications and excessive daily dosages, two types of

inappropriate drug use prevalent among the elderly. Likewise, by monitoring patient prescription drug use, pharmacy benefit management firms can detect a patient's failure to refill a prescription for a persistent medical condition such as high blood pressure. The firm can then alert the patient's doctor to this situation for further action if required.

Pharmacy benefit management firms can also develop initiatives to address the inappropriate use of drugs among the elderly. For example, Medco has instituted an educational program called "Partners for Healthy Aging." This program provides specialized information to doctors, pharmacists, and patients to alert them to potential concerns in the use of prescription drugs among the elderly.

As the number of patients served by these firms has increased so has the information gathered on patients. With the accumulation of data on patient characteristics, medical conditions, and drug therapies, pharmacy benefit management firms are developing the necessary database for engaging in outcomes research. Such research allows companies to demonstrate the effectiveness of different courses of treatment for a disease from both a therapeutic and cost perspective. This would permit doctors, patients, and payers to make both financially and clinically informed health care decisions.

A draft of this report was reviewed and commented on by five leading experts in the field of elderly clinical pharmacology. Where appropriate, the report was changed to reflect their comments.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will make copies available upon request.

This report was prepared by John C. Hansen, Assistant Director, Frank Putallaz, and Tom Taydus. Please call Mr. Hansen at (202) 512-7105 if you or your staff have any questions about this report.

Sincerely yours,

A handwritten signature in black ink that reads "Jonathan Ratner". The signature is written in a cursive style with a large, prominent 'J' and 'R'.

Jonathan Ratner
Associate Director
Health Financing Issues

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Abbreviations

AARP	American Association of Retired Persons
FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
HMO	health maintenance organization

Scope and Methodology

To determine the significance of the inappropriate use of prescription drugs among the elderly, we conducted a literature review and obtained documents and testimonial evidence from leading researchers in the fields of gerontology and elderly clinical pharmacology. Additionally, we interviewed other knowledgeable professionals concerning the issues related to the use of prescription drugs by the elderly. Included among these professionals were representatives of FDA, HCFA, senior citizen and consumer advocacy groups, the American Pharmaceutical Association, the Pharmaceutical Research and Manufacturers of America, the American Medical Association, the American Society of Consultant Pharmacists, and the American Association of Medical Colleges.

We interviewed state officials in Massachusetts, New York, and Vermont to see how state and federal health programs deal with the inappropriate use of prescription drugs among the elderly. Massachusetts was selected because of the number of prominent researchers in the areas of elderly clinical pharmacology located there. New York was selected because the state administers the Elderly Pharmaceutical Insurance Coverage program, which provides prescription drug coverage to low-income senior citizens. Vermont, a rural state in contrast to Massachusetts and New York, was selected because it was one of only eight states that had implemented a statewide automated prospective drug utilization review system for Medicaid prior to 1994. In each state, we obtained information on the operation of Medicaid drug utilization review systems as well as various state initiatives to help senior citizens avoid adverse drug reactions.

To update the results from earlier research studies, we analyzed data from HCFA's 1992 Medicare Current Beneficiary Survey, the most recently available data. According to HCFA, this survey is designed to provide reliable baseline data to project Medicare costs and is representative of the Medicare population as a whole.

To determine what causes the inappropriate use of prescription drugs, we reviewed the literature and interviewed the leading experts previously cited. We also obtained information on physician gerontology education and questioned state officials about the implementation of drug utilization review programs and their effect on the causes of the inappropriate use of prescription drugs.

To determine how physicians, pharmacists, and patients receive information on drug therapies, we identified actions that drug

manufacturers and FDA have taken to provide better dosage information for elderly patients as well as changes in how drug manufacturers disseminate information to physicians, pharmacists, and patients. We also obtained information on efforts by state agencies, senior citizen advocacy groups, pharmacy groups, and medical organizations to improve communication between and among physicians, pharmacists, and patients.

To identify emerging trends in the health care delivery system and their potential effects on the inappropriate use of prescription drugs, we obtained information on how managed care plans develop formularies, train their staff on new drug therapies, and track both patient and physician use of prescription drugs. To assess the effect of the growth of pharmacy benefit management firms, we obtained information on how these plans coordinate and monitor drug therapies.

Medicare Current Beneficiary Survey

The Medicare Current Beneficiary Survey is a continuous, multipurpose survey of a representative sample of the Medicare population. It is administered by HCFA's Office of the Actuary and began gathering data in 1991. The survey generates data on issues of prime importance to the management of the Medicare program and the development of health care policy. Focusing on health care use and expenditures, the survey generates data to (1) allow HCFA to monitor the financial effects of changes in the Medicare program; (2) develop reliable and current information on the use and cost of services not covered by Medicare such as prescription drugs and long-term care; and (3) obtain information on the sources of payments for costs of covered services not assumed by Medicare. Although its focus is on the financing of health care, the survey collects a variety of information about the Medicare population, including demographic characteristics, health status, insurance coverage, financial resources, and family support.

The survey is based on a sample of Medicare recipients drawn from the Medicare enrollment file. The sample is representative of the Medicare population as a whole. Since the survey is a longitudinal study, those selected for participation are interviewed three times a year for several years to form a continuous profile of their health care. Initial participants who completed the first round of interviews numbered 12,677. Of these, 942 resided in an institutional setting and 11,735 were community-based. The sample is adjusted annually for attrition and for newly eligible persons.

The initial interview gathers baseline data on demographic characteristics, health status, insurance coverage, financial resources, and family support. Subsequent interviews gather details of the participants' health care use since the last interview emphasizing the type of health care used and the source for paying for it. This includes information on the prescription drugs a participant is using even though Medicare does not provide reimbursement for their cost.

Information collected is edited for consistency, documented, and organized into files. Later, these files are merged with HCFA claims payment records. Also, administrative data such as Medicaid buy-in status and capitated plan membership are added to the file. All personal identifying information is removed.

20 Drugs Generally Considered Inappropriate for the Elderly

Table III.1 lists the 20 drugs deemed generally inappropriate for elderly patients by a panel of experts. The reasons given by this panel for judging a drug inappropriate are also provided as is the purpose of these drugs. The panel's results and methodology were published in 1991.¹⁹ Though the goal of this panel was to identify drugs inappropriate for the elderly living in a nursing home setting, a later examination of these drugs by another panel of experts also judged these drugs as generally inappropriate for elderly patients living in a community-based setting.²⁰ Several of the experts we interviewed agreed that these drugs should normally not be used with elderly patients though they stressed that there would be some medical situations where the use of these drugs would be appropriate. One expert noted the need for research studies based on patient-related outcomes data to confirm the views of the expert panelists.

Table III.1: Drugs Considered Generally Inappropriate for Elderly Patients and Why

Prescription drug	Use	Comment
Diazepam	As a tranquilizer or antianxiety medication	Shorter-acting benzodiazepines are safer alternatives.
Chlordiazepoxide	As a tranquilizer or antianxiety medication	Shorter-acting benzodiazepines are safer alternatives.
Flurazepam	As a sleeping pill	Shorter-acting benzodiazepines are safer alternatives.
Meprobamate	As a tranquilizer	Shorter-acting benzodiazepines are safer alternatives.
Pentobarbital	As a sleeping pill and to reduce anxiety	Safer sedative-hypnotics are available.
Secobarbital	As a sleeping pill and to reduce anxiety	Safer sedative-hypnotics are available.
Amitriptyline	To treat depression	Other antidepressant medications cause fewer side effects.
Indomethacin	To relieve the pain and inflammation of rheumatoid arthritis	Other nonsteroidal anti-inflammatory agents cause less toxic reactions.
Phenylbutazone	To relieve the pain and inflammation of rheumatoid arthritis	Other nonsteroidal anti-inflammatory agents cause less toxic reactions.

(continued)

¹⁹Beers, Ouslander, Rollinger, and others, pp. 1825-32.

²⁰Stuck, Beers, Steiner, and others, pp. 2195-2200.

**Appendix III
20 Drugs Generally Considered
Inappropriate for the Elderly**

Prescription drug	Use	Comment
Chlorpropamide	To treat diabetes	Other oral hypoglycemic medications have shorter half-lives and do not cause inappropriate antidiuretic hormone secretion.
Propoxyphene	To relieve mild to moderate pain	Other analgesic medications are more effective and safer.
Pentazocine	To relieve moderate to severe pain	Other narcotic medications are safer and more effective.
Isoxsuprine	To improve blood circulation	Effectiveness is in doubt.
Cyclandelate	To improve blood circulation	Effectiveness is in doubt. This drug is no longer available in the U.S.
Dipyridamole	To reduce blood-clot formation	Effectiveness at low dosage is in doubt. Toxic reaction is high at higher dosages. Safer alternatives exist.
Cyclobenzaprine	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity. Potential for toxic reaction is greater than potential benefit.
Methocarbamol	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity. Potential for toxic reaction is greater than potential benefit.
Carisoprodol	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity. Potential for toxic reaction is greater than potential benefit.
Orphenadrine	To relieve severe pain caused by sprains and back pain	Minimally effective while causing toxicity. Potential for toxic reaction is greater than potential benefit.
Trimethobenzamide	To relieve nausea and vomiting	Least effective of available antiemetics.

Note: While these drugs are generally considered inappropriate for elderly patients, individuals should always consult with their physicians before making any changes in their prescription drugs.

Use of Drugs Considered Generally Inappropriate for the Elderly

At our request, HCFA's Office of the Actuary used data from the Medicare Current Beneficiary Survey to determine the percentage of community-based elderly who used at least 1 of the 20 drugs identified in appendix III as generally inappropriate for their age group.²¹ The most current compiled data are for 1992. The first step was to identify survey participants who were 65 or older and who were noninstitutionalized. Of their survey population, 9,182 participants met these criteria. This group represented 29,862,854 Medicare beneficiaries nationwide according to HCFA's Office of the Actuary. The next step was to determine which of these participants used at least 1 of the 20 drugs sometime during 1992 and project that use to the national population. The results indicated that an estimated 17.5 percent or 5,219,811 noninstitutionalized Medicare beneficiaries 65 or older used at least 1 of those drugs during 1992.

These results are displayed in table IV.1. Specifically, the table lists the percentages of noninstitutionalized elderly found to be using each of the 20 drugs. The middle column details the results based on research using data from the 1987 National Medical Expenditure Survey covering noninstitutionalized residents 65 or older.²² The right-hand column presents the results of the analysis described above. We did not include the research results based on interviews conducted during 1989 and 1990 of a sample of noninstitutionalized elderly 75 or older residing in Santa Monica, California.²³ This was because the participants in this study represented one community rather than a national sample and belonged to a different age group than the other two studies. In addition, their use of the 20 drugs was measured during a period of 1 month versus 1 year in the other 2 analyses.

²¹For a complete explanation of the Medicare Current Beneficiary Survey, see appendix II.

²²Wilcox, Himmelstein, and Woolhandler, pp. 292-96.

²³Stuck, Beers, Steiner, and others, pp. 2195-2200.

**Appendix IV
Use of Drugs Considered Generally
Inappropriate for the Elderly**

**Table IV.1: Percentage of
Noninstitutionalized Elderly Using
Drugs Generally Inappropriate for
Their Age Group**

Prescription drug	1987 results	1992 results
Diazepam	2.82	2.13
Chlordiazepoxide	1.95	0.60
Flurazepam	1.25	0.77
Meprobamate	0.82	0.32
Pentobarbital	0.12	0.02
Secobarbital	0.03	0.01
Amitriptyline	3.13	2.63
Indomethacin	2.64	1.72
Phenylbutazone	0.28	0.11
Chlorpropamide	2.08	0.87
Propoxyphene	4.83	5.63
Pentazocine	0.30	0.14
Isoxsuprine	0.31	0.06
Cyclandelate	0.25	0.05
Dipyridamole	6.44	4.09
Cyclobenzaprine	0.70	0.59
Methocarbamol	0.42	0.40
Carisoprodol	0.38	0.68
Orphenadrine	0.33	0.30
Trimethobenzamide	0.27	No data available
Percentage of elderly using 1 or more of the 20 drugs	23.50	17.50

Glossary

Drug-Age Contraindication	Use of a drug not recommended for the age group of a patient.
Drug-Drug Interaction	The potential for, or the occurrence of, an adverse drug reaction as a result of the use of two or more drugs together.
Drug-Allergy Interaction	The potential for, or the occurrence of, an allergic reaction as a result of drug therapy.
Drug-Disease Contraindication	The potential for, or occurrence of, an undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of an additional disease condition. Also, the potential for, or the occurrence of, an adverse effect of the drug on the patient's disease condition.
Incorrect Drug Dosage	A dosage that lies outside the daily recommended dosage range as specified in predetermined standards as necessary to achieve therapeutic benefit.
Incorrect Duration of Drug Therapy	The number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.
Therapeutic Duplication	The prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the patient at risk of an adverse drug reaction or yields no additional therapeutic benefit.
Less Effective Drug Therapy	Use of a drug therapy that is less desirable than other alternatives because of factors such as therapeutic effectiveness, presence of side effects, ease of use, or cost.

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