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# MEDICARE DRUG UTILIZATION REVIEW

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**OFFICE OF INSPECTOR GENERAL**  
**OFFICE OF ANALYSIS AND INSPECTIONS**

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# **MEDICARE DRUG UTILIZATION REVIEW**

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**RICHARD P. KUSSEROW  
INSPECTOR GENERAL**

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## EXECUTIVE SUMMARY

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### PURPOSE AND OBJECTIVES

The overall aim of this inspection was to foster the development and implementation of an effective Drug Utilization Review (DUR) system under the Medicare program. Toward this end, it sought to promote a better understanding of the major problems and needs that a DUR program should address and of the relevant insights that emerge from research and experience.

### BACKGROUND

Among the many provisions of the Medicare Catastrophic Coverage Act of 1988 is the one calling for the Department of Health and Human Services (HHS) to establish a Medicare DUR program. This mandate offers the Department a significant opportunity to design and operate a multi-level DUR effort to improve quality of care, avoid unnecessary Medicare and personal expenditures, and maintain program integrity. This report presents information and recommendations that can help the Department take maximum advantage of that opportunity. In so doing, it draws heavily on a review of State Medicaid experience, demonstration efforts, and research findings.

### FINDINGS

- There is a widespread problem of miscalculation among older adults. That problem is likely to grow when the Medicare drug benefit is implemented, unless an effective DUR program is developed.
  - Although Americans age 60 and over comprise only 17 percent of the total U.S. population, they account for 39 percent of all hospitalizations and 51 percent of deaths from drug reactions.
  - In 1987, at least 200,000 older adults were hospitalized due to adverse drug reactions, or experienced an adverse drug reaction while hospitalized.
- The problem of miscalculation among the elderly reflects a series of systemic weaknesses throughout the drug therapy delivery system.
  - At the pharmaceutical manufacturer level, information about appropriate dosage levels and potential adverse reactions related to drugs consumed by older adults is inadequate.
  - At the physician level, there is evidence of widespread prescribing patterns that are suboptimal for older adults. For the most part, this is a product of inadequate training and education for physicians in geriatric pharmacology.

- At the community pharmacy level, findings indicate that only a small percentage of elderly patients receive drug counseling services even when such services are mandated by State regulations. Further, there is evidence that many community pharmacists do not perform adequate reviews of patients' drug regimens or consult with physicians and patients when potential problems are identified.
- Many utilization problems occur at the patient level in administration of drug therapy among older adults. Compliance with drug regimen rates range from 38 percent to 57 percent, with an average of 45 percent. Medication behavior problems include underuse and overuse of drugs, sharing of drugs among family and friends, use of outside prescriptions, and use of damaged medications.
- The results of DUR interventions instituted by some State level programs and by researchers and practitioners are relevant to the design of a Medicare DUR program. Significant findings include:
  - Some State programs use post payment review to identify quality of care problems among beneficiaries. Such reviews include automated analyses of patient profiles coupled with case reviews by peer committees. While this method is useful in identifying broad patterns of misedication, it appears less effective in correcting such problems.
  - The value of linking diagnostic codes with prescriptions for the purpose of DUR analysis is highly questionable.
  - In terms of effecting clinical changes in physicians' prescribing patterns, research indicates that in-person education efforts (sometimes referred to as academic detailing) result in significant improvements. Such interventions appear much more effective than mail education programs or peer review inquiry strategies.
  - When pharmacists are provided with information tools to review drug regimens and when they conduct consultations and counseling with physicians and patients, utilization problems can be significantly reduced. Patient counseling can be improved through training pharmacists in communication skills.
  - A number of education strategies for patients have resulted in improvements on rates of compliance. Improved labelling techniques, use of reminder aids and in-home counseling by pharmacists are some of the strategies that have proven successful.

## **RECOMMENDATIONS**

- The HCFA should plan for the phasing in of a comprehensive Medicare DUR program designed to promote quality of care, control program costs and ensure program integrity. The DUR process should encompass all beneficiaries, notwithstanding deductible status.
- The program should incorporate review and education functions at three levels of the drug therapy process. As soon as is feasible, the program should include the following elements at each level:

### **Pharmacist Level**

- The electronic claims processing (ECP) data base and system should enable the pharmacist to record all drug transactions for all beneficiaries, verify a patient's eligibility and deductible status, and be alerted by computer prompts to potential mismedication errors. Consistent with the stipulation in the Conference Report that requires all participating pharmacies to "review the medication profile of all beneficiaries...before filling prescriptions," the ECP system should also provide pharmacists with a full screen display of the patient's drug regimen.
- The ECP system should be compatible with those used for Medicaid claims processing.
- Participating pharmacists should be required to review all Medicare beneficiaries' drug regimens and assure that in accord with carefully developed criteria all Medicare patients have access to counseling services regarding appropriate administration of the drug, potential side effects and related therapeutic issues. When a potential adverse reaction exists, pharmacists should consult with physicians and patients before dispensing the drug.

### **Drug Bill Processor/Claims Processing Level**

The drug bill processor should:

- Utilize prepayment edits to identify cases of duplicate and erroneous billing, and perform other program integrity audit functions on a retrospective basis to identify cases of fraud and abuse.
- Evaluate the quality of information supplied by the drug bill processor to pharmacists and assess the range and nature of use of that information by pharmacists.

- Conduct some automated therapeutic review.

### **Post Payment Level**

- Using claims data collected at the drug bill processor level, a review of prescribing and utilization behavior should be conducted to identify physicians, pharmacists and patients who demonstrate patterns of mismedication and to target high risk segments of those groups for education efforts.
  - Education efforts for those target groups should be implemented at the local level and outcomes from such interventions should be monitored and evaluated for effectiveness.
- The Health Care Financing Administration (HCFA) and the Public Health Service (PHS), individually and collaboratively, should promote improvements in the prescribing, dispensing, and utilization of drugs for older adults by taking the following actions:
    - Make funding available to finance research and demonstration projects that will test DUR interventions and evaluate their relative benefits and cost.
    - Establish a blue ribbon panel to develop DUR criteria that will serve as a national standard for DUR programs conducted throughout the country; to make specific recommendations regarding expansion of curricula in U.S. medical schools in the areas of pharmacology and geriatrics; and to make additional policy recommendations, as needed, in regard to improving drug utilization among the elderly.
    - Expedite issuance of FDA guidelines to manufacturers to ensure adequate testing of drugs on elderly populations.

### **ADDITIONAL STUDIES**

- The OIG is conducting a number of additional studies related to Medicare DUR. They cover the following topics: the disciplinary practices of State pharmacy boards, the clinical role of the community pharmacist, the privacy implications of the Medicare prescription drug benefit's electronic claims processing system, the enforcement of drug regulations, the medication regimens of older adults, and the technical implementation issues associated with the Medicare prescription drug benefit.

## **COMMENTS**

The American Medical Association, the American Association of Colleges of Pharmacy, the National Association of Boards of Pharmacy, the Public Citizen Health Research Group, and the Public Health Service expressed considerable support for our recommendations. The Health Care Financing Administration, the National Association of Chain Drug Stores, and the Pharmaceutical Manufacturers Association expressed support for the concept of drug utilization review, but raised a number of concerns about our recommendations. Their comments and our response to them are presented in general in the final section of the main body of the report and in detail in appendix I.

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## TABLE OF CONTENTS

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<b>EXECUTIVE SUMMARY</b>	
<b>INTRODUCTION</b> .....	<b>1</b>
<b>FINDINGS</b> .....	<b>4</b>
<b>Mismedication Among Older Adults</b> .....	<b>4</b>
<b>Weaknesses In The Drug Therapy Delivery System</b> .....	<b>8</b>
<b>State Survey Results</b> .....	<b>14</b>
<b>Other DUR Interventions</b> .....	<b>17</b>
<b>RECOMMENDATIONS</b> .....	<b>24</b>
<b>Development Of The DUR Program</b> .....	<b>24</b>
<b>Design Of The DUR Program</b> .....	<b>25</b>
<b>Immediate Actions</b> .....	<b>29</b>
<b>COMMENTS</b> .....	<b>32</b>
<b>APPENDIX I</b> .....	<b>33</b>
<b>Detailed Comments On The Draft Report And OIG     Response To Comments</b>	
<b>APPENDIX II</b> .....	<b>58</b>
<b>Endnotes</b>	



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## INTRODUCTION

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In June 1988, Congress passed the Medicare Catastrophic Coverage Act. In anticipation that the final act would include a prescription drug benefit for Medicare beneficiaries as well as a requirement that the Secretary establish a companion Drug Utilization Review (DUR) program, OIG had initiated a study in February 1988 to identify the major policy and program issues relevant to development of a Medicare DUR strategy.

The Act's major provisions related to coverage of prescription drugs include the following:

- Effective January 1991, enrollees in Medicare Part B who have exceeded a deductible threshold of \$600 in a single year will be eligible for partial coverage of costs of outpatient prescription drugs (as defined in the Act). Copayment by the patient will be 50 percent in 1991, 40 percent in 1992, and 20 percent in 1993 and thereafter. Further, the deductible threshold will be adjusted each year to ensure that no more than 16.8 percent of Medicare beneficiaries will be eligible for the benefit.
- With certain narrow exceptions, use of a formulary is prohibited.
- Coverage will not include drugs dispensed in a quantity exceeding a 30-day supply. The Secretary may authorize up to 90 days in special circumstances.
- The Secretary is authorized to contract with "limited carriers," i.e., drug bill processors for operation of an electronic point-of-sale claims processing system and is to provide participating pharmacies with equipment and technical assistance necessary to participate in the claims processing system. The system will provide a data base for tracking beneficiary drug transactions, monitoring eligibility, and documenting deductible status.
- The Secretary is required to establish a DUR program to identify patterns of inappropriate prescribing and dispensing practices, and instances of substandard care and potential adverse drug reactions. Additionally, the Secretary must establish an educational program to educate physicians and pharmacists about quality of care issues.

For purposes of this inspection, we used the DUR definition and program objectives as developed by Dr. T. Donald Rucker and recommended by the American Medical Association:

"DUR is a formal program for assessing data on drug use against explicit, prospective standards, and, as necessary, introducing remedial strategies to achieve some desired end. The three primary objectives are (1) improvement in the quality of care; (2) conserving program funds and individual expenditures; and (3) maintaining program integrity, i.e., controlling problems of fraud and benefit abuse."

The focus on improvement in quality of care as well as program integrity issues was considered integral to the inspection strategy for two reasons. First, in deliberating on the bill, the Congress held a number of hearings related to problem of mismedication among the elderly and the implications of such problems for development of a DUR program. As a result of those hearings, specific language was included in the Act that requires the Secretary to establish a program geared to improving the quality of drug therapy for the elderly. Second, in the course of reviewing the relevant drug utilization research, the inspection team concluded that significant economic savings would be gained by including a quality of care dimension to a Medicare DUR program, and that, in fact, those potential savings may well exceed savings related to program integrity issues.

Data were gathered for the inspection from three major sources:

- A survey of 48 State agencies that had been providing prescription drug benefits to Medicaid patients and operating their own DUR programs, as well as an additional 6 State agencies that provide similar benefits through programs designed specifically for the elderly.
- Alternative review of relevant research findings related to drug utilization among the elderly, including topics such as overall utilization patterns, problems of mismedication, and experimental interventions to improve drug use.
- A series of interviews with researchers, academics, and practitioners in the fields of geriatrics and pharmacology; former and current policy makers at the State and Federal levels; congressional staff involved in drafting of the Act; and private sector pharmaceutical providers.

The findings from these data gathering efforts have been incorporated in this report which attempts to describe the widespread pattern of mismedication among older adults, identify those aspects of the drug therapy delivery system that have created the problem, and describe DUR interventions that appear most promising.

The mismedication of the elderly is an issue that transcends the new Medicare prescription drug benefit. It does, however, have a number of important implications for design and management of a DUR program. With implementation of the Act, HCFA policy makers will be presented with a unique opportunity to have major impact on a widespread health problem among the elderly. The HCFA is now preparing a request-for-proposal for the electronic claims processing system that will be the infrastructure for operating the benefit program. Equally important, that system will serve as the data base for all DUR activities. As one expert in the field has described it, the system will be an intersection for clinical practice, epidemiology, and computer technology. Because of the unique importance of the claims system in the overall operation of the program, we have made a number of recommendations regarding basic system requirements. On a broader level, we have also included specific

recommendations to HCFA and PHS that are geared to resolving some of the structural weaknesses in the overall drug therapy delivery system.

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## FINDINGS

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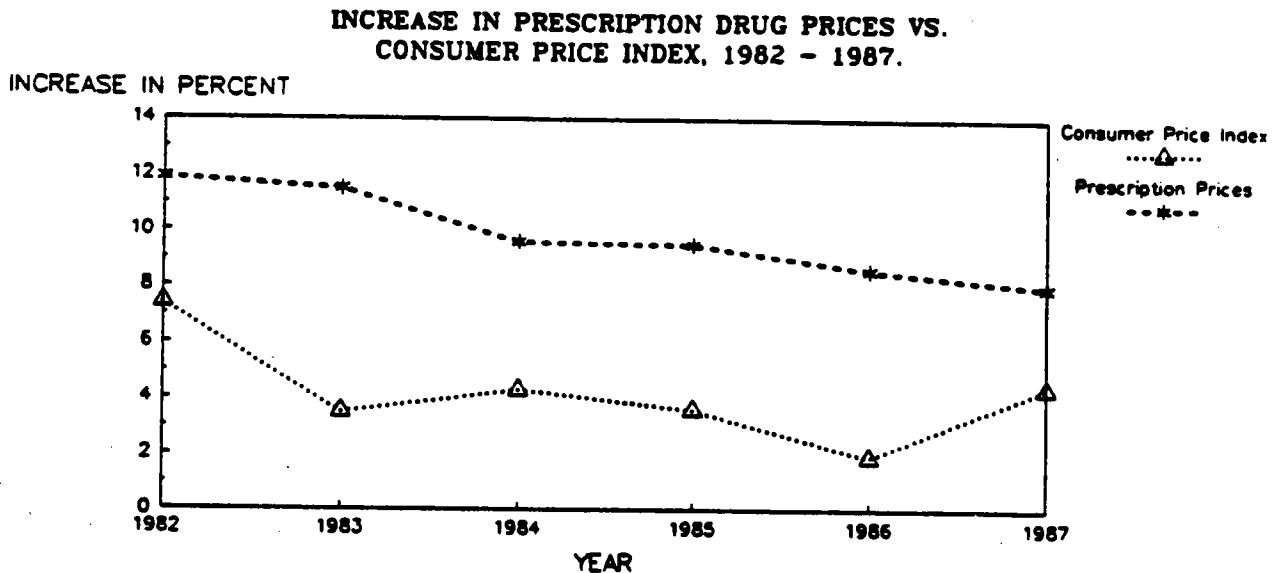
### MISMEDICATION AMONG OLDER ADULTS

***There Is A Widespread Problem Of Mismatched Medication Among Older Adults. The Problem Is Likely To Grow When The Medicare Drug Benefit Is Implemented, Unless An Effective DUR Program Is Developed.***

There are serious cost and quality of care risks associated with implementation of the new prescription drug benefit within the Medicare program. Anecdotal evidence from State pharmaceutical assistance programs for the elderly and independent research in the field of geriatric pharmacology indicate that, unless an effective drug utilization review program is instituted by HCFA, existing problems of excessive and inappropriate prescribing for the elderly will be further exacerbated by the new benefit.

In order to assess the potential risks associated with the prescription drug benefit, it is useful to review recent consumption and cost trends among the general population as well as within the subset of the elderly. For the entire U.S. population, the total number of prescriptions filled between 1976 and 1986 rose by 6.6 percent, while the number of pills per prescription increased by 14 percent over the same period.<sup>1</sup> At the same time, prescription drug prices have increased substantially and at a much higher rate than inflation<sup>2</sup> (figure 1).

**FIGURE 1**



Source: AARP Issue Brief, March 1987;  
Testimony before Senate Subcommittee on Aging,  
July 20, 1987.

Price increases and growth in consumption are reflected in the remarkable increase in total retail prescription drug sales between 1974 and 1986 from \$5.7 billion to \$18.9 billion, a 226 percent jump.<sup>3</sup>

Within the elderly population, utilization rates and costs are particularly high. Although Americans who are 65 years or over constitute only 12 percent of the population, they use over 30 percent of the prescription drugs and 40 percent of the nonprescription drugs dispensed.<sup>4</sup> Another measure of consumption by the elderly is that in 1986, a total of 613 million prescriptions were filled at retail drugstores for older adults, an average of 15.5 prescriptions per person.<sup>5</sup> The incidence of polypharmacy (the use of multiple drugs at one time) is also especially high among older adults. Sixty-one percent of the institutionalized elderly receive three or more different prescription drugs in a year; 37 percent receive five or more; and 19 percent seven or more.<sup>6</sup>

One of the primary reasons for this high level of use is that the elderly are more likely to have chronic diseases. Eighty percent of those over 65 have one or more chronic illnesses,<sup>7</sup> and across the entire elderly population, there is an average rate of three to five chronic diseases per non-institutionalized patient.<sup>8</sup> In terms of drug costs, the elderly have been particularly hard hit by the rising prices of prescription drugs, given the fact that cardiovascular, anti-hypertensive, and non-steroidal anti-inflammatory medications most often prescribed for the elderly are among the most expensive types of drugs.<sup>9</sup>

There is little question that drug therapy is an essential component of long-term health care for the elderly. Reductions in deaths from heart disease and strokes can be attributed in part to development and use of cardiovascular and anti-hypertension drugs. Effective outpatient drug regimens have also permitted the elderly to maintain independent living status and to improve the quality of their lives.<sup>10</sup>

Despite the obvious benefits, however, there are profound risks associated with use of prescription drugs, particularly among the older adult population. A growing body of evidence accumulated over the past 10 years indicates that mismedication of the elderly has become a critical health care issue. It has been labeled by some, including the National Council for Patient Information and Education, as the "nation's other drug problem."<sup>11</sup> The issue has become a subject of concern among researchers, practitioners, and policy makers at the national and international levels. Dr. Ira Bennett, editor of the Harvard Medical School Health Letter, has reported that "research shows overmedication and adverse reactions to drugs are prevalent and have probably become epidemic among the elderly."<sup>12</sup>

Mismedication can occur in at least four ways: (1) higher doses are prescribed in cases when a lower dose would provide the same benefits with lower risks; (2) drugs with a greater potential for adverse reactions are prescribed when a less dangerous drug would be just as effective; (3) the particular drug prescribed is unnecessary either because the patient's condition has been misdiagnosed or because nondrug therapy could be substituted; and (4) the combination of the prescribed drug with other drugs in the patient's regimen produces adverse effects.

There are many medical and social reasons that the elderly are more likely to be victims of mismedication; however, there are a few particularly important ones. The first is that there is a higher risk of adverse drug reactions (ADRs) as the number of different drugs taken increases;<sup>13</sup> consequently, the elderly, who use significantly more types and total amounts of drugs than the rest of the population, are especially vulnerable. Because they suffer from multiple chronic diseases, older adults are frequently under the care of more than one physician who may prescribe drugs without knowledge of the patient's full drug regimen. Thus, the physician may be unaware of the potential for drug interactions. Furthermore, as the drug regimen becomes more complicated, there is a greater likelihood that the patient will make an unintentional error.

Secondly, unique physiological changes associated with aging greatly affect the body's metabolism of drugs, thereby increasing the possibility that an appropriate dosage for a younger patient is not appropriate for an older one. Some physicians may not account for these changes when developing a drug therapy program for an elderly patient. "The risk of an adverse reaction is about 33 percent higher in people aged 50 to 59 than it is in people aged 40 to 49, increasing to two to three times higher when people are older."<sup>14</sup>

Identifying and treating cases of ADRs in the elderly can be problematic since symptoms of such reactions are often similar to those typically associated with the aging process and to symptoms of diseases common among the elderly. Further, the effects of mismedication may range from mild, temporary symptoms to serious illness and death.

Because ADRs are frequently misdiagnosed, it is difficult to determine with precision the full scope of associated illnesses, injuries, and deaths. However, severe effects of ADRs have been documented. An OIG analysis of Medicare hospital bills indicates that:

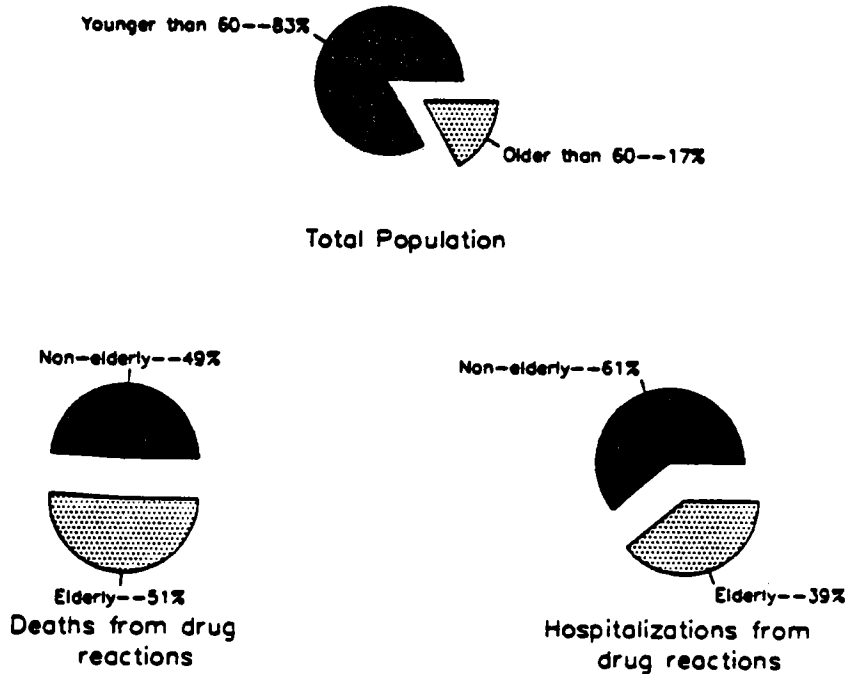
- In 1987, an estimated 200,000 older adults were hospitalized due to ADRs or experienced an ADR while hospitalized.

Other studies have found that:

- Each year, 32,000 elderly adults incur hip fractures due to drug-induced falls.
- 63,000 older adults experience serious mental impairment either caused or worsened by drugs.
- 61,000 older adults have developed symptoms that mimic Parkinson's disease due to prescribing of anti-psychotic drugs.
- Two million of the elderly are addicted or at risk of addiction to minor tranquilizers or sleeping pills because of using them daily for at least 1 year.<sup>15</sup>

In proportion to the general population, the elderly are considerably overrepresented in terms of hospitalizations and deaths as a result of adverse drug reactions:<sup>16</sup>

**FIGURE 2**  
**DEATHS AND HOSPITALIZATIONS AMONG OLDER AMERICANS AS A RESULT OF ADVERSE DRUG REACTIONS**



Source: Senate Special Committee on Aging.

Beyond the human costs associated with mismedication among the elderly, there are significant financial costs borne by patients, families, and public and private health insurers. One study conducted by Pennsylvania Blue Shield estimated that the annual cost of drug related hospital admissions of the elderly, along with their subsequent treatment, was \$4.5 billion in 1983.<sup>17</sup> (That estimate does not include costs associated with ADRs among the elderly who required treatment other than hospitalization.) Other estimates of health care costs associated with ADRs among the elderly are as high as \$7 billion per year.<sup>18</sup>

It is a basic microeconomic principle that price subsidies such as the new Medicare prescription drug benefit will increase both the consumption and, ultimately, the price of a good. The experience of the State of Pennsylvania in implementing its own drug benefit program (PACE), which subsidizes prescription drugs for the elderly, is illustrative. In 1985, at the end of its first program year, PACE beneficiaries were submitting an average of 18 prescriptions per year at a program cost of \$62 million. (This consumption rate was significantly higher

than that for the U.S. population as a whole.) As would be expected with a new entitlement, the program has grown substantially each year as the number of eligible beneficiaries, the number of prescriptions filled per beneficiary, and the average cost of each prescription have all increased steadily. The most recent projections for the current program year are that average number of prescriptions per enrollee will be 26 per year and total PACE program costs will exceed \$180 million.<sup>19</sup> (This represents a 44 percent increase in the average number of prescriptions and a 190 percent increase in program costs in just 4 years.) PACE program staff have also estimated that over 30 percent of PACE beneficiaries are on potentially conflicting drug regimens.<sup>20</sup> The magnitude of such potential conflicts varies among individuals.

The major risks associated with implementation of the new Medicare benefit are, therefore, two-fold: (1) subsidized prices may result in an increase in consumption, thereby exacerbating the quality of care problems of mismedication and overdrugging that already exist, and (2) as consumption increases, health care costs associated with ADR-related illnesses and hospitalizations and with the price of prescription drugs may accelerate.

## **WEAKNESSES IN THE DRUG THERAPY DELIVERY SYSTEM**

### *The Widespread Problem Of Mismedication Among The Elderly Reflects A Series Of Systemic Weaknesses Throughout The Drug Therapy Delivery System.*

The problem of widespread mismedication of the elderly is not the result of fraud, abuse, or malfeasance within the health care system. As one leading researcher in the field has described it: "There is no malevolent force in all of this. What we are fighting here is sheer ignorance and lethargy."<sup>21</sup>

A review of the entire process of administering drug therapy to the elderly reveals a series of fundamental weaknesses throughout the system, beginning at the manufacturer level and extending to the patient's management of his/her own drug regimen.

### **Manufacturer Level**

Systemic weaknesses in the delivery of drug therapy for older adults begins at the pharmaceutical manufacturer level. In the past, drug companies often performed clinical studies required to secure FDA approval on healthy younger adults even though the product may ultimately be approved and marketed for a condition that is common among the elderly. As one noted pharmacology expert described the situation, "We test drugs on young people for 3 months; we give them to old people for 15 years."<sup>22</sup> The FDA has been working with the industry to correct this problem, and indicates that in recent years much progress has been made in including older patients in clinical studies of new drugs.

For the past 5 years, the FDA has been developing and promulgating guidelines for the drug industry that would require inclusion of the elderly in premarketing clinical tests. In 1983, FDA began circulating a discussion paper on the subject. In 1986, the agency released a draft



of guidelines for review by the drug companies. In 1988, PHS issued in final "Guideline for Clinical and Statistical Sections of an Application." This guideline goes beyond the issue of whether or not the elderly are included in clinical trials and emphasizes the need for analyzing the influence of variables such as age on the results of these trials.

Also pertinent in this context is the extent to which manufactures provide labeling information on drugs commonly used by the elderly. The FDA reports that in a recent internal survey it concluded 212 of the 425 individual drugs used most often by the elderly contain geriatric information, and that 10 of the top 24 used by the elderly provide such information.<sup>23</sup> The FDA also reports that it has conducted a similar survey of all drugs approved in 1988 and will be providing the results as soon as possible.

As mentioned previously, physiological changes that occur as the body ages create particular sensitivities to drug usage.<sup>24</sup> Some of the changes that affect older peoples' reaction to drugs include:

- **Body size and composition:** after age 60 body weight decreases and the proportion of body fat increases. Drugs that concentrate in fat tissue will therefore remain in an older person's body for a longer time. Further, dosages appropriate for a younger adult may be too high for an older person whose body weight is lower.
- **Liver functions:** as adults grow older, the liver becomes less efficient thereby making it more difficult for drugs to be excreted from the body.
- **Kidney functions:** the filtering ability of the kidneys decreases by 30 percent by the time a person reaches 65 years and continues to decrease steadily thereon. This decreased kidney function can cause certain drugs to accumulate in an older person's body at higher levels and for longer periods of time than in younger people.<sup>25</sup>

It is important to recognize that these age-related changes in body size and composition, liver functions, and kidney functions are subject to wide variations, with some individuals showing significantly less change than might be expected for the population as a whole.

Failure to conduct thorough clinical drug tests on older adults can therefore result in a vacuum of knowledge about appropriate dosage levels and ADR risks. To further exacerbate the problem, the types of medications consumed by the elderly are often inherently more toxic.<sup>26</sup> One of the major risks that is run "by underrepresenting or ignoring the elderly in this important (clinical testing) process is the repeating of disasters such as that of Orflex in which widespread use of the drug by elderly patients once it was marketed resulted in high rates of side effects and even mortality before the manufacturer voluntarily withdrew it from the market."<sup>27</sup>

The Public Citizen Health Research Group recently conducted a review of the 287 most commonly prescribed drugs for non-hospitalized older adults, and compiled its recommendations

for a consumer publication titled *WORST PILLS BEST PILLS*. Among the findings are the following:

- The Group designated 104 of the 287 most commonly prescribed drugs (excluding drugs for treatment of cancer) as medications that should not be used by older adults because safer alternatives are available.
- 20 of the drugs not recommended for use account for more than 83 million prescriptions filled for the elderly each year, at a cost of over \$1 billion annually.<sup>28</sup>
- The entire list of 104 drugs in the "do not use" category represents 136 million prescriptions per year, or nearly 25 percent of the total number of prescriptions filled for the elderly each year.

Although reports such as Public Citizen's are useful in sensitizing older adults and health care professionals to the dangers of misedication, they cannot substitute for a formal set of guidelines that will ensure improved testing and labeling of medications for the elderly.

### **Physician Level**

It is frequently assumed that in treating the elderly, physicians make diagnostic evaluations and prescribing decisions based on the most up-to-date medical information available. A mounting body of evidence, however, suggests that this is frequently not the case and that sub-optimal prescribing patterns for the elderly are common: "drugs that are largely ineffective are widely used, dosages or combinations are often pharmacologically irrational, useful drugs are passed over in favor of newer agents that are no more effective but may be considerably more expensive."<sup>29</sup>

Nowhere is it suggested that poor prescribing patterns for the elderly are a product of lack of concern or general incompetence on the part of physicians. Rather, inappropriate administration of drug therapy is, for the most part, a reflection of a serious lack of training for many physicians in the fields of geriatrics and pharmacology.

In 1988, less than 2 percent of the students enrolled in the nation's 127 medical schools were required to take courses in geriatrics. This, however, is an improvement over the past decade. In the mid-1970s almost no geriatrics courses were offered in medical schools.<sup>30</sup> One study published in 1986 reported that medical schools today have only 10 percent of the faculty needed to teach and conduct research in geriatrics.<sup>31</sup> Further, only 1 percent of the continuing education courses for physicians are in the field of geriatrics.<sup>32</sup>

Despite the fact that the elderly population will continue to grow at a steady pace as the "baby boom bulge" ages, the most optimistic estimates are that by the year 2000 the United States will have between 900 and 1600 educators and only 8000 doctors trained in geriatric specialties.<sup>33</sup> (This compares to 479,000 physicians in the United States today.)

The lack of formal training for physicians in the field of pharmacology is equally striking. The problem is compounded by the introduction of hundreds of new medications to the market each year. A 1988 study published in the *Annals of Internal Medicine* reported the following:

- Most physicians receive only one course in pharmacology during medical school.
- By the time a physician completes residency, 100 new drugs have joined the market.
- Nearly every prescription written in 1988 by physicians who graduated from medical school in 1960 is for drugs about which those physicians have received no formal education.<sup>34</sup>

Studies measuring physicians' knowledge of prescribing reflect this educational gap, particularly with respect to psychotropic drugs.<sup>35,36,37</sup> One of the most recent and significant studies was conducted in 1985 and focused specifically on the prescribing knowledge of physicians who treat the elderly. Researchers at Temple University Medical School administered a questionnaire on knowledge of prescribing for elderly adults to a stratified random sample of physicians who treat Medicare patients. Over 70 percent of the respondents failed to pass the exam.<sup>38</sup>

In the absence of adequate education and training in geriatrics and pharmacology, physicians frequently rely on generalized stereotypes about the aging process, and, in selecting a particular drug regimen, they often depend on the promotional materials provided by drug manufacturers. "Many health professionals have a mistaken attitude about the elderly patient that perpetuates... 'an unfair elderly stereotype. This stereotype of confusion, lethargy, and weakness, forgetfulness and tremor...unfairly discriminates against the majority of elderly individuals who manifest none of these characteristics. Since the most common manifestations of (ADRs) in the elderly are precisely the same symptoms of this unfair stereotype, professionals who believe that aging is synonymous with deterioration of physical and mental function often overlook medications as the cause of their patients' deterioration."<sup>39</sup> The result of this stereotype can be an "illness-medication spiral,"<sup>40</sup> in which ADRs are diagnosed as new illnesses, leading to the prescribing of more and more drugs to treat symptoms and toxicities caused by inappropriate drug therapy. The consequences of such an illness-medication spiral can be as serious as permanent incapacitation and even death of the patient. In its hearings on adverse drug reactions among the elderly, the Senate Special Committee on Aging heard testimony from a number of witnesses whose family members have been tragic victims of this syndrome.<sup>41,42</sup>

In surveys that have asked physicians about the information sources on which they are most reliant in making prescribing decisions, scientific literature is nearly always accorded a more prominent position than commercial sources. However, in studies that do not rely on self-reports, findings indicate that commercial sources of information are relied on far more heavily.

ly than scientific literature. One project conducted by Harvard Medical School researchers studied a random sample of physicians in greater Boston and focused on two index drugs whose effects have been shown in published clinical studies to be minimal or not significantly different from those of over the counter drugs, but which are heavily advertised as being effective. The study found that "although the vast majority of practitioners perceived themselves as paying little attention to drug advertising and detail men, as compared with papers in the scientific literature, their beliefs about the index drugs revealed quite the opposite pattern of influence in large segments of the sample."<sup>43</sup>

Findings such as these are not surprising when one considers the resources and technologies used by drug manufacturers to promote their product. Last year, drug companies spent \$2.5 billion on promotional activities of their products to physicians.<sup>44</sup> An average of \$5,000 per physician is spent each year by drug manufacturers whose promotional activities range from provocative and elaborate print materials to face-to-face visits with physicians.<sup>45</sup> The issue is not one of deception, but rather of aggressive and sophisticated marketing techniques that are designed to sell the maximum volume of drug products. The sales staff are typically not formally educated in pharmacology; in 1988 less than 5 percent of the detail men promoting drug sales had formal pharmacology training.<sup>46</sup> Evidence, however, indicates that these detail men and their supporting print materials are the primary source of drug information for many physicians.

### **Community Pharmacy Level**

Within the health care delivery system, pharmacists are seen as providers of a unique service, that of "disseminating information concerning all aspects of medication (to both) health professionals and the general public."<sup>47</sup> Pharmacists' professional associations have, as one of their standards of conduct, the requirement to consult with physicians and counsel patients on administration of drug therapy and in sixteen States, boards of pharmacy have instituted mandatory patient counseling regulations.<sup>48</sup> Thus, in theory, the community pharmacists should serve as a quality control mechanism to identify cases of misedication.

As indicated in a number of surveys, community pharmacists see themselves as willing and able to provide counseling services to patients and believe that they do, in fact, provide such services on a regular basis.<sup>49</sup> However, a number of observational studies indicate that this may not be the case. Much of the literature emanating from these studies has been "critical of pharmacists in terms of the small percentage of patients who receive any consultation, the brevity of the consultations that do take place and the inadequacy and inappropriateness of the pharmacists' decisions in regard to patient care."<sup>50</sup>

Reports on the rate of verbal counseling provided by pharmacists have been as low as 30 percent for all patients served, and when dispensing refills, that rate is even lower.<sup>51</sup> Further, when filling a new prescription the average length of time spent in consultations during routine provisions of services has been found to be only 20-30 seconds.<sup>52,53</sup> "One pioneering observational study of pharmacists indicated that (they) devote little of their work time to

patient communication and half of the time they do spend talking with patients is on non-professional communication."<sup>54</sup>

Even when patient counseling is mandated by State board regulations the performance of pharmacists can remain unchanged. A study conducted in Kansas evaluated the effects of mandatory patient counseling regulations 2 years after they were implemented and found that the new requirement had no effect on the amount or quality of counseling provided by pharmacists. Among other findings of that study were:

- There was a significant increase in the number of pharmacists using auxiliary labels to supplement verbal instruction.
- The majority (53 percent) who did use labels used them as the only means of supplying patient information.
- A much higher percentage of chain pharmacists used auxiliary labels with no verbal counseling.
- In 38 percent of the pharmacies, non-professional staff gave the prescription to the patient "thus performing, unsupervised, the final and virtually most important step in the process....that of counseling the patient in proper self medication."<sup>55</sup>

In terms of community pharmacy services for the elderly, who typically have more complex drug regimens and are likely to be treated by more physicians than younger patients, the consulting role of the pharmacist is particularly important. However, studies show that the elderly fare poorly in this regard. Over 70 percent of all patients report receiving no information from pharmacists<sup>56,57</sup> and for elderly patients the incidence is even higher than for younger adults.<sup>58</sup>

The community pharmacy profession is in a state of flux at the present time, complicated by the fact that its traditional market has become considerably more competitive. "Expansion of hospitals with ambulatory care, mail order and deep-discount prescription services, and physician dispensing..." are just a few of the market challenges facing community pharmacies.<sup>59</sup> One response to these market challenges has been the new technology introduced to improve productivity and enhance competitiveness. Pharmacy robots capable of "reading" and filling prescriptions are being used in Japan and are being tested in the United States.<sup>60</sup> Although quality of service to the patient is seen as a useful marketing technique, technological and market forces have combined to "depersonalize" the services offered by community pharmacies to patients.

## **Patient Level**

Notwithstanding the systemic flaws at the manufacturer, physician, and pharmacist levels, drug utilization problems can and often do occur at the patient level in administration of drug therapy. Noncompliance, or medication behavior problems of patients, include underuse and overuse of a drug, as well as items such as sharing of drugs among family and friends, use of outdated prescriptions, and use of medications that have been damaged due to poor storage.

A review of the literature concerning compliance with prescription drug regimens indicates that older adults' compliance rates range from 38 percent to 57 percent, with an average rate of approximately 45 percent.<sup>61</sup> Some research indicates that "compliance is relatively good among children, poor among adolescents, good during middle years, and, again, relatively poor with advancing age."<sup>62</sup>

Advanced age is not in itself a reliable predictor of non-adherence.<sup>63</sup> However, studies indicate that use of multiple medications,<sup>64</sup> duration of drug therapy,<sup>65</sup> and living status<sup>66</sup> (i.e., living alone rather than with family or friends) are all variables that negatively affect a patient's compliance with drug therapy. Because older adults are more likely to suffer from chronic diseases and to take more types and amounts of drugs, they may be particularly prone to medication behavior problems. Compounding the problem is the fact that adults' vision tends to deteriorate over time, making it difficult for some elderly patients to read and understand instructions on labels.<sup>67</sup>

As mentioned previously, older adults consume nearly 40 percent of all over-the-counter (OTC) drugs, a practice that complicates prescription drug regimens for some elderly patients. With the increasing number of very potent drugs being reclassified for OTC use, self-prescribing becomes more risky, especially among older patients who may already have a complex prescription drug regimen. Patients who are self-administering OTC drugs may not communicate that fact to physicians and pharmacists who could identify potential drug interactions and other hazards.

Thus, even when the appropriate drug regimen is prescribed and dispensed, breakdowns can occur at the patient level. Although compliance problems are the product of a multitude of variables, all of which can never be resolved, evidence suggests that the development of a DUR program for Medicare beneficiaries should be focused to some degree on this critical stage of drug therapy.

## **STATE SURVEY RESULTS**

***From A Quality Of Care Perspective, State Medicaid Dur Policies And Program Functions Have Limited Applicability For A Medicare Prescription Drug Program.***

Our survey of the 48 State Medicaid agencies found that most DUR programs are geared to identify and correct problems of program integrity, rather than quality of care.<sup>68</sup> Given this policy focus and the fact that Medicaid populations differ significantly from Medicare popula-

tions, both in demographic profiles and in drug consumption patterns, the Medicaid DUR efforts alone should not be used as a model for developing a Medicare DUR program.

In general, State Medicaid agencies define the DUR problem as one of abuse by individual recipients, and, to a lesser degree, fraudulent billing practices by pharmacists and physicians. An overwhelming majority of survey respondents reported that drug utilization cases in the State Medicaid programs involve narcotics and controlled substances. Forty-two (88 percent) of the States reported that DUR cases involved certain types of drugs and nearly 80 percent cited narcotics and other drugs with street values as the specific drugs involved.

Because of the manner in which State Medicaid agencies have defined the drug utilization problem, resources have been allocated and monitoring devices selected to identify patients who abuse the system, either because of addiction problems or because of involvement in illegal sale activities. Program functions have also extended to monitoring pharmacists and physicians who may be involved in fraudulent or abusive activities.

Although we found that the majority of States (69 percent) use some form of prepayment method to identify utilization problems, those functions are almost exclusively geared to identify administrative problems or to enforce eligibility restrictions. The nature of prepayment review methods for the 33 States that use them are as follows:

- Five States require preauthorization to increase supply limits.
- Ten States require preauthorization for non-formulary drugs.
- Fifteen States perform prepayment edits to enforce lock-ins (requirements that patients suspected of misuse use a single doctor and/or a single pharmacy), to screen for dispensing of non-formulary drugs, or to identify duplicate or faulty billings by pharmacists.

Further, the majority of State agencies (65 percent) reported that they do not encourage pharmacists to review prescriptions prior to dispensing a drug.

It is clear, therefore, that at the prepayment level, Medicaid DUR programs are designed to screen for eligibility, formulary and quantity requirements, and instances of administrative error and abuse. With only one exception, State programs are not designed to flag quality of care problems (e.g., potentially dangerous drug interaction or duplicative therapy) at the point of sale.

In terms of post payment strategies, all States report using some method of profiling to identify utilization problems, but again, these "problems" generally fall into the category of patient, pharmacy, or physician fraud and abuse.

At the post payment level, all of the State agencies surveyed reported using the method of patient profiling to establish a data base for utilization review. A lower proportion of States use pharmacy and physician profiling methods. Ninety percent rated patient profiling as the most effective post payment strategy for identifying program integrity problems. Only five States reported using a peer review committee to review cases of suspected misuse of drugs, and only three States reported that post payment review systems were used to identify contraindicated prescribing patterns.

Another reflection of the State agencies' perspective on the DUR process is seen in the methods most typically used to address utilization problems. Lock-ins were reported by 69 percent of the States as the most frequently used corrective method. Only 33 percent of the agencies reported engaging in educational outreach prior to the onset of problems, and nearly all such outreach efforts consisted of journal articles, seminars, and bulletins. For those States that use educational methods to correct already-identified problems, 33 percent reported that such activities consist only of warning letters sent to one or more of the involved patients.

Despite the fact that Medicaid DUR systems are designed to focus on program integrity rather than quality of care problems, there are indications that State officials are aware that quality issues are deserving of more attention. Although significantly more prevalent among older adults, problems of mismedication unrelated to fraud and abuse are not confined to the elderly population and this fact has been recognized by State Medicaid agencies.

In terms of expanding their program scope to identify and include quality of care issues, some States face a number of constraints. Inadequate resources in terms of financing, staffing, computer software, and data gathering capabilities were cited as a significant impediment to program expansion. Further, some DUR program officials reported that State level regulations limited their authority to narrow program integrity review and enforcement.

Agency staff's responses to questions about their own future directions and about advice to Medicare administrators reflect a broader perspective than their own current practices suggest. When asked which approaches have the most potential for addressing utilization problems in the future, education (31 percent) and establishment of peer review committees (31 percent) were mentioned most frequently. Further, when respondents were asked to identify the most significant initiatives Medicare administrators should take in designing a DUR program, the following items were mentioned most frequently:

- Implement education programs (33 percent).
- Use sophisticated data collection techniques and software to identify utilization problems (29 percent).



In summary, the OIG State survey's most significant finding may be that in designing a national DUR program, Medicare administrators should do what the States say rather than what they do. Although some States have instituted practices to address quality of care problems, the survey findings indicate that more common State practice is not particularly relevant to a Medicare DUR program.

## **OTHER DUR INTERVENTIONS**

### ***The Results Of DUR Interventions Instituted By Some State Level Programs And By Researchers And Practitioners Are Relevant To The Design Of A Medicare DUR Program.***

Although, as a rule, most State Medicaid DUR practices are confined to program integrity issues, some State level Medicaid and pharmaceutical assistance programs have implemented efforts to identify and correct quality of care problems. Further, independent research and experimental education programs have also produced results that are instructive for Medicare. Some State Medicaid programs and pharmaceutical assistance programs for the elderly have instituted interventions focused on quality of care issues. One of the most sophisticated designs for such a program is that of the Minnesota Medicaid Agency. The major procedural components of the Minnesota program are as follows:

- A panel of medical experts develops a list of therapeutic criteria that identifies high risk drugs, drug use characteristics, and disease classifications that present the greatest potential for mismedication problems.
- The State agency contracts with a provider who uses the preselected therapeutic criteria to review Medicaid computer tapes of drug purchases and identify "exceptional drug profiles" of patients that appear potentially hazardous. These reviews are computer-generated and use algorithms to sort information so that high risk patient profiles can be flagged.
- The drug history profiles are then transmitted back to the State agency which uses DUR peer review committees of health care professionals to conduct a case by case review. Such a review attempts to isolate cases of suspected overutilization and underutilization, adverse drug interactions, and contraindicated drug therapy.
- The DUR committee sends written inquiries to the practitioners associated with the questionable therapy and evaluates each response to determine whether the information provided by the practitioners justifies the drug therapy in question or whether further remedial action (e.g., continued monitoring, referral to local providers' professional society, referral to State boards of medicine and pharmacy) should be taken.<sup>69</sup>

The model described above includes elements that appear to have potential applicability for a Medicare DUR program. First, the development of therapeutic criteria as an underlying con-

struct for the entire review process is seen as a valuable tool with which to screen large amounts of drug utilization data.

There may also be a value to developing additional criteria with more elaborate screens at the DUR committee case review level, as other research indicates. In a study conducted by Michael Smyer, et al., for the Pennsylvania PACE Program, members of multiple peer review committees within the State were surveyed and asked to rate specific drug interactions in terms of their clinical significance for elderly patients. Such ratings were then compared with scientifically based authoritative standards. "The most striking finding was a very high variability among DUR members (in terms of their ratings). Limited consensus was achieved for only a few types of interactions."<sup>70</sup> This suggests the need to develop a second level of more sophisticated screens/criteria at the committee review level to ensure that such reviews are consistently focused on the highest risk groups.

The value of developing a thorough drug utilization data base with which to conduct vital computer-generated screens is also instructive for Medicare DUR program planners. The volume of drug transactions projected for Medicare beneficiaries (700 million annually) will require the maximum amount of automated review that is feasible. According to experts, one crucial element that should be included in such a data base is a physician provider's identification number.<sup>71</sup> The absence of such a standardized national identification system would obviously limit the ability of DUR reviewers to institute remedial action.

There has been some discussion among congressional and HCFA staff about the advisability of matching diagnostic codes with prescriptions. Although the legislation does not require that diagnostic information be provided by the physician with the prescription, there is some interest in developing a DUR data base that would match Medicare part A and B claims data (which include a diagnostic code) with DUR patient profiles in order to expand the patient information available for DUR review. Findings indicate, however, that use of standard diagnostic codes would have limited utility for a Medicare DUR program. Researchers who have used Medicaid data bases (which include diagnostic codes) for DUR-related research report that there are a multitude of problems associated with use of such codes in making clinical judgments.<sup>72</sup>

First, there are several problems related to the accuracy and intelligence of diagnostic code data. For Medicare, part B procedure codes are frequently listed as "doctor's office visit", which provides no information about the patient's condition. Further, patients themselves sometimes complete part B claim forms, a practice that further exacerbates the accuracy problem. It is routine in some office practices for clerks who do not have clinical expertise to complete claim forms, and, even when they are completed correctly, computer sorting of information may be flawed. One university-based project that used diagnostic codes to conduct research on ulcer disease was seriously flawed because computers and clerks added trailing zeros to a code, unaware of the fact that such an addition resulted in a miscoding error that changed the diagnosis.

Secondly, even if the accuracy problems could be resolved successfully by improving coding models and training health care personnel, the problem of "paper compliance" would remain. Typically, multiple diagnoses are associated with treatment of the elderly, all of which may be addressed in a single office visit. It is likely that physicians would quickly learn which codes should be associated with particular prescriptions in order to avoid the administrative burden of responding to a DUR-related inquiry. A system of "paper compliance" would then be instituted among physicians treating Medicare patients, thereby adding no useful information for DUR purposes and resulting in no clinical change of behavior among practitioners.

Beyond the issue of the ingredients of a data base, other elements of State level DUR experiences are instructive for Medicare. Like Minnesota, several States have used the peer review committee method to identify quality of care problems, and, although this technique has been found useful in identifying questionable utilization patterns, there are serious questions about its efficacy in correcting such problems. The process itself is lengthy and labor intensive by nature; it can sometimes take 12 to 18 months from the time a drug is prescribed to the point at which a DUR committee sends a written inquiry to the physician. The requirements of assembling computer tapes, conducting automated screens, and completing case by case reviews of questionable profiles precludes timely identification of what could be life threatening instances of mismedication for elderly patients. By the time a physician is notified by a DUR committee that a patient's drug regimen is in question, the patient may have died, the drug regimen may have been adjusted, or the patient may have moved and/or changed physicians.

More importantly, the inquiry process itself has several severe limitations, both in philosophy of approach and effectiveness. Despite attempts to construct written inquiries that avoid offending the physician, the fact that a State authority is requiring a practitioner to justify his actions can carry an implied threat in many physicians' minds. The prospect of a DUR committee referring a physician for punitive action to a licensing board or enforcement agency is obviously not lost on the physician. The enforcement undertone of the entire process is therefore not likely to be perceived as a supportive, educative experience for the physician whose questionable prescribing patterns may be just the result of lack of appropriate information. Additionally, it is typical that DUR committees refer only the most egregious cases for sanction or punitive action. Instances of malpractice that require such enforcement action are difficult to document and prove, even when punitive action is clearly indicated.

In summary on this point, the peer review process, while somewhat useful in identifying potential problems, may not be a particularly effective technique for affecting changes in the behavior of physicians on a broad scale and, except in cases of clear abuse, is highly dependent on the willingness of practitioners to cooperate in what they may perceive to be an unnecessarily threatening process.

In terms of ameliorating patterns of mismedication, a number of initiatives by researchers and practitioners appear promising. Perhaps the most important and effective trial of interventions has been directed at the physicians' level of the drug therapy process.

Traditionally, the use of mailed educational materials has been a favored technique for providing physicians with continuing education services. However, research conducted over the past 5 years has raised serious questions about the efficacy of this method. A study published in the *Journal of the American Medical Association* in 1986 reported results of a mailed continuing education program for primary care physicians concerning management of hypertensive patients. A standardized trial in two urban communities in Canada "demonstrated no influence of a mailed...education program on the practices of physicians or on the control of the blood pressure of hypertension patients referred (by the project staff)."<sup>73</sup>

The pioneering work done by Dr. Jerome Avorn of the Harvard Medical School in measuring the relative effectiveness of various education methods on changing clinical behavior appears particularly relevant for design of a Medicare DUR program. Avorn and associates conducted a randomized controlled trial of 435 physicians in a four State sample. Using Medicaid patient profile tapes, project staff identified physicians who were participants in Medicaid programs and who prescribed high levels of one or more of three groups of target drugs that are questionable in terms of effectiveness or are unnecessarily costly.

A mailed education program was administered to one portion of the sample, using print materials that were commercially designed and fashioned in the style used by drug manufacturers to promote their products. These "unadvertisements" were designed to counter over-prescribing of the target drugs by means of attractive, easily read and understood messages. A second segment of the sample were visited by clinical pharmacists trained by project staff in the relevant pharmacological aspects of the target drugs and in communication techniques. These face-to-face contacts were conducted in a positive and supportive manner; physicians were not approached as problem prescribers, but rather, were told that they had been selected as subjects for a university-based drug information program. In addition to receiving the same "unadvertisements" sent to the print-only group, these physicians were visited twice by a clinical pharmacist who reviewed the print materials with them and encouraged them to reduce their prescribing of the target drugs. The third segment of the sample, the control group, was exposed to no intervention. Among the significant findings of this study are the following:

- There was no statistically significant effect of the education intervention on physicians who received the print materials only.
- For physicians who received face to face visits, there was an average reduction of 782 units of the target drugs per physician.
- Ninety-two percent of the group randomly selected for face to face intervention agreed to participate, and many asked for more drug education as a result of the visits.
- A time series analysis indicated that the improvements in prescribing habits remained constant over time, with "no significant diminution of effect 9 months after the start of intervention."

- The rate of prescribing change documented was independent of characteristics of physicians themselves (e.g., age, specialty, size of Medicaid practice, intensity of previous target drug use).<sup>74</sup>

A companion analysis by the study group analyzed the benefit/ cost ratio of the project and indicated that implementation of a personal visit intervention program for 10,000 physicians would lead to projected drug cost savings of \$2,050,000 compared to program costs of \$940,000. Further, the benefit/cost ratio could be increased to at least 3.0 if higher volume prescribers were targeted. "Net benefits would also increase if non Medicaid savings were added or if the analysis included quality of care considerations."<sup>75</sup>

Dr. Wayne Ray of Vanderbilt University has also conducted research on the effectiveness of physician education programs among Medicaid prescribers in Tennessee. As was the case in Avorn's research, mailed, commercially designed brochures had no effect on physicians' prescribing behavior. In the Ray study, the effectiveness of office visits by pharmacists was also measured against visits by physicians to target practitioners. The physician counselors were found to be even more effective than pharmacists in reducing prescribing of the target drugs.<sup>76</sup>

One particularly significant finding of both Avorn's and Ray's research is that physicians are equally receptive to education about drugs that are effective but unnecessarily costly (i.e., less expensive but equally effective drugs are available), as they are about drugs for which cost is not an issue, but effectiveness is questionable. Although it has been assumed by some researchers that physicians are less concerned with cost issues than with clinical concerns,<sup>77</sup> these studies demonstrate that physicians are willing to substitute more cost effective regimens if the educational approach is made in a positive professional manner.

At the dispensing level, there has been some recognition within the industry that significant value is added to community pharmacy services when pharmacists are given the tools to review a patient's drug regimen at the time of dispensing.<sup>78</sup> Several national retail chain corporations have developed a data system that their pharmacists are required to access when filling a prescription.<sup>79</sup> Personal computer screens display a history of prescriptions purchased by the patient at all of the company outlets (including out-of-State transactions) and the computer provides prompts to the pharmacist when a prescription that appears to conflict with the patient's regimen is about to be filled. Thus, the pharmacist has a complete record of the patient's drug regimen to conduct his own analysis and, when necessary, raise questions with the patient and/or physician, and is aided by a pre-programmed warning system that flags potentially dangerous drug combinations. This system is relatively new within the industry but it does demonstrate the feasibility of making automated drug records available to the pharmacist.

Considerable research has also been conducted to identify variables that affect the level of pharmacist consultation with patients. Studies have examined variables including age of the pharmacist, affiliation with chain vs independent pharmacies, and physical setting of the

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pharmacist's work station.<sup>80,81</sup> Two factors that appear to be reliable indicators are the pharmacist's attitude toward patient consultation<sup>82</sup> and the amount of privacy available to the pharmacist in the setting where consultation occurs.<sup>83</sup> Further, in studies measuring the effects of experimental interventions, it has been shown that patient counseling is improved when pharmacists are taught communication skills.<sup>84</sup>

Researchers in this field and segments within the pharmacy field itself are beginning to recognize the value-added aspect of pharmacist counseling with patients and physicians, particularly within the elderly population.<sup>85</sup> Some privately funded demonstration projects are underway to measure the clinical outcome and cost effectiveness of improving consultation services. The results of these and previous experimental interventions will be useful for Medicare administrators in designing that segment of the national DUR program that should occur at the pharmacist level.

Finally, studies conducted to determine the effectiveness of various patient interventions have also tested the relative value of various instruction and education techniques. In one study of 158 ambulatory patients who were elderly and receiving medication for cardiovascular conditions, the combination of oral instructions and a reminder calendar package was the most successful method for improving compliance behavior.<sup>87</sup> This reminder aid method has also been tested in other studies and found to be effective.<sup>88</sup> Labelling has also been found significant in terms of adhering to a drug regimen. Imprecise instructions (e.g., instructions such as "to be taken as directed"), and instructions that are not printed or typed in large letters have been negatively associated with patient compliance among older adults.<sup>89</sup>

One project conducted by researchers at the University of Washington studied the medication behavior of 183 elderly apartment residents.<sup>90</sup> The patients were provided written instructions and were visited at home by pharmacists who counseled them on compliance with and comprehension of their drug regimens, on potential drug interactions and other ADR's, and on appropriate drug handling and storage. The interventions were applied intermittently for almost two years. One year later, a final assessment indicated that there was a 39 percent decrease in the number of medication behavior problems and that a significant decrease of 11 percent had occurred in the number of prescriptions taken. "These results suggest that pharmacist consultation provides an effective health prevention strategy in elderly residential settings."<sup>91</sup>

The practice of "brown bag" lunches conducted in elderly residential settings, in which residents bring all of their medications to a meeting with a consulting pharmacist has also been recommended by experts as a useful educational technique.<sup>92</sup> The use of a drug worksheet such as that designed by the Public Citizens Health Research Group is another method designed to assist elderly patients in recording significant information about their drug regimens and in presenting such records to physicians and pharmacists.<sup>93</sup>

The cost savings associated with improving patient compliance have been well documented in a number of studies.<sup>94</sup> One project conducted by Joyner, et al., in 1983 was able to accomplish a mean compliance rate of 95 percent, at a cost of \$35 per patient for a sample of older adults living in a congregate housing facility. The benefit/cost ratio for the intervention

used was estimated in the range of 7.0 to 14.0, depending on the risk level of the population targeted.<sup>95</sup> This and other research leaves little question that improving patient compliance through education yields significant savings in both social and financial costs.



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## RECOMMENDATIONS

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### DEVELOPMENT OF THE DUR PROGRAM

- The HCFA should plan for phasing in a comprehensive DUR program designed to promote quality of care, control program costs, and ensure program integrity. The DUR process should encompass all beneficiaries, notwithstanding deductible status.

#### Discussion:

The HCFA has a formidable task before it just in terms of the technical aspects of implementing the drug benefit. Enrolling participating pharmacies, designing requirements for electronic claims processing, and contracting with providers to operate the claims system are only a few of the major tasks that will need to be completed. Organizational and resource related issues associated with planning and implementing the new system will consume the attention of HCFA staff at the policy and operational levels. However, a critical error will be made (1) if substantial attention is not given to the design and development of a comprehensive DUR program to be implemented, in phases, when the drug benefit becomes effective and (2) if approaches taken in establishing the electronic claims processing system impede the phasing in of the DUR program.

Although precise figures cannot be placed on the costs associated with mismedication and economically inefficient prescribing patterns for the elderly, there is little question that significant savings can be achieved through implementation of a DUR program. (As mentioned previously, some estimates of ADR related treatment costs alone range as high as \$7 billion annually.) Such savings will affect expenditures in the Medicare Health and Supplemental Insurance Funds if hospitalizations and treatment related to ADRs can be avoided, and will reduce outlays in the Drug Benefit Fund if cases of overutilization and prescribing of unnecessarily costly medications can be eliminated.

Notwithstanding potential program savings related to DUR, the new prescription drug benefit presents HCFA policy level officials with an opportunity to make a major impact on a widespread health problem among the elderly. The human costs associated with death, illness, and incapacitation among the elderly as a result of mismedication are incalculable. Establishment of a comprehensive Medicare DUR program that emphasizes therapeutic as well as program integrity issues will afford HCFA a leadership role in resolving this critical public policy problem and may serve as a model for public and private providers of drug benefits.

The DUR process should encompass all beneficiaries, regardless of an individual's deductible status. A number of elements support that policy direction:

- Data on all beneficiaries will be collected in any case so that deductible status can be documented by the claims processing system. Given the tremendous human and program costs associated with mismedication of the elderly, a valuable information

resource (i.e., the data base on all drug transactions) would be underutilized if DUR efforts were targeted only for those who have exceeded the deductible limit.

- Even though a beneficiary may never reach the deductible threshold, significant costs for treatment of ADR related illnesses may be incurred by the patient, by Medicare and/or by a supplemental carrier. Further, DUR interventions may actually preclude a beneficiary from reaching the deductible limit if a case of inappropriate utilization can be identified early in the process.
- All Medicare beneficiaries will be paying for this benefit, even though there is a statutory limit on the percentage of beneficiaries who will actually exceed the deductible threshold and become eligible for the subsidy. From an economic perspective, and in the interest of equity, the benefits derived from DUR interventions should be made available to all beneficiaries whose premiums are financing the program.
- Inclusion of all beneficiaries is clearly the intent of the Congress. A review of the conference report and correspondence between Members of Congress and HCFA, as well as discussions with committee staff, have all indicated that the intent of the legislation was that DUR should encompass all Medicare beneficiaries.

## **DESIGN OF THE DUR PROGRAM**

- The HCFA should develop a Medicare DUR program that incorporates review and education functions at three levels of the drug therapy process: pharmacist/dispensing level, drug bill processor/claims processing level, and post payment level. As soon as is feasible, the program should include the following elements and requirements at each level:

### **PHARMACIST/DISPENSING LEVEL**

1. The electronic claims processing (ECP) data base and system should enable the pharmacist to:
  - Record all drug transactions for all beneficiaries (regardless of deductible status).
  - Verify the patient's eligibility and deductible status.
  - Review a full screen display of the patient's drug regimen.
  - Be alerted by computer prompts to potential mismedication errors.

2. The ECP system should be compatible with that used by Medicaid claims processing, so that pharmacists will not be required to operate separate systems.
3. Nationally standardized physician, pharmacist, and patient identification numbers should be used.
4. Pharmacists should be required to conduct a review of the patient's drug regimen for all beneficiaries and assure that in accord with carefully developed criteria all Medicare patients have access to counseling services regarding appropriate administration of the drug, potential side effects and related therapeutic issues. In cases where a potential ADR exists, pharmacists should consult with the physician and patient when necessary before dispensing the drug.

### **Discussion:**

The pharmacist/dispensing level is the most critical point at which mismedication errors can be identified and corrected for individual patients. Although there are important functions to be served at the post payment level, reliance on the post payment review to identify and ameliorate suboptimal prescribing for individual patients would be unrealistic given the resource requirements and time delays associated with case by case analysis. For that reason, it is particularly important that the pharmacist have at his/her disposal all necessary information with which to make a clinical judgement about a prescribed medication. Such information should, at a minimum, include the patient's drug regimen.

There is some concern in HCFA that the cost of transmitting the amount of information associated with drug regimens would be prohibitive and that confidentiality concerns would preclude providing patient profile information to pharmacists. Instead, HCFA anticipates providing pharmacists with a one- or two-line display screen that will transmit information on eligibility and deductible status, and provide prompts to the pharmacist based on preprogrammed edits identifying potential ADRs.

A number of arguments support the proposal to provide full screen displays of patient drug regimens:

- Cost is clearly a relative issue and the estimated cost of transmitting drug regimen information should be evaluated against the program and human costs associated with medication errors. An assertion that the more elaborate system would be prohibitive is not meaningful unless its cost is measured in the context of the cost of not providing drug regimen information to the pharmacist.
- In calculating costs, it should be noted that the information technology industry is in a state of rapid advancement. It is reasonable to expect that the cost of transmitting information today may be significantly greater than the cost would be when the drug benefit becomes effective.

- Although a system of prompts to alert pharmacists to potential ADRs would be a useful tool and should be included in the data system, it cannot substitute for the judgement made by a pharmacist. As mentioned previously, ample research indicates that when pharmacists are provided sufficient information about the patient's drug regimen and engage in review and consultation with physicians and patients, significant improvements can be made in physicians' knowledge base, in patients' compliance behavior, and in overall quality of drug regimens. Further, it is difficult to imagine that even the most elaborate programming could encompass most significant ADR risks. ADRs are not confined to drug interactions, which may be the easiest category to define. The pharmacist who has face-to-face contact with the patient is in a position to engage in an interactive assessment, and to evaluate elements such as dosage levels based on body size, concurrent use of OTC drugs, and the appropriateness of the prescribed drug for the particular condition of the patient. None of these elements can be assessed by a programmed computer that would be relied upon if only prompts are provided to the pharmacist.
- The conference report itself specifies that "participating pharmacists will review the medication profile of beneficiaries for potential adverse reactions before filling prescriptions" (Conference Report, p. 191). Given this statutory requirement, it would appear to be difficult to justify providing pharmacists with a system that does not include regimen information. Further, in interviews with our expert panel as well as discussions with researchers and practitioners in the field, there was widespread agreement that the pharmacist should be provided with patient medication profile information, if any meaningful utilization review is to take place at the dispensing level.
- The issue of confidentiality should receive thorough attention and safeguards can and should be developed to protect the privacy of Medicare beneficiaries. In that respect, it is useful to note that some major pharmacy chains have implemented just such a system with the support of legal opinions that have analyzed the confidentiality aspect. Patient profile records are already maintained as a standard practice in most pharmacies for drugs purchased at that site, and pharmacies are already liable for protection of patient information. In terms of including price and names of other pharmacies used by the patient, those items can be easily coded to protect access to competitors' pricing schedules.

As mentioned previously, preprogrammed edits that will provide prompts to the pharmacist prior to dispensing a drug should also be an integral part of the system. Those edits which would occur when a potential ADR is identified should be detailed subsets of standardized DUR criteria developed at a national level and used as an operating framework by all providers of the electronic claims processing system.

In terms of nationally standardized identification numbers, it is essential that such a system be developed for purposes of tracking misedication problems and targeting patients and

providers for post payment DUR interventions. The Drug Enforcement Administration (DEA) has in place an identification system for most physicians. The HCFA should explore the possibility of adapting this existing DEA system to the needs of its own DUR system.

## **DRUG BILL PROCESSOR/CLAIMS PROCESSING LEVEL**

The drug bill processor should:

1. Utilize prepayment edits to identify cases of duplicate and erroneous billing, and perform other program integrity audit functions on a retrospective basis to identify cases of fraud and abuse.
2. Evaluate the quality of information supplied by the drug bill processor to pharmacists and assess the range and nature of the use of that information by pharmacists.
3. Conduct some automated therapeutic review.

### **Discussion:**

Given the fact that the quantity and quality of counseling provided by community pharmacists is relatively uneven, it will be necessary to establish some monitoring system to assess the performance of participating pharmacists. That function should be conducted at the drug bill processor level with the data available from the ECP data base and with the use of performance audits. Even the most elaborate data system would not ensure that the community pharmacist will actually use the data to conduct reviews and provide counseling services to the physician and/or patient. Consequently, some review mechanism will be required to evaluate performance and ensure quality of care review at the dispensing level.

One example of automated therapeutic review at this level would be cases in which a prescription has not been filled because it duplicates a drug already in the patient's regimen and prescribed by another physician. In such an instance, the drug bill processor could notify all physicians concerned by mail in a timely fashion. Functions such as this one could be carried out using automated review and notification, and would not require a case review.

## **POST PAYMENT LEVEL**

At the post payment level the following functions should be carried out:

1. Using claims data collected at the drug bill processor level, a review of prescribing and utilization behavior should be conducted to identify physicians, pharmacists, and patients who demonstrate patterns of mismedications and to target those groups for education efforts.
2. Once groups are targeted, education strategies should be implemented at the local level and outcomes from such interventions should be monitored and evaluated for effectiveness.

## **Discussion:**

The post payment level of review should be focused exclusively on quality of care and remedial and education efforts. For DUR purposes, post payment review interventions do not appear to be particularly effective in remedying mismedication cases for specific patients. Rather, a review of post payment interventions indicates that their greatest potential is in identifying *potential patterns* of mismedication.

Education efforts are most appropriately placed at this level where they can be tied directly to the targeting process. Further, because a variety of educational interventions will be implemented, particularly in the initial stages of the program, it will be important for each technique to be monitored from a benefit/cost perspective.

## **IMMEDIATE ACTIONS**

The HCFA and PHS, individually and collaboratively, should promote improvements in the prescribing, dispensing and utilization of drugs for older adults by taking the following actions:

- Make funding available for research and demonstration projects that will test DUR interventions and evaluate relative benefit/cost of each.

## **Discussion:**

In order for HCFA to develop an effective DUR program, more elaborate and broader based research will need to be conducted. The limited research that has already been completed and is underway will be useful in providing general direction, but not adequate to equip decision makers with refined policy options. According to congressional staff interviewed in the course of this study, the primary reason behind the decision to begin collecting revenues through the supplemental premium prior to program start-up was to provide funding for demonstration projects. Thus, funding of a demonstration program appears to be consistent with congressional intent.

Requirements for funding of projects should be flexible enough to allow for the testing of innovative DUR strategies with particular attention to educational intervention and should permit a broad range of providers (e.g., PRO's, private researchers, carriers) to compete for funding. However, several basic requirements should shape the overall demonstration effort:

- All interventions should be measured from a benefit/cost perspective.
- Some DUR interventions should also be focused on quality issues related to use of OTC as well as prescription drugs. This appears to be one of the areas with the greatest need for additional research. The elderly consume OTC drugs at an even

more disproportionate rate than prescription drugs, and, with more potent drugs being reclassified for OTC use, this aspect of drug consumption behavior has serious implications for the broader mismedication problem.

- Demonstration project findings should be generalizable for the Medicare population and interventions should be measured for effectiveness both in identifying problems *and* affecting clinical changes in behavior. Detection of inappropriate medication practices will not be useful unless it can be linked directly with strategies that produce well documented improvements.
  - A variety of projects should be funded to test interventions with the three primary target populations: physicians, pharmacists and patients. As the findings indicate, the problem of mismedication among the elderly reflects systemic problems at all three population levels.
  - Some projects should also be geared to development of ADR edits that will ultimately be programmed for use in the ECP system.
- Establish a blue-ribbon panel to: (1) develop DUR criteria that will serve as a national guideline for DUR programs carried out throughout the country; (2) make specific recommendations regarding expansion of curricula in U.S. medical schools in the areas of pharmacology and geriatrics; and (3) make additional policy recommendations, as needed, in regard to improving drug utilization among the elderly.

### **Discussion:**

In order to design an effective post payment DUR process it will be necessary to develop general criteria that reflect high risk categories of drug treatment. This should not be confused with the Act's requirement that the Secretary, using compendia published by the American Medical Association and other professional groups, establish standards for use for each covered outpatient drug (see p. 192, Conference Report). Rather, criteria in this context refer to treatment issues (e.g., the use of prescription sleeping pills by the elderly) that are associated with high risk patterns of drug therapy.

The development of standardized criteria is not a particularly novel strategy. In States that do conduct post payment therapeutic DUR (e.g., Minnesota, PACE) establishment of criteria is considered a necessary first step and serves as the basis for more specific and elaborate DUR activities at the local level. The panel should include clinical pharmacologists who specialize in geriatrics, selected medical specialists, and others knowledgeable in drug utilization review. The development of criteria will be an evolutionary process and will require periodic review and revision throughout the life of the drug benefit program. All criteria proposed by the panel should be subject to a public review and comment process.

The issue of medical school curricula development should be the second focus of this group. As outlined in the findings section, it does not appear that the nation's medical schools are adequately prepared to train physicians in the area of geriatric pharmacology during a period when the elderly population is steadily growing. The panel should assess this apparent problem more thoroughly and make recommendations regarding the appropriate Federal role in filling this educational gap.

It is recommended that HCFA collaborate with the National Institute of Aging (NIA) in designing and monitoring the demonstration program and that NIA take an active role in selecting panel members and managing panel activities. The NIA has long been concerned with drug therapy for older adults and with the issue of adequate training for physicians in geriatric pharmacology and can serve as a valuable resource in this process.

- Expedite issuance of FDA guidelines to manufacturers to ensure adequate testing of drugs on elderly populations.

#### **Discussion:**

If any commitment to reduce the incidence of misedication of older adults is to be made by the Department, it must include the finalization of FDA regulations regarding drug testing. Even though some progress has been made in this area, the finalization of these guidelines will serve to reinforce that progress and to signal the Department's commitment to improving the drug testing process as it relates to the elderly.



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## COMMENTS

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Within the Department of Health and Human Services, the Health Care Financing Administration (HCFA) and the Public Health Service (PHS) provided comments. The American Medical Association (AMA), the National Association of Boards of Pharmacy (NABP), the American Association of Colleges of Pharmacy (AACP), the National Association of Chain Drug Stores (NACDS), the Pharmaceutical Manufacturers Association (PMA), and the Public Citizen Health Research Group also commented.

These commenters expressed considerable support for the concept of drug utilization review. The AMA, the AACP, the NABP, the Public Citizen Health Research Group and the PHS indicated much support for our recommendations, but the other commenters, and to a lesser degree the PHS, raised a number of concerns about them.

Chief among these were the costs of DUR and the possible privacy infringements. Also prominent was a concern about how much emphasis ought to be placed on prospective DUR and in particular on the clinical role of pharmacists. Finally, both HCFA and NACDS expressed a strong desire that nothing be done to impede the efficient and timely implementation of the electronic claims processing system. They assert that this undertaking will be complex and difficult enough without introducing elaborate drug utilization review requirements.

We recognize that the establishment of a national DUR program is a complex undertaking that must be carried out carefully, with broadly based input, and over time. We also recognize the enormity of HCFA's responsibility in establishing an ECP system that can handle an estimated 700 million claims in 1991, in developing an on-line transaction mode, and in enrolling participating pharmacies.

At the same time, we must reassert that the well-documented misedication problems facing the elderly are quite serious and ought to be carefully addressed as part of HCFA's planning for the new drug benefit. At a minimum, nothing should be done initially to preclude the development of a comprehensive drug utilization review system. It is in that context that we offer a wide range of recommendations for consideration of all affected parties. In appendix I, we present, in full, each set of comments and respond to each of them.

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## **APPENDIX I**

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### ***DETAILED COMMENTS ON THE DRAFT REPORT AND OIG RESPONSE***

#### **HEALTH CARE FINANCING ADMINISTRATION COMMENTS**

We have reviewed the draft report which presents a comprehensive view of what the OIG believes the ultimate DUR program should entail and accomplish. We agree that HCFA's DUR program must improve quality of care, avoid unnecessary Medicare and personal expenditures, and maintain program integrity. HCFA intends to give appropriate consideration to and review of potential DUR activities at all levels of the drug delivery system throughout our design process. Our specific comments are attached.

As we develop a DUR system, we must make it flexible enough to allow for necessary modifications to attain additional programmatic goals as time and resources permit.

Thank you for giving us the opportunity to comment on this draft report.

#### **Development and Design of DUR Program**

We are concerned that the report does not adequately address the fact that in order to develop a realistically designed DUR system, it must be considered within the context of the current estimates for the Catastrophic Drug Program (i.e., benefit outlays, revenues, administrative costs, and claims volume). The HCFA's DUR system, which will be complex and unlike any other existing system, must be able to accommodate an estimated 700 million claims in 1991. The OIG does not appear to recognize this when discussing either pharmacy or fiscal intermediary (FI)/carrier criteria. For example, the OIG emphasizes certain one-on-one counseling and education activities for physicians, pharmacists, and beneficiaries, again without any acknowledgment of the possible number of encounters for these populations (e.g., 34 million beneficiaries).

The OIG's recommendations must be evaluated within the self-financing design of the Catastrophic Drug Program. Congress set rigid program income and outlay factors through 1993 that severely limit HCFA's flexibility. Benefit costs in the drug program are uncertain, but HCFA has consistently maintained that the financing will be inadequate. Although OIG claims that benefit savings will accrue if its suggestions are implemented, we must first spend the requisite dollars for those activities before the savings will occur. Also, the money to finance those activities must be available, especially research and demonstration dollars. The President's Fiscal Year (FY) 1990 budget now projects FY 1991 funding for DUR payment safeguard activities to be approximately \$16.1 million (\$4.3 for Medical/Utilization Review and \$11.8 for Pharmacy Audits).

Within this framework, implementation of any of the OIG's recommendations would add significant additional administrative costs. For example, HCFA has planned for the drug proces-

sors (DPs) to provide the pharmacists with two lines of information: i.e., whether the beneficiary is eligible and the amount of co-payment, if any. (There will be an additional response if there is the potential for any adverse drug reactions.) The OIG suggests that the DPs provide the pharmacists with a full screen of information concerning the beneficiary's drug regimen. Although this recommendation has considerable merit, HCFA anticipates the cost of transmitting the planned two lines of information to the pharmacists to be \$441 million for FY 1991. The cost of providing an additional screen of information as recommended by the OIG would probably be proportional and would be prohibitive without additional revenue from beneficiaries. There are also beneficiary privacy and confidentiality concerns that would have to be addressed.

Although we concur with the general approach recommended for the DUR program, it must take into account, in addition to cost limitations (1) patient privacy and confidentiality, (2) time considerations inherent in an on-line transaction processing mode, (3) equipment and software cost implications and (4) pharmacy enrollment concerns. All these elements will have to be carefully weighed in designing the entire system.

Through the Part B Data Policy Workgroup, we have been identifying those data elements which HCFA would require to support studies that review prescribing and utilization behavior of physicians, pharmacies, and beneficiaries. These drug data are to be linked to other claims data to develop patients' histories for use in designing and testing prospective utilization review screens. We will continue to consider the data needs of the DUR as implementation models are determined.

The OIG recommends that the system should enable the pharmacist to be alerted by computer prompts to potential medication errors. While we do not disagree, drug-related problems are not confined to drug interactions. The pharmacist who has face-to-face contact with the patient is in a unique position to engage in an interactive assessment of the patient and to evaluate elements such as dosage levels based on body size, concurrent visits to other health care practitioners, concurrent or recent use of prescription or non-prescription drugs or other treatment remedies, the appropriateness of the prescribed drug(s) for the particular condition of the patient, and other factors that influence the patient's welfare. None of these elements can be assessed by a computer-based system. In evaluating a patient's drug regimen and making a judgment as to the level of counseling, the pharmacist assesses the significance of the problem. Is the problem significant enough to contact the physician and/or is the problem of such a degree that it is obvious to the patient (requires no intervention on the part of the pharmacist)? This is a professional judgment. In some cases, a professional judgment is made, based on the pharmacist's knowledge that it is better not to discuss a certain issue or problem with a patient. Therefore, since the degree of patient drug counseling is a professional judgment decision, we believe it should be left to the pharmacist, and that the system is merely a tool to facilitate application of that professional expertise.

It probably is not feasible to make our system compatible with those used for Medicaid claims processing. All of the State systems have been developed independently, and there is considerable variation among them. Therefore, no system established by Medicare could fit per-

fectly with all State systems unless the States moved toward standardization. We are attempting to mesh our system with Medicaid as much as feasible, including obtaining input from the State Pharmacy Technical Advisory Group. However, it is not possible to make the Medicare and Medicaid systems fully compatible.

The OIG is recommending that pharmacists should be required to provide counseling to all beneficiaries regarding appropriate administration of a drug, potential side effects, and related therapeutic issues. The Medicare Catastrophic Coverage Act (MCCA) requires participating pharmacies only "to offer" to counsel each Medicare beneficiary. While we agree with the emphasis expressed by the OIG concerning the importance of counseling, the language of the Act does not necessarily mean that each patient must receive counseling, especially if counseling is intended to mean verbal counseling. Moreover, not every patient may want or require counseling.

On page 31 of the report, it is recommended that the results of drug utilization review be used to educate physicians, pharmacists, and patients. The report recommends that education strategies are to be implemented at the local level and outcomes from such interventions should be monitored and evaluated for effectiveness. We note that, while section 202(b)(5)(A) of MCCA requires education programs for physicians and pharmacists, patients are not specifically mentioned. Consistent with the law, we believe Federal education programs should focus on physicians and pharmacists. In turn, as physicians and pharmacists become more informed about drugs, they would be prepared to provide better drug education to their patients.

### **Make Funding Available for Research and Demonstration Projects**

HCFA already has a number of initiatives under way as a result of the enactment of the MCCA. In order to assess the impact of the new benefit program on cost, access and utilization, studies have been required, as well as a series of demonstration projects.

Currently, we have a research and demonstration process under way to receive and award possible projects related to the new drug program. These awards may include studies relating to effectiveness, appropriateness, and cost patterns of drug usage in the Medicare population.

### **Establish a Blue-Ribbon Panel to Develop DUR Criteria**

Establishment of a blue-ribbon panel to develop DUR criteria to serve as a national standard for DUR programs is a noteworthy idea as it applies to Medicare. However, we believe development of Medicare DUR criteria for use as a national standard by the private sector is beyond HCFA's purview. Additionally, use of Medicare DUR standards for possible inclusion in medical school curricula and to improve drug utilization among the elderly are ideas that would better be handled by groups outside HCFA designed for that purpose.

## **State Medicaid DUR Efforts**

While it is true that many States focus the majority of their efforts on program integrity to reduce fraud, waste, and abuse, nearly all States have programs to enhance the quality of care provided their beneficiaries with regard to pharmaceuticals. While the draft report highlights Minnesota's noteworthy program in this regard, it fails to cite other States which have developed very effective DUR programs.

Two of the best examples can be found in Medicaid programs which have high percentages of elderly beneficiaries: Florida and California.

*Florida*--Quite apart from the activities of Florida's Program Integrity Office, the Medicaid Pharmacy Consultant in this State serves as project leader on a DUR program which focuses on the therapeutic value of its drug program. Drug-to-drug interactions, poly-pharmacy dispensing practices, and patients with cardiac, respiratory, digestive, and diabetic disorders are key decision parameters used in building Florida's patient profiles. Utilizing committees of pharmacists and physicians, Florida sends letters to prescribing providers when a potential problem is identified, with follow-up letters or phone calls in 30 days. Jerry Wells, R.Ph. Pharmacist Consultant (904-487-4441), may be contacted for additional information.

*California*--Currently, this State is analyzing the effect of its DUR programs on two large population groups which have been statistically selected based upon urban/rural, age, contraindications, and disease types to learn of the therapeutic as well as financial benefits of their Program. Similar to Florida's system in that individuals are identified based upon decision criteria Previously selected, follow-up is 30 and 60 days apart. Carlo Menotti, R.Ph. (916-324-2477) is the person in charge of this program.

### **Technical Note**

The Medicare drug program is a Part B benefit and will be generally administered by special contractors (drug bill processors), rather than the fiscal intermediaries to which the report refers.

### **OIG RESPONSE TO HCFA COMMENTS**

While HCFA does not disagree with the overall directions we set forth for the development of a Medicare DUR program, it indicates that considerations involving cost, complexity, and privacy preclude any major progress in carrying out these directions in the near term.

We agree that there are important considerations concerning cost, complexity, and privacy that must be addressed. However, given the scope of the problems involving adverse drug reaction among the elderly, we do feel a sense of urgency in addressing the above-noted considerations. The phasing in of a multi-faceted DUR program can have a very positive effect on the well-being of thousands of Medicare beneficiaries. Moreover, it is worth noting that since in a given year less than 20 percent of the beneficiaries will reach the deductible threshold and

thus become eligible for partial coverage of the costs of their prescription drugs, the DUR program looms as the major drug-related benefit that most beneficiaries will receive for their increased financial contribution.

Our recommendations to HCFA, we must underscore, call for immediate action in planning a comprehensive Medicare DUR program and for its implementation "as soon as is feasible." We recognize that the program must be phased in and that refinements must regularly be made based on operational experience and on research and demonstration results. In this regard, it is particularly important that at the outset HCFA express its commitment to develop a comprehensive, well-designed, and cost-effective DUR program and assure that its initial actions in establishing the electronic claims processing system are consistent with that commitment.

On the matter of privacy, in accord with discussions with HCFA officials, we conducted some follow-up inquiry and issued a management advisory report entitled "Privacy Implications of the Medicare Prescription Drug Benefit's Electronic Claims Processing System" (OAI-01-89-89170). This brief report, based largely on meetings with privacy advocates, indicates quite clearly that with proper safeguards, privacy considerations would not preclude the development of the comprehensive DUR system outlined in our report.

With respect to the remaining HCFA comments on the report, we respond briefly to each of them below.

On the Role of the Pharmacist. The HCFA points out that "drug related problems are not confined to drug interactions" and that the pharmacist "who has face-to-face contact with the patient is in a unique position to engage in an interactive assessment of the patient" and to make evaluations on matters such as dosage levels. It later adds that "since the degree of patient drug counseling is a professional judgment decision, we believe it should be left to the pharmacist, and that the system is merely a tool to facilitate application of that professional expertise."

It is because we believe that it is important to reinforce the pharmacists' role in providing professional counseling that we are urging HCFA to provide the pharmacists with full screen displays of patient drug regimens as soon as is practical. Without such information, we feel the application of the pharmacists's "professional expertise" would be seriously hampered, particularly with respect to the many patients who visit multiple physicians and/or pharmacies.

On the Compatibility of Medicare and Medicaid Claims Processing Systems. We recognize the difficulties involved in achieving full compatibility of these systems. We are pleased that HCFA is attempting to mesh the systems "as much as feasible." We urge that full compatibility be embraced as a long-term goal.

On the Language of the Medicare Catastrophic Coverage Act Concerning Pharmacist Counseling. In interpreting the statutory language and in its forthcoming regulations, we urge that HCFA not engage in an overly narrow interpretation of "counseling." We feel it is important for the pharmacists' responsibility "to offer" counseling to be clearly stated and defined. A

study we are conducting concerning the clinical role of the community pharmacist will offer some suggestions in that regard.

On the Importance of Patient Education. We agree that the Medicare DUR program should concentrate on physician and pharmacist education. However, we believe that there is also an important role for patient education which HCFA ought not overlook. Some innovative systems are now being developed to facilitate direct patient access to drug information. The HCFA, in consultation with the Public Health Service and Medicare beneficiary advocacy groups, should review them to assess their effectiveness and to determine how they might be incorporated into a comprehensive DUR effort.

On the Establishment of a Blue-Ribbon Panel. The HCFA comments that it does not feel it would be appropriate for it to participate on a blue-ribbon panel that would develop DUR criteria to serve as a national guideline for DUR programs and to make specific recommendations regarding medical school curricula in the area of pharmacology and geriatrics. As we indicated in the report, we feel it is extremely important to have Departmental leadership in these areas. The American Medical Association, as noted in its comments on our report, expresses its support for such a panel (provided that the representation of members is sufficiently diverse and that proposed criteria are subject to a public review and comment process). The PHS also expresses its support for the panel.

On State Medicaid DUR Efforts. We underscore that most State Medicaid DUR efforts are aimed at identifying and correcting problems of program integrity, rather than quality of care. This reality became quite clear from our State survey. At the same time, we recognize that States other than Minnesota have initiated therapeutically oriented DUR efforts. In elaborating on the Minnesota program, we sought to explain the approach of one State that has long been involved in this area. We welcome HCFA's explanations of the efforts underway in Florida and California.

On the Term "Fiscal Intermediaries". In our draft report, we used the term "fiscal intermediaries" in a generic sense, not in reference to Medicare Part A Fiscal Intermediaries. We recognize that the Medicare drug program is a Part B benefit and will be generally administered by special contractors or drug bill processors. To avoid any confusion, we have used the term "drug bill processors" rather than "fiscal intermediaries" in the final report.

## **PUBLIC HEALTH SERVICE COMMENTS**

### **General Comments**

We express general concern that the evidence presented in the OIG draft report to support the findings of misedication among older adults may not have been based on objective information. The OIG report relies on secondary sources such as anecdotal evidence and unpublished reports as the basis for the findings. We believe that findings of this significance should be supported by incontrovertible data, preferably data that have been peer reviewed and

published in medical and scientific documents. A more detailed explanation of our concern is provided in the technical comments.

Since 1981, the Food and Drug Administration (FDA) has worked closely with the National Council on Patient Information and Education (NCPIE) to coordinate the development and implementation of major patient education initiatives in the public and private sectors. In 1987, NCPIE released the report, "Priorities and Approaches for Improving Prescription Medicine Use of Older Americans." The OIG draft report does not reference the NCPIE report or its programs. We recommend that the NCPIE report and programs be incorporated in the OIG report. In addition, FDA issued a report, "Prescription Drug, Medical Device, and X-Ray Patient Education Activities," that highlights FDA's current activities in this area. We also recommend that such activities be cited in the report.

The following are comments on the OIG recommendations.

### **OIG Recommendation**

The HCFA should develop a Medicare DUR program that incorporates review and education functions at three levels of the drug therapy process: pharmacist/dispensing level, fiscal intermediary/claims processing level, and post payment level.

### **PHS Comment**

Even though this recommendation is directed to HCFA and we generally concur with the recommendation it appears that two highly significant issues must receive further consideration. These are (1) the confidentiality of a patient's drug regimen and (2) questions about the adequacy of the quality of the HCFA database for reliable therapeutic review.

#### **(1) Confidentiality**

The prescription of certain drugs is strongly associated with certain diagnoses, e.g., neuroleptics with psychotic disorders and AZT with AIDS.

What measures will be taken to ensure the confidentiality of a patient's drug regimen?

Will clerks and other non-professional pharmacy personnel have access to the computerized database?

Will a patient have the right to request that his drug regimen not be included in the drug database?

We believe that these issues require further attention prior to the implementation of a national program.



## **(2) Quality of the HCFA Database**

Although the report recognizes the limitations of the HCFA database for the purpose of therapeutic review, the recommendation states that the fiscal intermediary should "conduct some automated therapeutic review."

The results of automated therapeutic review utilizing the HCFA database will not be reliable because of the inadequacy of the diagnostic information included in Medicare Part B claim forms. Geriatric patients commonly suffer from multiple diseases requiring complex drug regimens. A drug used to treat one disease may have side effects which have an adverse impact on a second disease. Therefore, a complete list of accurate diagnoses is important for therapeutic review. Researchers experienced in the use of automated Medicaid databases are concerned that the quality and lack of comprehensiveness of the diagnostic information which will be available in the HCFA database will result in erroneous conclusions if this information is used for therapeutic review. A conference which will include discussion of this issue is currently being planned by the Institute of Medicine (IOM).

Following the IOM conference, HCFA should consider funding research directed towards modeling various methods of therapeutic review using existing databases to reveal the potential and limitations of different approaches to this problem. This might help avoid future large scale problems which will result if the HCFA database is asked to serve purposes for which it is not adequately designed.

### **OIG Recommendation**

The HCFA and PHS, individually and collaboratively, should promote improvements in the prescribing, dispensing and utilization of drugs for older adults by taking the following actions:

- Establish a blue ribbon panel to (1) develop drug utilization review (DUR) criteria that will serve as a national guideline for DUR programs carried out throughout the country; (2) make specific recommendations regarding expansion of curricula in U.S. medical schools in the areas of pharmacology and geriatrics; and (3) make additional policy recommendations, as needed, in regard to improving drug utilization among the elderly.

### **PHS Comment**

We concur. The National Institute on Aging, NIH, will collaborate with HCFA in designing and monitoring the demonstration program and will also participate in selecting panel members and managing panel activities.

## **OIG Recommendation**

- Expedite issuance of FDA guidelines to manufacturers to ensure adequate testing of drugs on elderly populations.

## **PHS Comment**

We concur. Guidelines have been circulated in draft form which we believe drug sponsors have been following. One element of the proposed guidelines that sponsors analyze beneficial and adverse effects to see whether there are age related differences in response was incorporated into the "Guideline for Clinical and Statistical Sections of an Application," which was published in final in mid-1988. Other aspects of the guideline such as studies to determine better the effects of abnormal kidney or liver function on the excretion of the drug are also being implemented by drug companies.

We disagree, however, with the assertion that mismedication among older adults is a consequence of inadequate drug testing among elderly populations. The report states that studies required to secure FDA approval are typically performed on relatively healthy young adults for products that will be prescribed to elderly patients. Although Phase I clinical trials in small numbers of subjects are normally performed on healthy volunteers, these early trials are a tiny fraction of the overall drug exposure and are concerned primarily with initial safety of the drug. Elderly patients have regularly been included in Phase II and III studies, which are the largest studies concerned with efficacy, side-effects and risks in persons with disease to be treated by the drug. In 1983, FDA conducted a brief study on age distributions of patients in clinical trials of 12 marketing applications. It covered a good representation of patients in their sixties and seventies, and whether the disease being treated was common in those age groups.

FDA provides information to physicians and other health professionals concerning the use of drug products. This is accomplished primarily through the products' labeling that must be approved as part of the new drug application process. In another recent study, FDA reviewed the labeling of new molecular entities approved during 1987 and 1988 and found, after excluding some special cases such as topical and cancer drugs, that about 50 percent carried some information relating specifically to the elderly. Further, not all products require special instructions for geriatric use.

FDA is currently developing a regulation to be incorporated into 21 CFR 201.57, "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs," which will require a geriatric use section in the labeling of human prescription drugs.

## **Technical Comments**

- Page 3, FINDINGS, Second Paragraph

The sentence "Anecdotal evidence from State pharmaceutical assistance programs for the elderly . . ." implies that existing mismedication problems may be exacerbated by new benefits. We believe that stronger evidence should be used to support this finding.

**-Page 4, Second Full Paragraph**

The report states that "Although Americans who are 65 years or over currently constitute only 12 percent of the population, they use over 30 percent of the prescription drugs and 40 percent of the nonprescription drugs dispensed." This reference is from an unpublished report. We believe that such a statement should be based on incontrovertible data and published in a credible peer-reviewed data. Likewise, the next reference cited is from a report which is not peer-reviewed data.

**-Page 6, Third Full Paragraph, Second Sentence**

The report states that "32,000 hip fractures are incurred annually due to drug-induced falls." The report does not provide substantiating data.

Further, the report states that 61,000 older adults developed Parkinson-like symptoms due to the use of antipsychotic drugs. It should be noted that this is a well recognized side effect of certain of these drugs and occurs across all age groups. We believe that the data provided do not allow a conclusion to be drawn that this represents a mis-medication problem.

**-Page 9, Second Paragraph, Second Sentence, Subsections**

The report states that "...the filtering ability of the kidneys decreases by 30 percent by the time a person reaches 65 years...." We believe that this reference is stated incorrectly. It should indicate that the number of nephrons decreases 30 to 40 percent between the ages of 25 and 85 years (Goldman, R. in Wyngaarden and Smith (eds.), *Cecil Textbook of Medicine*, Saunders & Co., 1985).

Also, we suggest that the following be inserted at the end of this statement.

"It should be noted that the above described age-associated changes in body size and composition, liver functions, and kidney functions are subject to wide variation with some individuals showing significantly less change than might be expected for the population as a whole."

**-Page 11, Last Paragraph, First Sentence**

Two of the OIG references cited for this statement indicate an educational gap in the knowledge of prescribing psychotropic drugs and not a generalized educational gap. We believe the report should be changed to reflect that the educational gap refers to that of prescribing psychotropic drugs.

## **Endnotes**

We note that 32 of the 95 references cited are not peer-reviewed and published in medical or scientific documents. These references include testimony of individuals and interest groups (12 citations) before Congressional committees, OIG "discussions" with "expert panels" (4 citations) and other references including speeches, unpublished articles, newspaper and magazine articles, lectures and presentations, and documents prepared by interest groups such as the American Association of Retired Persons and the Public Citizen Health Research Group. While information reported from these sources may, in fact, be entirely correct, the reader must assume that all of these represent opinions of individuals or groups with variable expertise and interests in the area of concern.

## **OIG RESPONSE TO PHS COMMENTS**

We are pleased with the PHS' generally positive response to our recommendations and with its clarifications, which add to the value of the report. On the matters of confidentiality and the importance of further research and development (particularly in regard to automated therapeutic review and the use of diagnostic codes) we agree that these are vital, sensitive matters warranting serious attention. Our response to the HCFA comments offers some elaboration on both of these matters.

The PHS took exception to the finding that clinical studies are typically performed on healthy young adults. It noted that elderly patients have regularly been included in phase II and III studies, and that guidelines issued in 1988 require that analysis be conducted concerning adverse effects and age-related differences. We made a number of changes in the text to incorporate recent information developed by FDA and to reflect the importance of its recently issued guidelines. We continue to urge the issuance in final of the FDA guidelines to manufacturers to ensure adequate testing of drugs on elderly populations. The FDA agrees with us on this point.

In regard to the more technical comments offered by PHS, we have incorporated into the report and the footnotes a reference to the National Council on Patient Information and Education (NCPIE), a clarification concerning physicians' education gap in the knowledge of prescribing drugs, and PHS' suggested qualification concerning changes in body size and composition and liver and kidney functions. With respect to PHS' call for further, peer-reviewed citations, we recognize that there is much additional research that can be conducted on problems concerning the mismeasurement of the elderly. We urge that scholars undertake such research, both to expand the existing knowledge base and to synthesize the knowledge that already exists. On the basis of our own broadly based review, drawing on insights from peer-

review journals and many other sources, the evidence is compelling that there exists a serious problem concerning the mismedication of the elderly.

## **NATIONAL ASSOCIATION OF CHAIN DRUG STORES COMMENTS**

The National Association of Chain Drug Stores, Inc. (NACDS), appreciates the opportunity to comment on the draft report entitled "Medicare Drug Utilization Review." NACDS represents 173 chains drug corporations operating in excess of 21,000 retail pharmacies nationwide that dispense over 40 percent of the nation's prescription drug products. As an integral component of the health care delivery system, NACDS members take seriously their role as the final step in the dispensing process of prescription drugs. As committed health care professionals, NACDS members' paramount concern is the health and well-being of their customers, including the elderly. Historically, retail pharmacy has served as the link between the physician and the patient on proper usage of prescription drugs. This dedication to service and health care is evident by public opinion polls that hold pharmacists as America's most respected health professional.

However, NACDS must register its disagreement with many of the report's assumptions and conclusions. An issue as important as "drug utilization review" (DUR) cannot be decided on the basis of one report and a brief comment period. Examination of this subject in a vacuum ignores fundamental questions and implications for the health care delivery system. The discussion of issues, such as privacy, liability alternatives, and cost, are too important to be avoided. From retail pharmacy's viewpoint, a computer and "star wars" application does not make an effective and quality DUR system. NACDS respectfully submits that subjective science cannot be made objective by imposing mechanical standards.

NACDS also suggests that the report assumes a Congressional intent regarding the imposition of a "mandatory" DUR system that is absent from the actual legislation, the legislative history, and accompanying conference history. NACDS proposes that the system envisioned by Congress and that which is suggested by the report are not compatible.

Furthermore, NACDS believes that the report findings are incomplete and based on anecdotal and often, insubstantial evidence, hearsay, and false assumptions. In particular, as to the report "findings" [on] community pharmacy, NACDS disagrees with conclusions that only a "small percentage of elderly patients receive drug counseling services," that "pharmacists do not perform adequate reviews of patients drug regimens"; or "consult with physicians and patients." Counseling and DUR can and should take many forms. Both verbal and non-verbal communication, such as the use of auxiliary labels, have become a routine part of the practice of pharmacy. In essence, the standard of care for pharmacy is such that examination of the patient's drug regimen is conducted on a regular basis.

As to the report's recommendations, NACDS strongly supports the implementation of an electronic claims processing (ECP) system to verify a patient's eligibility and deductible status. These functions alone represent an enormous undertaking--a fact recognized by the

Congress--and surely, one of the reasons Congress did not specify how DUR's and patient counseling were to be conducted. The ECP system is the heart and soul of the program.

Lastly, although NACDS disagrees with the apparent conclusion that mismedication is a national epidemic, we agree that mismedication among any segment of the population must be of concern to all health care professionals. As outlined on page five, paragraph three of the report, mismedication can occur in at least four ways. However, it must be recognized that of the four ways stated, only point number four can be directed specifically to the pharmacist. We find the lack of this fundamental understanding to be most disturbing. NACDS does not believe that the absence of physician accountability to their patient should be attributed to or be the entire responsibility of the pharmacist.

The above presumption indicates an unrealistic assumption and a basic lack of understanding of the role of the pharmacist in a dispensing of prescription drugs. In any system envisioned, the pharmacist will always be operating from an incomplete data base. For example, over-the-counter (OTC) medication is most frequently purchased in non-pharmacy settings. In addition, the growing incidence of physician dispensing of prescription drugs further complicates the report's recommendations.

In conclusion, NACDS hopes that you will continue to review this issue in light of our comments. NACDS hopes that you will contact us to further discuss this important issue.

## **OIG RESPONSE TO NACDS COMMENTS**

We believe NACDS has taken too limited a view of the role of a DUR program and of pharmacists in addressing the problems of mismedication of the elderly.

We responded to a number of the NACDS concerns in our previous comments. In addition, we note that the Catastrophic legislation clearly calls for the establishment of a Medicare DUR program and the conference report specifies that "participating pharmacies will review the medication profile of beneficiaries for potential adverse reactions before filling prescriptions." With respect to the role of the pharmacist, we have been informed by many pharmacists and by much literature that the counseling and consultation practices may indeed involve more than identifying inappropriate combinations of drugs. Our understanding is that the professional training of pharmacists increasingly prepares them for a broader role that enables them to identify various kinds of mismedication problems.

## **PHARMACEUTICAL MANUFACTURERS ASSOCIATION COMMENTS**

Your report, "Medicare Drug Utilization Review," focuses attention on the need to ensure that older people receive and use appropriate medicines and on the potential benefits of a Medicare drug utilization review system.

The Pharmaceutical Manufacturers Association recently completed a series of surveys that show its enormous commitment to discovering and developing medicines that will help older

people live longer, more productive lives. The results showed that the research-based pharmaceutical industry is developing 221 medicines to treat 23 diseases prevalent among older people. The pharmaceutical industry will invest an estimated \$3.6 billion in research on diseases of the aging in 1989--approximately half of its projected \$7.3 billion research and development budget for this year.

Because of the industry's role in discovering and developing medicines for older people, we are very concerned that information about the research and development process be accurately portrayed. PMA is particularly concerned about the Report's assertion that clinical studies on new drugs for use in older people are typically performed on healthy young adults for a short period of time. This, however, is only the *first* phase of human testing--a multiphase process that averages 6 years to complete. In subsequent phases, new drugs for the elderly are tested for years on large numbers of older people, because they are the people with the conditions that the drugs are intended to treat.

FDA reports that today's New Drug Applications contain data on an appropriate number of older people, indicating that the pharmaceutical industry is observing testing guidelines even though these guidelines have not been formally adopted by the FDA.

In addition, we wish to note that PMA supports the following principles:

- Older people should obtain a primary-care doctor to coordinate their care, because older people are more likely to have several conditions that require that they see a variety of specialists and take a complex regimen of prescription drugs. This helps explain why older people use a higher proportion of pharmaceuticals and experience more medicine-related side effects.
- Older people should take their medication according to their doctors' instructions. Noncompliance with medication instructions results in problems of undermedication as well as overmedication.
- Medical education authorities should emphasize programs that ensure physicians become aware of key principles in the emerging field of geriatric medicine.

Regarding drug utilization review, PMA supports the DUR provisions of the 1988 Medicare Act and appropriate DUR programs at the state Medicaid level. Accordingly, there are several points about DURs that we wish to emphasize in response to your report:

- PMA believes that the critical objective associated with drug utilization review is to improve the quality of care. Whether this will reduce drug program costs is not a certainty, because DUR would likely identify cases where there is a serious "under-utilization" of prescription drugs (which could actually increase drug program costs). Therefore, it is more appropriate to focus on the fact that DUR may improve quality and yield savings for *overall* health care costs.

- PMA believes that the objective of maintaining program integrity should be a key component of Medicare DUR. The Report asserts that Medicaid DUR policies have "limited applicability" for Medicare because of their emphasis on fraudulent or abusive activities. PMA believes the value of this area of DUR should not be underestimated. Instances of fraud and abuse may be quite costly, are easily identifiable and may have a major impact on the integrity of the Medicare program.
- PMA believes that the Report may be overly optimistic about the capabilities of prospective DUR. Experts in the DUR field have raised serious questions about the ability of the point-of-sale system envisioned by HCFA to accomplish prospective DUR. Besides questions about its feasibility, prospective DUR raises additional concerns about safeguarding patient confidentiality and to avoiding unnecessary interference in the patient/physician and patient/pharmacist relationships.
- PMA believes that, given the lack of experience of applying DUR to an outpatient drug program with over 700 million claims, it is essential that deliberations and ultimate decisions on Medicare DUR be open to input and debate by the public and scientific community.

We hope that these comments are helpful in continuing a productive exchange of ideas on the beneficial use of medicines by older people and in implementation of the DUR component in the new Medicare outpatient prescription drug benefit. Please let me know if you have any questions or if we can be of any further assistance.

## **OIG RESPONSE TO PMA COMMENTS**

Maintaining program integrity certainly should be an objective of a Medicare DUR program. However, given the documented scope and severity of adverse drug reactions among the elderly, we feel there is a solid basis for devoting primary attention to this issue.

How much attention ought to be placed on prospective DUR at the start is a question warranting further inquiry. We feel counseling and consultation efforts at the point-of-sale can have a valuable preventive effect. However, we recognize that there is much to be learned in this area and that research and demonstration efforts can be useful in that regard.

We continue to feel that the issuance of FDA guidelines to manufacturers would help to prevent mismedication resulting from lack of attention to the special conditions of elderly patients.

## **AMERICAN MEDICAL ASSOCIATION COMMENTS**

The American Medical Association (AMA) is writing to express its views concerning the draft report of the Office of the Inspector General (IG) entitled, "Medicare Drug Utilization



Review." The stated purpose of the report was to "foster the development and implementation of an effective Drug Utilization Review (DUR) system under the Medicare program. Toward this end, it sought to promote a better understanding of the major problems and needs that a DUR program should address, and of the relevant insights that emerge from research and experience."

The AMA believes that, in general, this report presents an appraisal of potential contributors, i.e., the Food and Drug Administration, manufacturers, physicians, pharmacists and elderly patients, to any problem of mismedication in the elderly. The AMA agrees with the report's recommendation for an effective DUR system that places major emphasis on improving the quality of patient care with education as the primary remedial strategy. The AMA is particularly pleased that the IG's report recognizes that improving the quality of care is vitally important and should result in significant savings in the overall cost of the Medicare program. The Association also agrees that the DUR program should be applicable to all beneficiaries regardless of deductible status.

The IG's recommendation for the establishment of a "blue-ribbon panel to develop DUR criteria" is consistent with the AMA's proposal to the Health Care Financing Administration (HCFA) for a government-funded Drug Utilization Review Board to manage the DUR program. The AMA agrees with the IG that representation of gerontologic specialists is essential for optimum function of a DUR Board. We recommend, however, that the Board also should include representation of clinical pharmacologists who specialize in geriatrics. In addition, representation of individuals from other disciplines (e.g., selected medical specialists, physician experts in medical quality assurance, pharmacists and physicians knowledgeable in drug utilization review, pharmacoepidemiologists, and biomedical statisticians) will enhance the DUR Board's effectiveness. The AMA recommends that all proposed criteria emanating from the DUR Board be subject to a public review and comment process.

One of the proposed functions of the IG's proposed blue-ribbon panel would be to "develop general criteria that reflect high-risk categories of drug treatment", presumably to serve as prospective standards for post-payment DUR studies. We have two recommendations concerning this issue. First, any such prospective standards developed should be based on adequate documentation in the peer-reviewed medical literature, reflect a strong consensus of practicing physicians, and be subject to public review and comment.

Second, the AMA takes exception to the IG's statement on page 33 of the report that AMA's *Drug Evaluations*, one of the compendia named in the Conference Report to P.L. 100-360, is not a resource for the development of general criteria that reflect high-risk categories of drug treatment. *Drug Evaluations* is a comprehensive, consensus-derived compendium designed to offer physicians unbiased and clinically relevant discussions of drug selection guidelines for various diseases, disorders or conditions as well as establish standards for outpatient drugs to be covered in the Medicare Catastrophic Coverage Act. Evaluations of drugs in *Drug Evaluations* may be favorable or unfavorable. This compendium covers both labeled and unlabeled indications and references the medical literature. Thus, it is precisely those general criteria

that *Drug Evaluations* does include and that clearly separates it from the two other compendia named in the Conference Report to P.L. 100-360.

The IG report emphasizes DUR at the pharmacist/dispensing level, because it is "the most critical point at which misedication errors can be identified and corrected for individual patients." The AMA believes that caution should be exercised in implementing *prospective* DUR. While prospective reviews can be effective in preventing adverse drug reactions and in ensuring proper utilization of drugs, the lack of sufficient, accurate and timely patient-related data available to the pharmacist during the point-of-sale process can severely limit the usefulness of prospective DUR. The AMA has strongly recommended against HCFA requiring prospective DUR until the DUR Board (blue-ribbon panel) establishes that such review is valuable and determines what specific types of reviews can be performed effectively. Funding for demonstration projects in this very important area should be provided.

The AMA also is concerned that the amount of time devoted specifically to gerontology and clinical pharmacology education may be inadequate and needs to be addressed. A need exists for innovative strategies of continuing education to extend the training of physicians in these disciplines into the postgraduate and active-practice years.

The AMA appreciates the opportunity to express its views. We urge you to consider carefully our recommendations for improving the report.

#### **OIG RESPONSE TO AMA COMMENTS**

We are pleased with AMA's generally positive reaction to the report. Below we respond to the three suggestions/exceptions which it set forth.

First, with respect to the blue-ribbon panel, we agree with AMA's comments concerning participation on the panel and public review of DUR criteria developed by the panel. We have made the corresponding changes in the report.

Second, concerning the relevance of the AMA's *Drug Evaluations* as a resource for the development of DUR criteria, we agree that it can serve as such a resource. Our intent in the report is only to distinguish our recommendation calling for the establishment of general DUR criteria from the Catastrophic legislation's requirement that the HHS Secretary establish standards for the use of each covered outpatient drug.

Third, in reference to the AMA's caution concerning prospective DUR, we agree that HCFA must move carefully and that funding for demonstration projects in this area is very important. We recognize, as the AMA points out, that "the lack of sufficient accurate and timely" patient-related data available to the pharmacist during the point-of-sale process can severely limit the usefulness of prospective DUR. It is for that reason that we urge the provision of a full screen drug regimen as soon as practical.

## **AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY COMMENTS**

Thank you for the opportunity to comment on the draft report, "Medicare Drug Utilization Review." On behalf of the nation's 74 colleges of pharmacy, 3,500 full-time faculty and 25,000 professional and graduate students, I am pleased to do so.

The Office of the Inspector General is to be commended for a fine piece of work. It generally and fairly describes the relationship between providers, third-party administrators, payor and post-payment responsibilities. My comments, therefore, will be very specific and focus primarily on pharmacists and their relationship to the system described in the Report.

- Page 15; final paragraph - excellent observation.
- Page 18; first bullet - suggest a Pharmacy and Therapeutics Committee-like structure, thus enhancing physician/pharmacist interface.
- Page 21; discussion about peer review - should separate out and not confuse the process of peer review/DUR from how peer review is applied/enforced. The process may be quite satisfactory while the way we enforce or apply peer review standards on practitioners may be the shortcoming. Further, paragraph 2 on page 21 and Avorn's study, as described on page 22, are consistent with and precisely why peer review works. Page 23, targeting prescribers, is a method of applying peer review.
- Page 24 and others - use of the word "industry." Does this refer to pharmacy practice or the pharmaceutical industry? If the former, I certainly support the use of that terminology.
- Page 26; regarding targeting DUR only for patients exceeding deductible - data collection and DUR should apply to all patients, but various levels of counseling can be identified based on specific patient need (the pharmacy literature supports this observation).
- Page 27; regarding computer prompts to potential medication errors - should be passive only; pharmacists must still realize their responsibilities for ensuring safe and effective drug use.
- Page 28; item 3 - the profession is undergoing a major pharmacy manpower (census) effort, headed by AACP. In order to create the census and maintain it, the profession requires unique identifiers for pharmacists. If the Department and the profession could work together on this aspect of data collection, it would probably benefit both of us.
- Page 28; item 4 - improving prescribing through cooperation/interface between pharmacists and physicians should be considered as well. Additionally, the question of

should all patients receive counseling or only have access to counseling based on carefully described criteria must be asked. It may not be cost effective (or necessary) for all patients to be counseled; some clearly will need counseling; all should have counseling available to them on request.

- Page 28; regarding confidentiality - pharmacists already have access to confidential information and this must continue for them to perform their role as required by good standards of care.
- Page 29, second paragraph - excellent.
- Page 29, third paragraph - the availability of the patient's diagnosis or treatable illness would assist immensely with DUR and counseling. Again, the institutional model and that used by the U.S. Indian Health Service in its outpatient clinics could be applicable to your observations.
- Page 30; regarding pharmacist-only access to ECP data system - it appears to me that a necessary goal is to free up pharmacist time from the count and pour and lick and stick aspect of practice (technical functions) so he can spend more time with patients for counseling and DUR. Locking the pharmacist to a CRT display only relegates him to maintaining these technical aspects of his job at the expense of desired clinical interaction with patient and physician. A look at the institutional model, plus activities as currently carried out in community pharmacy, would demonstrate supportive personnel access to this information without compromise of confidentiality.
- Page 31; regarding automated therapeutic review by fiscal intermediaries - these are the wrong parties to conduct such activities. Although they may be "less biased," they don't have the expertise or local perspective. Suggest model similar to Pharmacy and Therapeutics Committees in hospitals be considered using pharmacists and physicians.
- Page 31; regarding assessing performance of participating pharmacists - agreed!
- Page 32; regarding variety of educational interventions - must take time to describe these in specific terms in advance of program implementation.
- Page 33; regarding the blue ribbon panel - not only do DUR standards need criteria, but so do drug use standards.
- Page 34 - programs should be initiated to influence and support both medical school and pharmacy school curricula.

Finally, some references need correcting:

- Page 2 - Dr. Donald T. Rucker
- Page 39; Endnote 59 - Hepler, C.D.  
Endnote 71 - Benjamin Hershenson

You may also wish to contact Dr. Henri R. Manasse, Jr., Dean of the University of Illinois at Chicago College of Pharmacy. Dean Manasse has just completed a public paper on "drug misadventuring" which elaborates on and further clarifies many of the observations appearing in the Report.

Again, thank you for the opportunity to comment on the Report. If we can be of further assistance, please let me know.

### **OIG RESPONSE TO AACP COMMENTS**

The AACP comments provide helpful clarifications and elaborations. We have made some clarifications and revisions in response to them. Most notably, we have amended our recommendation concerning pharmacy counseling to urge that pharmacists in accord with carefully developed criteria assure that all Medicare patients have access to counseling services. Previously, we simply recommended that pharmacists provide counseling services to all Medicare patients.

### **NATIONAL ASSOCIATION OF BOARDS OF PHARMACY COMMENTS**

I am pleased to comment on behalf of the National Association of Boards of Pharmacy (NABP) in regard to the draft report entitled "Medicare Drug Utilization Review." NABP is the national association of the 50 state boards of pharmacy, the District of Columbia, Puerto Rico, the Virgin Islands, some provinces of Canada, and the Pharmacy Board of Victoria, Australia. I, again, would like to commend Dr. Yessian and his staff for the concise and comprehensive review of the subject. We are pleased that the Department of Health and Human Services and the Office of the Inspector General are involving themselves in issues and concerns that have been of interest to pharmacy for some time. An unbiased examination of issues, such as the "Medicare Drug Utilization Review," provides pharmacy regulators and practitioners with a much needed "outside perspective."

The comments offered on behalf of NABP will focus on those findings and recommendations that affect the protection of the public health, specifically, the design and operation of a multi-level DUR effort and the need to develop safeguards to protect the integrity of the Medicare DUR Program. The other issues raised in the report, although important, are not within our scope as the national association for state boards of pharmacy.

## **Findings**

We concur with the report's finding on page 3 that the problem of mismedication in the elderly population is significant. Furthermore, the problem does not seem to be lessening but appears to be increasing as the elderly population grows and the pharmaceutical industry introduces countless "me too" drugs. We agree further that the Medicare Drug benefit program will increase the occurrence of mismedication if it is not effectively implemented and managed.

The report notes on page 5 another serious cause of mismedication in the elderly, polypharmacy; "Because they suffer from multiple chronic diseases, older adults are frequently under the care of more than one physician who may prescribe drugs without knowledge of the patient's full drug regimen." This finding should be an important consideration when developing the Medicare DUR Program. Related to this, but not mentioned in the report, is the issue of physician dispensing. Under the Medicare Catastrophic Coverage Act, physicians are entitled to participate as providers in the drug care benefit program. An effective DUR system should also provide access to the medications dispensed by physicians.

## **Recommendations**

### ***Development of the DUR Program***

In the interest of the public health and safety, we agree that attention must be given to design a comprehensive DUR program. "The human costs associated with death, illness and incapacitation among the elderly as a result of mismedication are incalculable." It is imperative that "a comprehensive Medicare DUR program that emphasizes therapeutic as well as program integrity issues" be established.

### **Design of the DUR Program**

#### ***Patient Drug Regimen***

The report identifies the pharmacist/dispensing level as "the most critical point at which medication errors can be identified and corrected for individual patients." We agree wholeheartedly with this statement and urge the HCFA to develop and design the Medicare DUR program with this in mind. If mismedication can be prevented and controlled at this level significant public health and cost benefits will be realized.

And, if mismedication is to be prevented and controlled, the pharmacist must have access to a patient's drug regimen. We do not believe that the proposed prompts to pharmacists identifying potential ADRS will provide the pharmacist with all of the necessary information to make a decision about a patient's course of therapy. The report affirms this point; "Although a system of prompts to alert pharmacists to potential ADRs would be useful tool and should be included in the data system, it cannot substitute for the judgement made by a pharmacist."

Of course, NABP recognizes that access to a patient's drug regimen raises serious concerns about confidentiality. These concerns should not be ignored. However, we believe that a program can be developed that ensures this confidentiality and provides a mechanism for informed consent from participants.

### **Nationally Standardized Identification Number**

NABP concurs with the report that it is essential for the program to identify providers for the purposes of tracking mismedication problems. We would add that it is also necessary to identify providers for the purpose of ensuring that only qualified and competent providers participate in the program and dangerous or incompetent providers are eliminated or barred from the program.

NABP and the National Council for Prescription Drug Programs (NCPDP) currently maintain a national listing of pharmacies that identifies 97% of all the licensed pharmacies in the United States. Pharmacies are systematically assigned a unique NABP Number by the NCPDP only after verification of licensure in good standing with the appropriate state board of pharmacy or licensing agency. The NABP Number is currently used by pharmacies as an official identifier for licensure and third party reimbursement programs. In some states, the NABP Number is the pharmacy's official license number.

NABP also operates with the state boards of pharmacy a national clearinghouse for pharmacist licensure. Briefly, the disciplinary data bank serves as a central data bank for the state boards of pharmacy. Almost daily, the state boards of pharmacy provide NABP with disciplinary information on the final actions they have taken against the licenses of pharmacists in their states. NABP collates this information (name, license number, states licensed in and state where action was taken) monitors the licensure and disciplinary status of pharmacists, and reports information under secure and confidential conditions to the appropriate state and federal agencies.

The NABP Number and Clearinghouse System would provide HCFA with the mechanisms necessary to protect the integrity of the Medicare DUR System and protect the public from unqualified or dangerous providers. We hope that HCFA will consider utilizing these existing systems rather than unnecessarily expending resources to develop new, duplicative systems.

### **Fiscal Intermediary/Claims Processing Level**

#### ***Patient Counseling***

NABP agrees with the report on the value and importance of patient counseling. Undoubtedly, it is one of the most effective ways to contain mismedication, not only in the elderly population, but for all patients. However, the quality and quantity of patient counseling required is difficult to define and monitor. The system established to monitor this requirement of the Medicare Drug Program should involve a concerted effort between the boards of pharmacy and appropriate federal agencies utilizing data from the Medicare DUR program. We

ask that the HCFA *proceed cautiously* in this regard and not rely solely or entirely on the fiscal intermediary or ECP data base information.

Patient counseling is an integral part of the practice of pharmacy, which is regulated by the state boards of pharmacy. To create separate federal regulations for one aspect of the practice of pharmacy may be shortsighted and interfere with the responsibilities of the states. Efforts would be better served to create a minimum standard or requirement for patient counseling and work with the state boards of pharmacy to refine state practice acts or rules and regulations to meet the desired outcomes and provide the desired monitoring systems.

NABP is pleased to submit these comments and hope that they will assist the Department of Health and Human Services, the Office of the Inspector General and the Health Care Financing Administration implement a monumental health care program. If you have any questions, please feel free to contact me.

### **OIG RESPONSE TO NABP COMMENTS**

We appreciate the information and clarifications provided by NABP. We agree on the importance of a broadly based dialogue to determine appropriate minimum standards for patient counseling and to attempt to apply these standards to pharmacy practice in general. Research and demonstration efforts can be very helpful in this regard.

### **PUBLIC CITIZEN HEALTH RESEARCH GROUP COMMENTS**

Thank you for the opportunity of reviewing your excellent report on the problems of medicating the elderly and, specifically, the pending issue of Medicare Drug Utilization Review.

It is clear that financial barriers prevent many older adults from obtaining medications which they actually need, but it is just as clear that financial barriers protect many other older adults from prescription drugs which will do them more harm than good. The challenge, then, is to figure out a way to reduce or eliminate the first kind of harmful barrier without causing the damage that would result from the second barrier being eliminated. In addition, for those older adults for whom there are no financial barriers, the current problems in mismedication and overmedication urgently need to be addressed.

We have estimated that two-thirds of prescriptions written for older adults are wrong for one of three reasons:

1. The patient's condition, as with mild hypertension, adult-onset diabetes, mild obesity or similar problems is one for which a non-drug treatment should be tried and will often work.
2. A prescription drug is indicated, but the one prescribed is unnecessarily dangerous. (See *Worst Pills, Best Pills*, for the 104 "do not use" drugs and 183 safer alternatives.)



3. The right drug was prescribed but the dose was too high.

In all three of these circumstances, the situation is set up for preventable adverse drug reactions to occur which make up a large proportion of the estimated \$7 billion per year spent on health care costs in the elderly attributable to adverse drug reactions.

We agree with the remedies proposed for better regulation by FDA in requiring the drug companies to do more age-appropriate testing of drugs which are intended largely for older adults and the related issue of better labeling concerning the need to usually lower the starting dose of most drugs for older adults.

But the enormity of the epidemic of mismedication of older adults needs more than better education of new doctors and pharmacists and the collection of doctor and patient-specific prescribing data. Contrary to the views expressed by some, the studies done by Ray, Schaffner and colleagues at Vanderbilt on patterns of misprescribing by doctors using the Medicaid billing data have generated very useful data concerning the small fraction of doctors accounting for a disproportionate amount of the worst kind of prescribing such as the dangerous drug chloramphenicol for trivial infections.

I would strongly support, as your study and the legislative history do, the inclusion of encrypted doctor identifiers in the data which is collected along with encrypted patient identifiers so that problems can be discovered as soon as possible.

On page ten of the draft report, commenting on our book, *Worst Pills, Best Pills*, you state that although this kind of information "is useful in sensitizing older adults and health care professionals to the dangers of mismedication," it "can not substitute for a formal set of guidelines that will ensure improved testing and labeling of medications for the elderly." While agreeing with this, I must add that your report would be more complete if it included a recommendation to restore the important patient prescription drug package insert program which was to have gone into effect for 10 categories of drugs amounting to more than 14% of all prescriptions filled but was cancelled entirely by the Reagan administration in the spring of 1981.

Finally, and omitted entirely in the drug portion of the catastrophic coverage legislation, is the issue of drug formularies, limited lists or similar restrictions on which drugs will be reimbursed for by Medicare. (Aside from the "certain narrow exceptions" referred to in your report, the use of a formulary is prohibited.)

It is true, as it is in many other respects, that Medicaid can hardly be used as a model for limiting the scope of reimbursed drugs. No state Medicaid program, in my view, has begun to place adequate limitations on the large number of drugs which should not be reimbursed or which should only be reimbursed for certain indications. Even if we surprisingly revamped current medical education so that future students and residents had much better training in geriatric pharmacology and prescribing, this would still leave over 90% of the doctors who take care of the elderly without the skills to prescribe intelligently. As one geriatrician said,

correctly describing the dangerous current state of affairs, the purpose of a geriatrician is to take older people off of drugs other doctors put them on.

What is thus needed, in addition to reforms in FDA's requirements for drug testing and labeling and improvements in education of health care professionals and older people, is a formulary or restricted list of drugs. With 100% certainty, this will come to pass as it has in the best hospitals in this country, in other health care delivery settings in the U.S and in many foreign countries.

The question is, therefore, not whether it will happen but when, and what needs to be done now to hasten the day when an amendment is passed to the existing drug-coverage legislation for Medicare which requires, rather than prohibits, such a formulary. The present legislation prohibits the use, for reimbursement purposes, of formularies. But within the scope of Drug Utilization Review program objectives is room for studying the usefulness of formularies in improving drug prescribing and as remedies for this epidemic of drug-induced disease and waste of billions of dollars in elderly people. I hope you will make this recommendation.

#### **OIG RESPONSE TO PUBLIC CITIZEN HEALTH RESEARCH GROUP**

We appreciate the positive assessment and the supplemental information provided by Public Citizen Health Research Group. We agree that the problem of misedication of the elderly is quite serious warranting concerted government action. With respect to the additional recommendations called for, we recognize the arguments put forth but feel that our own inquiry does not provide sufficient basis to make the recommendations.

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## APPENDIX II

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### ENDNOTES

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