S. HRG. 98—392

DRUG USE AND MISUSE: A GROWING CONCERN FOR OLDER AMERICANS

JOINT HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

AND THE

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

OF THE

SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES

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DRUG USE AND MISUSE: A GROWING CONCERN FOR OLDER AMERICANS

TUESDAY, JUNE 28, 1983

U.S. SENATE, SPECIAL COMMITTEE ON AGING, AND THE SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE, OF THE SELECT COMMITTEE ON AGING, U.S. HOUSE OF REPRESENTATIVES,

Washington, D.C.

The joint committees met, pursuant to notice, at 9:02 a.m., in room 628, Dirksen Senate Office Building, Hon. John Heinz, chairman of the Senate Special Committee on Aging, and Representative Claude Pepper, chairman of the Subcommittee on Health and Long-Term Care, copresiding.

Present: Senators Heinz, Grassley, and Burdick; Representatives Pepper, Oakar, Bilirakis, Lantos, McCain, Daub, Ridge, and Ferraro.

Also present: From the Senate Special Committee on Aging: John C. Rother, staff director and chief counsel; Isabelle Claxton, communications director; Trish Neuman, professional staff member; Robin Kropf, chief clerk; and Angela Thimis and Nancy Mickey, staff assistants. From the House Select Committee on Aging Subcommittee on Health and Long-Term Care: Bill Halamandaris, staff director; and Kathleen Gardner Cravedi, assistant staff director.

STATEMENT BY SENATOR JOHN HEINZ, COCHAIRMAN

Chairman HEINZ. Good morning, ladies and gentlemen.

This is a joint hearing between the House Select Committee on Aging and the Senate Special Committee on Aging. I am very pleased that my good friend and former colleague from the House, the distinguished chairman of the Rules Committee, Congressman and former Senator, Claude Pepper, is here to cochair these hearings with us today.

I have had many pleasant occasions to work with Chairman Pepper, both when we served on the House Aging Committee, and in many ventures and adventures since.

There are a few brief remarks I would like to make before I turn to Chairman Pepper. The subject of the hearing today is drug use and misuse among older Americans. We in the Congress have often focused on the heartbreak and devastating waste of young lives through drug abuse. Yet, to date, we have ignored the emotional and physical agony of older Americans who suffer needlessly because of drug misuse.

The problem of drug misuse is real. It is a pervasive problem and a potentially deadly problem. With this hearing, we hope to focus attention on the special problems of drug use for older persons.

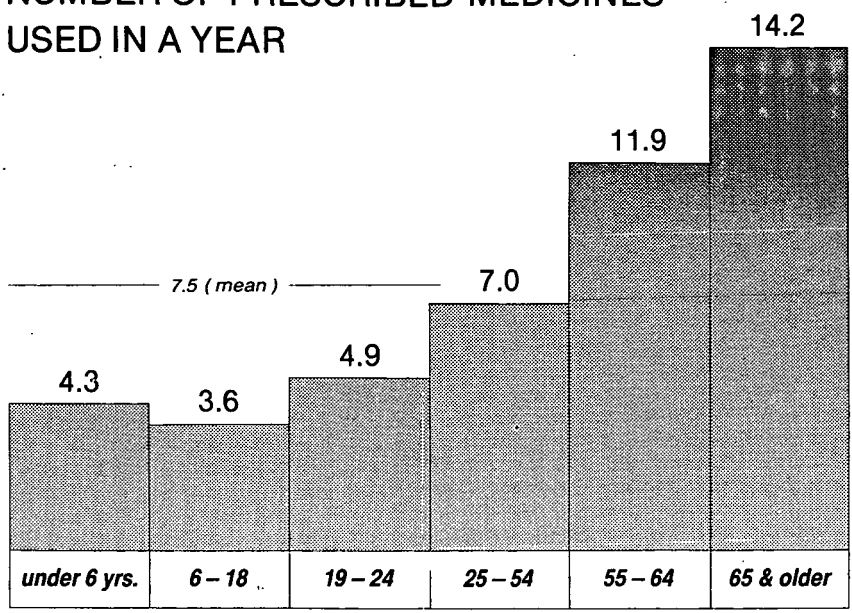
Problems caused by the interaction of physiological change and drug usage require careful attention from doctors, pharmacists, the drug industry, and the Food and Drug Administration. Because these problems are rooted primarily in an absence of relevant and useful information, we will hear today from those who develop, sell, prescribe, and use medication. We hope to learn what information is now available and, more importantly, what information is lacking about the effect of drugs on older persons.

This much is already known. First, persons over age 65 use more drugs than any other age group in our society. Approximately two-thirds of all older persons use nonprescription drugs on a regular basis. The same group also uses over one-fourth of all prescription drugs sold in America.

As you can see in the chart, those over age 65 use, on average, over 14 prescription drugs within 1 year, which is nearly twice the average amount used by persons between the ages of 25 and 54. Those older persons who are hospitalized are given an average of 10 different drugs during each stay in the hospital.

Second, we know that the simultaneous use of multiple drugs is not always healthy. The incidence of adverse reaction is likely to increase with the number of drugs used. Between 12 and 17 percent of hospital admissions—that is, one out of every six hospital admissions—for persons over age 70 are due entirely to adverse drug reactions. That is compared with only 3 percent, or 1 in 30 or 35, for the entire population.

Third, although the elderly are among the highest users of prescription and nonprescription drugs, we know that they generally know very little about the drugs they take. Most older Americans



see more than one doctor to prescribe whatever medicines are necessary. However, doctors often prescribe medication without knowing which drugs are already being taken, or their potential interactions. The problem is exacerbated because older patients frequently are reluctant to ask their doctors many questions.

It is our hope that this hearing will stimulate interest and action among older Americans to learn more about the drugs they take. To meet this goal, the Senate Special Committee on Aging is today

releasing a committee print explaining and advising older Americans concerning the proper use of medications. It is entitled: "You and Your Medications: Guidelines for Older Americans."

Let me just say in closing that the problem of inadequate information, does not rest entirely with the consumer. Physicians often have inadequate information available to them concerning the specific effects of drugs on older persons. Most, in fact, rely almost exclusively on salesmen and advertisements issued by the drug industry.

The pharmaceutical industry is responsible for providing vital information to the Food and Drug Administration, physicians, and pharmacists. There are, however, no requirements for the drug companies to gather information concerning the specific effects of drugs used by older persons, in spite of the fact that they are required to gather information about the effect of drugs on young people, pregnant women, and a number of other specific groups.

Unfortunately, no representative from the pharmaceutical industry accepted our invitation to testify here today, although they were invited. I do look forward to the testimony of our distinguished witnesses who are here this morning on this important matter.

Let me turn at this point to the distinguished former chairman of the House Aging Committee, the present chairman of the House Rules Committee, my good friend, Congressman Claude Pepper.

Claude.

STATEMENT BY REPRESENTATIVE CLAUDE PEPPER, COCHAIRMAN

Chairman PEPPER. Well, Senator Heinz, you know that as your very long-time and very good friend, it is a particular pleasure for me to be here with you this morning. You served with great distinction on the Aging Committee in the House, and have continued to serve with great distinction as the chairman of the distinguished Committee on Aging in the Senate. It is a great pleasure for me to continue to work with you as our committees are doing. You and I had the privilege of working together on the Social Security Commission and many other endeavors that are meaningful to the elderly people of the country.

I think this is a very pertinent subject that we are to discuss here this morning, namely, the use of drugs—you might say, the misuse of drugs—by the elderly people of the country.

Today, as you know, older Americans—that is, people over 65 years of age—represent about 11 percent of our population. Yet they consume about one-third of the 1.5 billion prescriptions written annually. On the average, the elderly take about 13 prescriptions per year.

By the year 2000, our elderly will number about 33 million persons. Today, there are about 26 million elderly Americans in the country. By the year 2000, it is estimated that the elderly will consume 50 percent of all the prescription drugs in our country.

Hospital emergency room studies show that the elderly are admitted twice as often for adverse drug reactions as those under 60. I remember very well, Senator, an elderly man calling me at my

home in Miami, telling me that his doctor was out of town and that he did not know how to take his medicine. He could not read it, he was not sure whether or not he understood what he was to do, and he said, "What am I going to do until my doctor gets back? I have all these medicines I am supposed to take, and I am all mixed up and confused. I do not know what I am going to do."

When drug reactions are experienced, the average hospital stay is nearly doubled in the case of elderly people. The estimated national cost of drug-induced hospitalization, according to a 1969 new Task Force Panel on Prescription Drugs, was in excess of $3 billion annually. I don't have the figure here, but I think there are a great, great many fatalities among the elderly in the country on account of reactions to drugs that they take or excessive use of drugs that they take. So today, taking into account inflation, drug-induced hospitalization is closer to a $21 billion problem annually.

Now, what are the major reasons for drug misuse and adverse reactions among our elderly?

Well, I suggest that the problem is threefold. In the first place, only about 10 to 15 of the 127 certified medical schools in the country require their students to take geriatrics, so that a lot of the doctors are simply not adequately informed about the elderly and the reactions in the elderly. It is pretty generally accepted that symptoms are different in the elderly than in people of a younger age. If you are not aware of the problems of elderly people, you are not really in a position to give them wise advice.

Errors made by the patients in self-administering their drugs can lead the elderly to fail to take necessary medication. Studies show that over half of those over the age of 65 do not take their prescriptions as instructed. About 10 percent never even get their prescriptions filled. Thirty-five percent leave the doctor's office with no information on the drugs that they are to take. Seventy-four percent are not told about the possible side effects, and only 6 percent get written information on the drug. You know, taking too many drugs together may have an adverse effect or cause an adverse reaction among those drugs that are taken.

Second, many elderly patients lack awareness regarding the drugs they take, and thus, are more likely to swap old, outdated drugs with their friends, and take more medication than necessary. We all know that medicare does not pay for drugs that are prescribed by a physician if they are taken at home instead of at a hospital; this is contrary to what it should be. So, applying the philosophy that "If one is good, two are better," they simply, a lot of times, take neighbors' or friends' drugs, thinking that that will be all right. Sometimes, they simply fail to fill prescriptions due to the expense involved.

On the average, seniors pay about $140 annually for their prescriptions. Now, when you take into account that even with social security, about 16 percent, or about one-sixth of the elderly in the country, have incomes below the poverty level, that is a rather high share of their income.

Last, the third major reason for drug misuse among the elderly stems from the fact that drugs are often not manufactured, tested, or monitored, taking into account the unique problems of the elderly patient. The responsibility for such oversight rests with the Food

and Drug Administration of the U.S. Department of Health and Human Services.

Consider the following facts: Patients in FDA's premarketing studies do not represent all those who would be taking the drug. For example, while about 50 percent of the elderly suffer from arthritis, medications designed to treat arthritis are generally tested on people who are not senior citizens, and frequently do not have arthritis. I do not know why they exclude the elderly. Maybe they are fearful of the results.

Take, for example, an ordinary testing by the Food and Drug Administration—about 3,500 people and about 500 animals. Those 3,500 people are basically younger people, and consequently, those drugs actually have not been tried out on elderly people. That is my understanding of the practices of the Food and Drug Administration.

Once a drug has been approved for sale, it is not incumbent upon elderly patients or prescribing physicians to report adverse drug reactions. Monitoring of the drug is essentially limited to the voluntary reports of problems made known to the manufacturers and transmitted from the manufacturers to the FDA.

I wonder if there is any significance, Senator, in the fact that none of the drug houses have accepted our invitation to be here today. They could have given us some very helpful information. All we are trying to do is find out the facts so as to help a very important segment of our citizenship, and they, of course, know more about these facts than anyone.

As a result, a vast number of adverse drug reactions go unreported and thus, uncorrected. In so many homes in our country, these elderly people are taking their drugs daily, sometimes they have a lot of them in a group; sometimes they take them, sometimes they do not. They run out, and they haven't gotten another prescription filled, it costs so much, and they will wait awhile. They will take something else, and maybe that will do just as well.

So you can see that we ought to develop some way or another to have a better reporting system where we would understand better what are the actual reactions of drugs that are intended to alleviate the suffering, to aid the elderly people of the country.

So all our committees are trying to do today is to find out the facts and to develop certain information that we hope will be helpful to the elderly people of our country.

It is a great privilege, Senator, to be here with you, and I am very sorry that I have to go into something much less exciting and worry with some rules.

Chairman HEINZ. The Rules Committee may not be exciting, but we know what it does in the House, and as a former Member, I have nothing but respect for the ultimate authority of the Rules Committee.

Chairman PEPPER. Thank you, Senator.

Ms. Oakar, who, I am proud to announce, is a distinguished member of my subcommittee, will remain here. We are proud that she and other members of the subcommittee have come over to this side of the Capitol to be here with you.

Chairman HEINZ. I am very pleased, and maybe we can reciprocate.

Thank you, Claude.

Chairman PEPPER. Thank you very much.

Chairman HEINZ. Congresswoman Oakar, do you have an opening statement?

STATEMENT BY REPRESENTATIVE MARY ROSE OAKAR

Representative OAKAR. A brief statement, Senator, if I may. First of all, I want to commend you and my chairman, Senator Pepper, for having this very, very important hearing.

Historically, the Aging Committee has always been interested in drugs and the elderly, and I just wanted to make a couple of quick observations.

Today, there are about 300,000 over-the-counter drugs and about 7,000 prescription drugs on the market. This is a big industry—it is worth about $25 billion—and the drugs and sundries industry, of course, has, as its biggest customer, the elderly. The elderly take up to 13 prescriptions per year, plus many over-the-counter drugs. Adverse drug reactions for the elderly are seven times greater than for 29-year-olds.

You and the Senator have mentioned many things that are of concern to me. I want to focus on one point that I do not think has been mentioned. I am going to look forward to questioning members of the FDA when they come up along with our other witnesses. We must not neglect a vital element in the overall picture—the role of Government and the role of the Food and Drug Administration. The FDA is charged with the responsibility of protecting the public from potential health hazards of drugs. We must direct our attention to the FDA when the question arises: How did this drug get on the market in the first place?

I must say that I have a very serious concern about some of the drugs currently on the market, both prescription and over the counter. This raises very real concerns about the FDA's testing process, its clinical testing procedures for approving new drugs, and its ongoing review process of over-the-counter medication. Senator, I certainly look forward to questioning the witnesses today. I am very delighted that they are able to be here. I especially look forward to raising some questions with FDA.

Thank you, Senator.

Chairman HEINZ. I do not think you will be alone in that. I thank you for an excellent opening statement.

Congressman Bilirakis.

STATEMENT BY REPRESENTATIVE MICHAEL BILIRAKIS

Representative BILIRAKIS. Thank you, Mr. Chairman.

I, too, commend you and our subcommittee for these hearings.

I represent the Ninth Congressional District in Florida, which is along the central gulf coast. Approximately 50 percent of my constituents are retirees. We do have fantastic problems down there, particularly in the area of drugs. I also am disappointed the pharmaceutical industry is not represented here today, but I will tell you that I have something like half a dozen pharmacists in my family, and I have been on the telephone, communicating with them, to learn some of the problems they run into with many of

our elderly in this area. And we have also been in communication with some of the health agencies down there—HRS, particularly. We find that, in addition to some of the areas that Senator Pepper mentioned, we have problems because many of our elderly, being on fixed incomes, shop around an awful lot. They shop one doctor to another, and each of those doctors, of course, prescribes drugs to them, and conversely, they take these drugs, which quite often interact with one another and result in an awful lot of adverse reactions. It is a practical problem, it is a realistic problem, and it is a problem that we can solve only if we tackle it head on. I would like to ask some questions later on about computerized systems, patient profiles, things of that nature, which may not be the only way to solve that, but I would be interested in looking into it.

We also find an additional problem involving the interaction of alcohol. I know we are planning to hold specific hearings on the use of alcohol by the elderly, but there is a great interaction of alcohol with these drugs, and it affects many of the people in our area.

So, Senator, I again commend you, and look forward to participating in this. And, like Senator Pepper, I, too, have conflicts. I am just a freshman up here, but I cannot understand why we cannot solve the problem of these conflicts with committees. I serve on three committees and all three of those committees are meeting at the same time today—two of them, of course, are way over on the other side of creation. But we are going to do the best that we can, shuttling back and forth, to try to contribute.

Thank you very much, sir.

Chairman HEINZ. Congressman, thank you very much. Of course, we in the Senate have absolutely no problems with multiple committees being scheduled simultaneously. According to my schedule, I only have three other committees I have to appear before this morning at 10 o'clock. That is why we are starting this one early. I think you must have learned to mimic us when it comes to committees. I am sorry for both of us.

Representative BILIRAKIS. That is unfortunate, yes.

Chairman HEINZ. It is a pleasure to welcome Congressman Tom Lantos.

Tom.

STATEMENT BY REPRESENTATIVE TOM LANTOS

Representative LANTOS. Thank you very much, Senator.

I think we are all anxious to get on with the witnesses, and I just have a couple of comments I would like to make.

First, I would like to pay tribute to you, Senator Heinz. You have been a national leader in the field of dealing with the problems of the aging, and as one who does not share your party affiliation, I am proud to pay public tribute to your leadership, which has been significant and growing and nationally recognized, and we are all deeply indebted to you.

Chairman HEINZ. Thank you.

Representative LANTOS. I also would like to recognize at the outset the enormous contributions made over the years of former Senator Frank Church, who used to chair this committee on the

Senate side, whose work in this field is a proud chapter in American history as it relates to the aging. Obviously, I am delighted to be serving under Senator Pepper, whose contributions have become legendary.

We are dealing with a very important issue, Mr. Chairman, and I think it is critical that we put it in some perspective. The reason we are having a hearing is to look at the problems, but I think it would be unrealistic not to recognize the enormous contributions that the industry has made over the years to relieving pain, anguish, and suffering, and making life more bearable as we get on. And I think it is critical in this field, as in other fields, that while we focus on problems, we recognize the achievements, which have been enormous and, in a quantitative sense, overwhelming. When we come to problems, Mr. Chairman, I think analytically, it is also important for those of us in a policymaking position to differentiate sharply between the various types of drug misuse, because very different remedies are called for. We have drug misuse which is the fault of the provider or the physician, and we have to devise more effective strategies of dealing with it. We have drug misuse and drug abuse which is the fault of the patient, and I think, in all candor, we must recognize that, particularly as we are dealing with a population that in many ways has more difficulty in following instructions and directions than the population at large, due to poor eyesight, due to a whole variety of reasons, we need to focus on ways and means of dealing with patient abuse. And finally, of course, as my friend and colleague, Congresswoman Oakar, has indicated, we must deal with the problems that arise out of Government action, or the failure of the Government to act in the field of approval, testing, and monitoring of drugs.

I, too, wish to apologize for the fact that at 10 o'clock, the Foreign Affairs Committee is beginning a hearing on Soviet human rights abuses, and I need to be there. But I want to commend you, Mr. Chairman, for calling the hearing.

Chairman HEINZ. Congressman Lantos, I thank you for a most articulate statement and would only note, having seen you perform and question witnesses a few days ago at our hearings on the Helsinki Commission, that I know of your interest in human rights—it is a profound one. And it is hard to be in two places at once. We are going to miss you, but we know that you have an important calling.

Representative LANTOS. Thank you, Senator.

Chairman HEINZ. Congressman McCain.

STATEMENT BY REPRESENTATIVE JOHN McCAIN

Representative MCCAIN. Thank you, Senator.

I also appreciate very much that you and Chairman Pepper have called this hearing. It is a very serious and often ignored problem. In my home State of Arizona, we are already in a situation where 30 percent of our economy is devoted to health care. A large portion of that, obviously, is to the elderly.

Drug misuse among the elderly is a problem that can be controlled, I believe, only by a cooperative effort from every segment of the population—doctors, pharmacists, family, media, and the el-

derly themselves. In Arizona, two programs have been initiated by the Arizona Department of Health Services, called Elder Ed and Keys to Healthy Aging. Both of these have performed a vital role in our State in educating our elderly citizens as to the problems with drug misuse, and the problems they face when they go to a doctor who is not well aware of their unique requirements. I believe that programs such as these will go a long way. I look forward to the testimony of our witnesses today, who I know will contribute a great deal to this hearing.

Thank you, Mr. Chairman.

Chairman HEINZ. Thank you, Congressman McCain.

Congressman Daub.

STATEMENT BY REPRESENTATIVE HAL DAUB

Representative DAUB. I appreciate the opportunity to be here today, Mr. Chairman, and I commend your leadership in the field of determining what we can do in Congress to assist in solving the problems of our elderly and aging community.

This particular hearing is going to turn out to be, I predict, a very crucial one. Drug misuse and abuse among the elderly in our country have extreme medical and economic consequences. It is important to document today some of these consequences and possible alternatives to alleviate this devastating problem. The problems with drugs and our elderly are destined to increase. With the aging of our population, by the year 2000, it is expected that from consuming about 30 percent of the prescribed medications, the elderly may easily come to account for 50 percent of all medication consumed in the United States. It is estimated that in 1983, expenditures for drugs and drug sundries will account for 8 percent of health care expenditures, a total of about $25 billion—and medicare does not cover the costs of medication. In some instances, medicaid will cover portions of drug expenditures.

In my State of Nebraska, drug benefits are available both to the categorically and medically needy, and I would be proud to let you know that the limits on these are minimal.

Drug expenditures are the largest single expenditure after hospital, physician, and nursing home outlays. This makes it imperative that we look into this to insure that the elderly do not forego necessary medications because of cost, or endure a hardship in another area in order to pay for their medications.

Adverse reactions are another important consideration. Older people react differently than younger persons do to drugs. The testing of drugs must be looked into to determine the feasibility and desirability of age-specific testing. In addition, we must investigate the means to control and know the reactions of the elderly intake of a multiple number of drugs.

I believe that education is a very important item that must be addressed, not only for the elderly, to show them the consequences of multiple drugs, drug swapping, over-the-counter drugs, and not following directions, but we have to take this message to our physicians as well, to make them more informative to their patients, and to insure that they understand fully the effects of drugs on the

elderly, the effects of multiple drug intake, and the importance of reviews of medication.

I want to thank the witnesses who will be testifying here today on this very important problem. It is crucial to bring attention to this so that we can help ourselves in our search for solutions to both the medical and economic problems, Mr. Chairman, that do arise from the misuse of drugs by the elderly.

I want to thank you very much.

Chairman HEINZ. Congressman Daub, we are delighted to have you and Congressman McCain from the House side, as well.

Before we hear from the first panel of witnesses, I am told that there are several members of the Senate Aging Committee who cannot attend today's hearing. They have submitted statements for the record, and without objection, they will be inserted into the proceedings at this point.

[The statements follow:]

STATEMENT OF SENATOR LARRY PRESSLER

Mr. Chairman, I would like to thank you for your work in organizing this morning's hearing on this very important subject. There are some efforts currently underway to help disseminate information with regard to the wise use of drugs by older Americans, but there is much that remains to be done in this area.

According to the General Accounting Office, prescription drugs account for almost 75 percent of drug-related deaths in this country. Forty percent of those suffering from adverse drug reactions are over 60 years old. One of the major problems in this area is that we do not possess very much information on the special effects of drugs on older persons. As our medical schools develop geriatric medicine specialties, our new doctors will have better training in this area, but for those who are practicing now, this lack of knowledge is a real problem.

We do know that many older persons suffer from multiple chronic illnesses and often take a number of prescription drugs, all at the same time. The potential for dangerous interactions among these drugs presents a real problem for many older persons. Very often they are given no information about possible side effects such as this.

There are questions remaining about the ability of older persons to metabolize drugs as quickly as younger persons which may mean that the "normal" adult dosage is not appropriate for older Americans. Along these same lines, there are questions about the absorption rate of generic as opposed to other drugs. Many older persons use generic drugs as a means of saving money, and if these drugs have a different rate of absorption, this is information that could be very useful for them.

In my home State of South Dakota, the Office of Adult Services and Aging has conducted several training sessions on the wise use of medications. These sessions have been given at local senior centers and before the State Association of Senior Citizens. One of the community education programs in Sioux Falls, S. Dak., has also run an entire course on this subject. As a result, I am extremely proud of the efforts that have been made in my State to address this problem.

On a national basis, the American Medical Association has just begun a program in the last 6 months to provide patient medication instructions for its members to dispense with prescriptions for the most commonly prescribed drugs. I applaud this effort and hope that this excellent program will be widely used by AMA members.

Mr. Chairman, I know that, despite the positive things that are occurring in this area, there are still some problems remaining. I look forward to the testimony of our witnesses today to tell us what these problems are and to point the way for future action.

STATEMENT OF SENATOR JOHN GLENN

I am pleased to have this opportunity to join my colleagues from both the House and Senate Aging Committees in discussing the vital issues associated with drug use and misuse among older Americans.

At this hearing, we will explore the extent of drug use among the elderly and the problems that sometimes occur from adverse reactions and overuse. We will exam-

ine the actions being taken by the pharmaceutical industry, the medical community, and consumer groups to properly educate older Americans, their doctors, and their pharmacists about safe and effective drug use. We will receive testimony about the current Food and Drug Administration (FDA) regulations for premarket testing and postmarket surveillance of drugs, and consider whether these regulations adequately protect elderly patients. And finally, we will discuss what additional measures for drug use may be needed to assure the physical and mental health of our Nation's senior citizens.

Because older Americans are particularly prone to medical discomforts, they seek a greater amount of medication than the younger population. More than 80 percent of people over the age of 65 have at least one chronic condition, and many have multiple ailments. These conditions often require regular medication. When used correctly, drug therapy can provide an older patient with significant relief from pain and can promote healing. When drugs are used incorrectly, however, the cost to the patient and society can be devastating in both human and monetary terms.

Drug use among the elderly is quite prevalent. Although the elderly represent about 11 percent of the population, they consume about 30 percent of all prescription drugs. An average of 13 medications per year are dispensed for persons over age 65. Sixty percent of the elderly population are using medication daily. As the population of older Americans continues to rise, it is estimated that by the year 2000, older persons may account for 50 percent of all prescription medication consumed in the United States.

There are many factors which lead to problems in drug use by the elderly. Because there is a 50-percent reduction in physiological functions from ages 30 to 90, drugs act differently on older people. For example, kidney and liver functions decreases with advancing age, and drugs are metabolized by the body more slowly. Therefore, older persons may require lighter doses of a drug and at less frequent intervals. It is my understanding that most premarket testing of drugs is done on young, relatively healthy individuals. However, the therapeutic value and side effects of a drug may be very different for older persons. Perhaps we should consider including vulnerable populations, such as the elderly, in premarket testing of drugs.

There are many other factors which contribute to drug misuse among the elderly. The presence of multiple chronic diseases in elderly persons, combined with multiple drug use, can lead to a higher incidence of drug-induced illnesses. Possible side effects of such multiple drug use include memory disorders, depression, confusion, dizziness, and tremors. Unfortunately, because these symptoms mimic the stereotypes associated with old age, they are often incorrectly diagnosed as evidence of senility. Institutionalization may occur or additional drugs, such as antidepressants, may be prescribed.

There also seems to be a lack of patient-provider communication regarding drug use among the elderly. Most doctors have not received training in geriatric medicine or geriatric pharmacology, and, therefore, may not recognize the special needs of elderly patients. A survey by the Food and Drug Administration indicates that there is a significant reluctance on the part of elderly patients to ask questions of their physicians and pharmacists.

The problems we are discussing today are not limited to prescription drugs, but include over-the-counter drugs as well. The elderly purchase 70 percent of all over-the-counter drug products. Many over-the-counter drugs can interfere with the action of prescription drugs. If used inappropriately, they can cause complications by themselves. Problems can occur because many physicians are unaware of the over-the-counter drugs their patients are taking.

In addition to the human consequences of drug misuse, there are significant monetary costs associated with this problem. Drugs are a $25-billion industry and account for the fourth largest health care expenditure, following hospitals, physicians, and nursing home costs. Because medicare does not offer drug benefits, the bulk of this $25 billion comes out of the pockets of elderly consumers. About 300,000 people are hospitalized each year because of adverse drug reactions. The estimated national cost of drug-induced hospitalization is nearly $3 billion per year.

Advances in modern drug therapy have saved countless lives. Drugs contribute to increased longevity and improve the quality of life for millions of older Americans. But when used improperly, drugs can be a dangerous threat to our Nation's senior citizens. I hope that through this hearing, we will learn of programs and procedures being implemented or proposed which offer improvements.

As the ranking Democratic member of the Senate Special Committee on Aging, I am pleased to join with other committee members in releasing a report entitled, "You and Your Medicines: Guidelines for Older Americans." This information paper describes why medication is often improperly taken, and describes the responsibil-

ities of the patient, doctor, and pharmacist in the safe and effective use of drugs. The report also offers seniors a helpful list of do's and don'ts to assure proper use of medication. Hopefully this publication will prove valuable to many of our older constituents and will lead to similar consumer education projects.

STATEMENT OF SENATOR CHRISTOPHER J. DODD

Mr. Chairman, I want to commend you for holding this timely hearing on drug use and misuse by older Americans.

It is alarming indeed that drug misuse among senior citizens is so often mistaken for the "natural" decline in physical and mental ability associated with aging. Such misuse can lead to tragic results, including unnecessary confinement in nursing homes and other institutions.

We must do all we can to prevent such tragedies from occurring. I know that my colleagues on this committee and the House Select Committee on Aging join me in calling for new research on the effects of various drugs on our elderly population. We must also examine the issues of drug testing and drug promotion as they relate to seniors. Finally, we must devise some means of encouraging medical students and practicing physicians to study new ways to advise older patients on the use of medications in order to prevent misuse and unintended side effects.

Mr. Chairman, again I congratulate you on holding this hearing on a pressing issue which may affect the health and well-being of hundreds of thousands of our senior citizens.

Chairman HEINZ. It is, of course, a pleasure for us all to introduce people from our congressional districts or States. We have loaded the panel a little bit with a couple of Pennsylvanians, and it is a great pleasure, therefore, to introduce members of the panel to the committees, and to call upon our first witness, Michael Flaherty—not an uncommon name in western Pennsylvania politics, I might add.

Mr. Flaherty is the director of the Addiction Treatment Center of the St. Francis General Hospital in Pittsburgh.

STATEMENT OF MICHAEL T. FLAHERTY, DIRECTOR, ADDICTION TREATMENT CENTER, ST. FRANCIS GENERAL HOSPITAL, PITTSBURGH, PA.

Mr. FLAHERTY. Good morning. On behalf of St. Francis General Hospital and the elderly of Pennsylvania, please accept our appreciation for the opportunity to be here today. We are here to share with you some of the startling results of two studies recently completed in Pennsylvania, that have uncovered a growing unmet fear and concern in our elderly about their medications and their health.

In addition to Nettie A. Powell, Ethel Slade, whose testimony I believe you are previously familiar with, Dr. William E. Mooney, and Tod Marion, our senior researcher, have accompanied me today with this testimony. Our work was also fortified by the consultation of a special volunteer professional and senior citizen task force.

Chairman HEINZ. Mr. Flaherty, since you have introduced them, perhaps they could just rise so we can know who they are. Could you call their names out one more time?

Mr. FLAHERTY. Nettie A. Powell, Ethel Slade, Dr. William E. Mooney, Tod Marion.

Chairman HEINZ. Thank you very much.

Mr. FLAHERTY. Thank you. Our work was also fortified by a special senior citizen and professional volunteer task force with the

intent to study the patterns of medication use and misuse in the elderly in our area.

In conducting our research, we have found many frightening statistics, some of which I will now share with you.

Concerning substances used, 28 percent of the Allegheny County study and 67 percent of Beaver County's study reported taking four or more medication prescriptions daily. This is in the light of a 1979 New York City study that documented that three medications was the maximum that a 65-or-older person could safely manage, even with guidance. Forty-two percent of Beaver and 24 percent of Allegheny County reported adding over-the-counter medications to their prescriptions without ever consulting their doctors.

Forty-six percent of the Beaver respondents and 29 percent of Allegheny respondents reported experiencing unexpected side effects, including overdose, which they also never told their doctors.

Sixty-nine percent of the respondents reported being dependent upon their medications to maintain their daily functioning; 29.5 percent of Beaver respondents seen by home health agencies reported taking as many as eight or more medications daily.

Thirty-three percent of the sample received their prescriptions from two or more physicians at one time; 62.3 percent of the respondents never discussed the need to avoid certain foods, drinks, or other medications when taking a new prescription; 49.5 percent of the population studied left their doctor's office without feeling they did not know everything they should about that medication. Twenty-seven percent felt the medication prescribed was not necessary. What did they do? Twenty-three percent sought additional information about the medication from a friend; 26.6 percent varied their doses subjectively; 22.3 percent shared their medications; 33.3 percent of the elderly use alcohol; 10 percent drank it daily in some amount; 14 percent mixed alcohol with their medications; 7.2 percent actually washed their pills down with alcohol; 74.6 percent said they had never been asked to refrain from drinking when taking medicine.

Sixty-eight percent of those interviewed felt their doctor was the one person most responsible for their health, yet 40 percent admitted they did not tell their doctors about the other medications they were taking on their visit. They either forgot or were afraid to hurt his feelings if, for example, they were seeing another doctor.

Concerning certain subject practices, we found that 29 percent indicated receiving a prescription and never filling it; 57 percent stopped taking medications before the time indicated; 36 percent used old prescriptions; 62.3 percent renewed a prescription over the phone; 30.2 percent received a new prescription over the phone.

The elderly had the following prioritized problems with their medications.

While more than one-half of them could not open the containers, fully one out of every four of them could not read or understand the directions when they did open the containers.

Concerning professional input, we found that 27 percent of the physicians studied felt they were not sufficiently trained to recognize and treat substance abuse problems in the elderly. Seventy-four percent of the health care professionals studied believed sub-

stance use/misuse problems among the elderly merited special educational/treatment efforts.

Other researchers have found similar results in other parts of the country. Brady points out that 3 to 5 percent of hospital admissions in the elderly are the results of drug reactions or "drug misadventures," and this accounts for some 30,000 deaths annually.

Our study found that 11.2 percent of the admissions in a local drug and alcohol rehab center were for those 55 or older.

Obviously, I could go on. However, I hope that by now, my point is clear. Indeed, we are living longer because of our improved medical and health care. This solution, too, however, has brought new problems. We are told that while those over 64 constitute only 10 percent of the population, they consume 25 percent of the prescription medications. This translates into a $3 billion annual industry, or 20 percent of the expendable income the American elderly have. Pennsylvania is already at 13 percent over age 65, and this is progressively growing.

In sum, while many more of us will live much longer, we will progressively use more medications than any of our ancestors. Our study confirms a growing need now to better understand the use of medication by the older patient.

In terms of recommendations, I will summarize what I have written here. First, the need for further research, geographically specific, to understand the unique needs in each area of the elderly. Additionally, research is needed to understand drug interactions, long-term effects, side effects in the elderly, and geriatric dose levels need to be established.

We need to develop prevention education programs not only for the elderly, but also for the professional community. The elderly need to be able to talk to their doctors.

Legislation regarding prescribing and dispensing of medications in order to safeguard the elderly—larger print, safe but accessible containers, and directions that can be understood—are needed.

Treatment facilities need to be established where elderly can safely turn and feel that they can go; and the health insurance program that covers both substance misuse and addiction in the elderly is certainly needed.

Thank you.

Chairman HEINZ. Thank you very much, Mr. Flaherty.

Accompanying Mr. Flaherty down from Pittsburgh is another valued constituent, Nettie Apple Powell.

Mrs. Powell, would you be our next witness? We are delighted you could come. Please, proceed.

STATEMENT OF NETTIE APPLE POWELL, PITTSBURGH, PA.

Mrs. POWELL. My name is Nettie Apple Powell, and I am nearly 80 years old. About 10 years ago, my doctor said I had some kind of heart ailment and prescribed a heart medication for me. Shortly after, I began having what I call my sneak attacks. They felt like a bomb exploded in my stomach and caused uncontrollable crying jags afterward. These attacks happened to me every 2 or 3 days and continued for 7 years. They came without warning and really affected the quality of my life and my feelings about myself.

My doctor diagnosed my problem as nerves. I guess I do not find that so surprising—older people with funny symptoms have a problem explaining them plainly to their doctors. I got a prescription for a tranquilizer, but I did not take it as prescribed. I was too mistrustful of drugs like that. Later, I got these prescriptions renewed when I changed doctors, and got a painkiller, too, for arthritis. I stopped the painkiller on my own, because it upset my stomach. At no point did my doctors and I discuss with one another the possible side effects of medications, and when I did not trust a drug, I just stopped using it.

Finally, a third doctor stepped in after I had a real heart attack. He changed my heart medication, and my sneak attacks stopped. I have not had one now in nearly 3 years.

I really do not blame my doctors. I guess, what with all the new medications now, it is hard to know what possible side effects may be, especially when, as in my case, you may be the only person who happens to be affected in a certain way. But I would hope doctors would become more aware that some symptoms may be side effects, and not conclude that elderly people, especially women, are naturally nervous. I tell my friends to watch themselves carefully after taking a new medicine, and report any changes immediately to their doctors. And I believe many senior citizens, like myself, need to ask more questions of their doctors, for their own education.

Today I feel good—some days I feel better than others—but I would rather put up with some discomfort than take medications that I do not absolutely need.

Chairman HEINZ. Mrs. Powell, thank you very much, and I hope that a part of what you said, especially the last part, where you hope that senior citizens will ask their doctors about their medications, was well-recorded on all those television cameras there, because that is one of the messages that we want to get out today.

I thank you very much.

Our next witness is James Hall, director of Up Front, Inc., in Coconut Grove, Fla. I do not know whether he is a constituent of Congressman Bilirakis or of Congressman Pepper, or whether he is not so fortunate to have either as his Congressman, but Mr. Hall—may I ask the Congressman, if he is one of your constituents?

Representative BILIRAKIS. No, he is not.

Chairman HEINZ. I was going to yield to you for introducing him, if he was.

If not, Mr. Hall, let me welcome you. Senator Chiles of Florida has been for many years a member of this committee, and was the chairman of it before my tenure. I know that had he not gone on to the Budget Committee that he would otherwise have been here today, and on his behalf, I also welcome you.

STATEMENT OF JAMES N. HALL, DIRECTOR, UP FRONT, INC., COCONUT GROVE, FLA.

Mr. HALL. Thank you, Mr. Chairman.

Senator Heinz, Ms. Oakar, members of both committees, it is a pleasure to be here.

Up Front, Inc., has been providing factual drug information to Florida residents for 10 years. Our telephone call-in service is avail-

able toll free to citizens of Florida, to ask anonymously any question about any drug. Our educational outreach programs go into schools, civic groups, and senior centers to teach basic concepts of pharmacology.

Up Front has served more than 90,000 clients since its beginning as a storefront office with a few books and a telephone. Each year, it has shown a steady growth, and we expect to reach more than 30,000 clients in 1983.

The need for specific outreach to senior citizens became apparent to the Up Front staff in the organization's early years. This year, calls from senior citizens have been averaging 33 percent of our total drug information requests, and I should emphasize that Up Front is a drug abuse prevention center.

Seniors call to ask what their prescription medications are for, what side effects they may have and can expect, and if they can safely combine various medications. Nearly half the callers are taking two more more medications at the time of their call. The majority of these medications fall into four categories—anti-inflammatory agents; cardiovascular medications; central nervous system drugs; and medications for regulating caloric and water balance, such as diuretics.

Based on our 10 years of listening and talking to clients, we have identified numerous areas of concern specifically related for senior citizens. These include:

No. 1. The sharing of drugs—trading or exchange of prescription medications without professional consultation, amongst each other, for a variety of reasons, including economic.

No. 2. Drug interactions—the synergistic effects of two or more drugs in the body at the same time.

No. 3. Overdosage—taking too much of the same drug, or receiving a prescribed dosage that is too much in light of the physiology of the older person.

No. 4. Self-medication—the clients choosing which medication to use, based upon his or her own judgment or decision.

No. 5. Medication omission—deletion of medication by a client's own determination—"It did not do any good anyway. I feel fine. I do not think I need it today."

No. 6. Polydrug use—taking two or more medications prescribed for the same indication, or combining medications prescribed for different indications obtained from several physicians or specialists. On the average, elderly callers to Up Front inquire about four prescription medications. A recent caller asked about 13 medications prescribed by four different doctors, plus two more that she had not yet had filled.

No. 7. Outdated drugs—retaining unused prescriptions, and self-administering them at a later date, often even several years after the original issue.

No. 8. Automatic refill—continuous refilling of medications without a recent consultation with a physician.

No. 9. Confusion about medication is one of our most common caller complaints—the number of drugs being taken often make it confusing and hard to remember when to take them. Sometimes the medications themselves are at the heart of the confusion.

No. 10. Cost—the cost of medication hits the elderly very hard and can interfere with proper health care. "I cannot afford to take it all the time" is an all-too-often comment from callers to Up Front.

No. 11. Unfilled prescriptions—cost and self-regulation of medications leads to unfilled prescriptions often needed for proper health care.

No. 12. A new concern has recently cropped up: Tamperproof packaging—while the concept is admirable for public safety purposes, such packaging can be particularly difficult for seniors. "I would take it if I could get into it," was a recent statement from a caller to Up Front.

These problems illustrate that a need exists in the senior citizen community for accurate, factual, and understandable information and education about medications. In addition to information on medicines, Up Front also discusses nondrug alternatives with callers when appropriate.

It is not possible here to cover every aspect of our work. However, our 10-year experience has taught us that there is a tremendous need for information and education from a variety of sources including physicians, pharmacists, health fairs, information centers, such as Up Front. We would hope that your work in these committees would lead to encouraging medical schools and other health-related educational programs to include courses on communications as well as geriatric medicine; would encourage local, State, and Federal agencies to look favorably upon funding drug information centers.

Federal involvement will help promote publicity through existing Government publications; to highlight drug education needs and medication problems in Government-sponsored symposia; and finally, to promote the greater availability of literature, such as the Elder Ed program, to senior citizens.

Thank you.

Chairman HEINZ. Thank you very much, Mr. Hall.

[The prepared statement of Mr. Hall follows:]

PREPARED STATEMENT OF JAMES N. HALL

Up Front, Inc., has been providing factual drug information to Florida residents for the past 10 years. We could give you lots of numbers and statistics, but the heart of our work is people—people with need for drug information—all kinds of people and all kinds of information.

Briefly then, Up Front has served more than 90,000 clients since it began as a storefront office with a few books and a telephone. Each year has shown a steady growth and we expect to reach more than 30,000 clients in 1983 alone.

The need for specific outreach to senior citizens became apparent to the Up Front staff in the early years. This year, calls from senior citizens have been averaging 33 percent of our total drug information calls.

And what are these seniors asking for? They want to know what their prescription medications are for, what side effects they may have, and if they can safely combine various medications. Nearly half the callers are taking two or more medications.

The majority of these medications fall into four categories—anti-inflammatory agents, such as those prescribed for arthritis; cardiovascular medications, prescribed for a variety of heart conditions; central nervous system drugs, including antidepressants, tranquilizers, sedatives, hypnotics; and medications for regulating electrolytic, calorie, and water balance, such as diuretics. It is not uncommon for a caller to follow the Chinese menu system of medication. One from column A, one from column B, etc.

Based on our 10 years listening to clients we have identified several areas of concern relating to senior citizens and drugs:

(1) Sharing drugs: Trading or exchanging prescription medication amongst each other for a variety of reasons, including economic. "My friend takes this drug to sleep and it really helps her, would it help me to?" Our advice is not to take anyone else's medications, talk with your own doctor.

(2) Drug interaction: The synergistic effects of two or more drugs in the body at the same time. One caller was taking five prescription medications for heart and arthritis conditions, plus fish oil and an enzyme. We were able to tell the caller the side effects to watch for that might indicate adverse interaction. Among other information we told the caller, that two of the medications and the fish oil can prolong bleeding time and that the medications do not mix well with high doses of vitamin C. Based on this information the client said he would drop the fish oil and cut back on the vitamin C.

(3) Overdosage: Taking too much of the same drug or receiving an overprescribed dosage for the physiology of the older person. A 93-year-old woman called to relate a drug experience—she said she had been taking Slo-K, a potassium supplement, among other medications, and had developed paralysis in the extremities. Her doctor referred her to an orthopedic surgeon who said the condition was permanent. She said she stopped the Slo-K on her own and the numbness went away. We told the caller that numbness is a possible sign of too much potassium, the caller responded that it was a relief to know it might have been the medication. Senior callers are also routinely advised of special precautions or side effects that affect those over 60 because of the physiological changes of aging.

(4) Self-medication: The client's choosing which medication to use based upon his or her own judgment and decision. Many elderly self-medicate, but this seems to be a particular problem with heart medication, especially related to high blood pressure. It is not uncommon to hear callers say, "I didn't take my pressure pills because I felt OK and they make me tired." We stressed the importance of taking medications as prescribed for maximum benefit. We also discussed the side effects and why a client may feel tired as a result of the medication.

(5) Medication omission: Deletion of medication by client's own determination. It is also not uncommon for senior callers to tell us they don't remember if or when they took a medication, or to say they just quit taking it because "it didn't do any good anyway." We have a special senior packet which includes a chart to help people remember when to take medications. We also advise clients that medication decisions are best made in conjunction with a doctor.

(6) Polydrug use: Taking two or more medications prescribed for the same indication, or combining medications prescribed for different indications obtained from several physicians or specialists (on the average, elderly callers to Up Front inquire about four prescription medications). A recent caller asked about 13 medications prescribed by four different doctors, plus two more she had not yet had filled. She said she takes pills from doctor A on Tuesday, B on Monday and Thursday, and C when she feels the need. After researching the list, we advised the caller that a high potential for depressant overdose exists, and suggested she take all the medications to a pharmacist to help her straighten out the situation.

(7) Outdated drugs: Retaining unused prescription drugs and self-administering them at a later date (often even several years after originally being issued). While this problem occurs with all classes of drugs, antibiotics seem to be a favorite to keep for later use. We have even had callers ask about using medications that had been prescribed 10 years ago. We advise such callers not to take outdated medications for two reasons, drugs do not last forever and can change composition with age, also medications are prescribed for specific conditions and this infection, for example, may not be the same as the original problem for which the drug was prescribed.

(8) Automatic refill: Continuous refilling of medication without a physician's recent consultation. Not only do the effects of drugs vary from person to person, but the same person can experience different effects at different times, this is particularly true of senior citizens, because the effects of aging change the physiology of the body. Because of these changes, seniors may be more likely to experience adverse side effects, and be more prone to overdose effects, even with limited dosages. Regular medical evaluation is important for reducing potential problems.

(9) Confusion: The physiological and psychological deterioration of a client resulting in his or her confusion about taking or omission of medication. Confusion about medications is one of our most common caller complaints. The number of drugs being taken often make it confusing and hard to remember which to take when. Sometimes the medications themselves are at the heart of the confusion. In this

case, we recommend that the caller discuss adjusting the dosage to lessen this side effect. We stress that such medication adjustments should not be made by the client without the doctor's advice.

(10) Cost: The rising cost of medication hits the elderly very hard and can interfere with proper health care. "I can't afford to take it all the time" is an all-too-often comment.

(11) Unfilled prescriptions: Cost and self-regulation of medications leads to unfilled prescriptions often needed for proper health care.

A new concern has recently been added to the list.

(12) Tamperproof packaging: While the concept is admirable for public safety purposes, such packaging can be particularly difficult for seniors. "I'd take it, if I could get into it," one caller said.

These problems illustrate that a need exists in the senior citizen community for accurate, factual, and understandable information and education about medications. In addition to information on medicines, we also discuss nondrug alternatives with callers when appropriate.

For many of our callers, the drug information is only part of their need—they simply want some reassurance and to know that somebody understands and cares. Up Front staff have a good reputation among seniors for our caring and helpful attitude. Many callers begin by saying, "I don't want to bother you * * *." We explain their call is not a bother, and that answering their questions is what we are here for.

I have cited here only a few of the examples of information calls related to prescription medication. Their area is confusing enough for today's senior citizens who are the first to face an overwhelming chemical age, considering the fact that the majority of the drugs have been developed in the last 25 years. Many seniors are also concerned about street drugs use as it affects their families. For example, one woman was very concerned about her 33-year-old daughter, who was taking Quaaludes. Others are concerned about family members using cocaine, marihuana, herion, and more.

In addition to the call-in service, Up Front also provides drug education programs for groups. Fully half of these programs have been presented to senior citizen groups, and as training sessions for staff at senior serving agencies.

It is not possible here to cover every aspect of Up Front's work. However, our 10-year experience has taught us that there is a tremendous need for information and education from a variety of sources, including physicians, pharmacists, health fairs, and information centers, such as Up Front.

We have also learned that senior citizens are concerned about the role of medications and will take advantage of information services. An outreach program specifically directed toward senior citizens resulted in a 50-percent increase in calls to Up Front from seniors.

We know there is a need for drug information and that seniors utilize such services. Where we fall short is in being able to meet the tremendous needs. Involvement from the Federal level could go along way in helping to better meet the needs. Such as:

(1) Encouraging medical schools and other health-related education programs to include courses on communication to help professionals understand the need for dialog, the need to fully explain medications, and ways to talk effectively with patients.

(2) Encouraging local, State, and Federal agencies to look favorably upon funding drug information centers, both expansion of current programs and establishment of new ones in areas not now covered.

(3) Promoting, through existing Government publications, greater awareness of the problems faced by elderly with medications, and the need for health care professionals to have special sensitivity to these problems.

(4) Highlighting drug education needs and medication problems as part of Government-sponsored symposiums of health care providers and senior citizen conferences.

(5) Promoting greater availability of the Elder Ed program to senior citizen centers, service agencies, and drug information centers.

I hope this information will help you better understand the problem and to know that there are people involved in meeting the need—though sometimes we feel like the kid with his finger in the dike trying to keep from being overwhelmed.

Senator HEINZ. Our next witness comes from the Boston, Mass., area, Rose Zimny. Mrs. Zimny is accompanied, I understand, by her daughter, Gloria.

Mrs. Zimny, we thank you very much for coming down from Boston. It is a little hotter down here than it is in Boston, I am sorry to say. But we thank you for giving us the benefit of your experience.

I note a few packages on the table in front of you, which I suspect you are going to tell us about.

Please, proceed when you want to.

STATEMENT OF MRS. ROSE ZIMNY, EVERETT, MASS.; ACCOMPANIED BY MS. GLORIA ZIMNY

Mrs. ZIMNY. My name is Rose Zimny. I am 67 years old, and a resident of Everett, Mass. I am here to let you know what happened to me as a result of the many medications that were prescribed for me in 1981.

Because I became so confused and disoriented during this time, to the point where I wound up in the psychiatric ward, with hallucinations, I have asked my daughter to tell my story.

Chairman HEINZ. Ms. Zimny, do you have a comment you wish to make?

Ms. ZIMNY. If you want me to tell you what happened——

Chairman HEINZ. I think that would be very helpful. Yes, please.

Ms. ZIMNY. At the end of 1980, my mother was brought early in the morning to a local hospital because she could not breathe. The emergency room doctor, who happened to be a well-known internist, examined her, and prescribed steroids for what he diagnosed as asthma.

From the beginning of 1981, through the middle of that year, her condition was worsening some, so he prescribed more medicine. When he noticed her becoming extremely allergic to some of the medications, he substituted some other ones for them. By the beginning of August, she was on at least 10 to 12 prescribed drugs. My mother told me that anything she complained about, he would give her a prescription to take away the pain.

I went with her and, sure enough, saw for myself what he was doing. He told me that tests were run, and the pain she had was from a previous injury.

My mother was starting to show some signs of memory loss and became very nervous and agitated. At first, I did not question what was happening because I was told that without the pills, she would not have much chance of surviving everything that was wrong with her.

About the second or third week of November, she had the worst attack of all. Nothing seemed to help her breathe. I brought her to the same doctor, because I figured he knew her history and would be able to treat her better. This time, the doctor started giving her high doses of everything to try to control her breathing, and nothing would work. She was highly allergic to steroids, but he gave them to her anyway. After 3 weeks of visiting her, I started to notice that she was talking when nobody was there, and praying to God to please let somebody help her, because the doctor she had once placed all her trust in was trying to kill her. When I asked her what was wrong, she tried to tell me, but the words were not

coming out right, so I pieced together on my own what she had said, and she confirmed it.

She was also unable to walk and had severe heart palpitation. Her doctor was away every weekend, and it became increasingly difficult to reach him. On the 25th, I received a phone call from the doctor, and my mother was screaming in the background. I asked him what was wrong, and he said, "I think you had better come over here, because she is going crazy." I told him that she was not, and if she was, it was his fault. He tried to blame it on an upset in her life, but I told him it was ridiculous. I had seen her upset before, but she was hysterical. He told her that I would be there soon, and she seemed to calm down He sent in a psychiatrist and just talked with her, and the psychiatrist agreed with what the doctor had said.

On the 28th, I waited early in the morning with my aunt for the doctor to come in. My mother had not slept in 2 or 3 days because of all the medications. The asthma was gone, but he had left her unable to walk. We asked him if it was necessary for her to be taking so many pills. His response was, "No; I am just giving them to her for fun."

I told him he probably was, and asked when he would release her. He said not until she could walk. So my mother held onto the hospital bed and dragged herself a few steps. He said that was fine and made arrangements to release her in 2 days. I insisted that he release her now, and he did, sending her home with about 20 different prescriptions. He felt he was doing nothing wrong, but he was practically killing her slowly. While she was home, she knew exactly when it was time to take her pills, and screamed in horror just looking at the bottles. I knew then it was the pills doing this to my mother, and stopped giving them to her off and on, because I did not know what would happen if I kept her on them or took them away from her. After seeing her like this for a day and watching her have no bodily function at all, I called the doctor, told him what was happening, and dismissed him from her case. The next night, she fainted. She seemed to be slipping in and out of comas. We rushed her to the nearest Boston hospital, and the doctor asked why she was taking certain drugs when she did not need them. We told the doctor that her previous doctor had prescribed them for her.

She was admitted into the hospital and acting as if she were dead. To see my mother like this made me even more furious. Her appetite was very small, and nothing else was changing. I needed a doctor who was not afraid to take the pills away from her. She was discharged the same as before. She was referred to a private physician, but it was hard to trust anybody anymore, especially a doctor.

I told my mother that as long as I was with her, nothing would happen to her. After 2 days of constantly calling this doctor, I told him to please help me and take the pills away from her. He in turn told me of the Hahnemann Hospital and Dr. Lieff. When I arrived with my mother, I explained to him what was happening, and he was very understanding. He arranged for me to stay with my mother because she was so afraid of being left alone.

Dr. Lieff worked with Dr. Zubaragu and immediately took the pills away from her. Within 4 days, she was slowly starting to walk

and act exactly like herself. I will always feel that if it was not for these doctors, she might not be here today.

Chairman HEINZ. Thank you very much, Ms. Zimny.

Dr. Lieff, you are our next panelist, and you are uniquely qualified, because you are both familiar with Mrs. Zimny and you are also an expert in your field. I imagine you will be able to address both the general and the specific case.

Would you proceed, please?

STATEMENT OF JONATHAN D. LIEFF, M.D., DIRECTOR OF PSYCHIATRY AND CHIEF OF GERIATRICS, LEMUEL SHATTUCK HOSPITAL, JAMAICA PLAINS, MASS.

Dr. LIEFF. Thank you, Senator Heinz, Ms. Oakar, Congressmen, Senators. It is a great honor to talk to this committee.

Unfortunately, the case of Mrs. Zimny is all too common. We applied what we call "the plastic bag test," where we ask the patients to put all the medications that they are taking in a plastic bag, and we came up with this. I took a photograph at that time, because I was so amazed at the number of pills that she was prescribed by the other physicians.

Chairman HEINZ. Let me ask you this. There are three groups of medications there on the table. Was she taking all of it at once?

Dr. LIEFF. Well, what happened is that she had been given groups of medicines from two different sources, and some of them are overlapping. But basically, there are medicines for asthma, steroids; then sleeping pills, anxiety pills, tranquilizers; there are antacids for indigestion which was caused by some of the medicines; cardiac medications and potassium, because of side effects from the other medication. So, the meds created a vicious cycle; she started having tachycardia and from there, ended up with cardiac meds; one thing led to another, until she had the 22 medicines at that time.

Unfortunately, this is a very common problem. I think the panel has already heard of statistics about the large number of medications taken by the elderly, the average being 5 to 10; and the average person taking many over-the-counter and prescription medications. One study at University Hospital showed that out of 815 random admissions to the hospital, 33 percent had complications from treatment by the physicians.

As the director of one of the large public health programs and as a geriatric specialist at Hahnemann Hospital, I see many elderly patients. As the director of geriatric fellowship at Boston University, I train doctors and see what the reaction of the medical profession is to the elderly. I would like to make a couple of brief comments as to other possible reasons for this problem

One obvious reason is that many elderly people have multiple chronic illnesses and need multiple medications.

I think one problem is that it is literally impossible for physicians to keep up today with the information explosion. Actually, if you just look at aspirin alone, and try to memorize the number of interactions with aspirin, there are 25 known interactions with aspirin. One physician could not memorize them all. Yet, every single over-the-counter medicine and every single prescription medicine

has interactions, and has side effects interacting with many diseases. It is literally impossible for a doctor to keep up, so it is not all the doctors' fault.

Of course, many doctors do not pay a lot of attention to the elderly.

One other problem which I do not think has been mentioned is that the elderly often need specialists, sometimes multiple specialists. In addition, many elderly shop around for doctors. So they end up with two, three, four, five doctors, several pharmacies, all prescribing two, three, four medicines, and no one is coordinating the various treatments. We have already mentioned alcohol as a major contributing factor to increased confusion. Perhaps 5 to 15 percent of the elderly are new alcoholics. These are not people who grew up as alcoholics, but people who became alcoholics because of their problems. We have heard of vision and hearing as a problem. And we have heard of the general compliance problem, where 50 percent of any group of patients do not take medications as prescribed. But here we have a unique problem. Just imagine trying to figure out how to take six medicines three or four times a day. It is almost impossible. It is almost a full-time job just to keep track of this many medications. We have already heard about the side effects. The elderly are uniquely sensitive for physiological reasons. All psychiatric medicines have much longer half-lives, and most of the medical medicines have much longer half-lives. Alcohol, because of the decrease in the elderly bodily water content, is uniquely toxic in the elderly, and a lot of physicians do not seem to realize this.

To summarize, I would say that there are several solutions, but they are not going to be easy solutions. One is that the patients have to get adequate information somehow, and there has to be a general level of education through the media, through the Government, to alert people, with simple, easy-to-understand information. I think NIA has done some education, as well as AoA and other Federal agencies.

A second solution is that doctors need better information. It is really not totally the doctors' fault today, because they really cannot keep up, even if they want to. If someone tries to keep up with one or two medications, it is a full-time job staying in the library reading the literature. The information is so great that it is literally impossible.

In geriatrics, it is necessary to work in teams with internists, specialists, neurologists, psychiatrists, and to try to coordinate these teams in some sensible way. Only with that coordination of effort can any help be brought to this problem, because many elderly do need multiple medications, and they have multiple problems. So a third solution is somehow coordinating the medical geriatric teams. We have been able to create a couple of teams in Boston, but it is not an easy job. It involves doctors sitting around and talking to each other, talking with nurses and social workers, and coordinating the amount of information and coming up with sensible treatment plans. So that is not going to be an easy job, but coordinated teams are absolutely necessary.

Thank you very much.

Chairman HEINZ. Thank you very much, Dr. Lieff.

Before we go any further, we have two additional Members of Congress, Congressman Tom Ridge of Pennsylvania, and my friend and colleague from North Dakota, Senator Burdick. Let me ask if either of you have an opening statement you would like to make at this point.

Representative RIDGE. I appreciate the offer, Senator, but no, thank you.

Chairman HEINZ. Senator Burdick?

Senator BURDICK. No, Mr. Chairman.

Chairman HEINZ. All right. Senator Grassley, who was here a few minutes ago, had to leave to chair a hearing that I am supposed to testify before at 10 o'clock. He is the chairman of the Aging Subcommittee of the Human Resources Committee. Because he had to leave, I would ask unanimous consent that his opening statement be a part of the record. Without objection, so ordered.

[The statement of Senator Grassley follows:]

STATEMENT OF SENATOR CHARLES E. GRASSLEY

Mr. Chairman, I want to thank you, and the staff of this committee, for preparing this oversight hearing on drug use and misuse among other Americans.

The information gained today may be put to good use by professionals in the field of gerontology, medicine, and pharmacology—but the real beneficiaries will be the 11 percent of the American population who are 65 years of age or older.

This group will now have available educational data that will allow each of them to more realistically assess his or her own drug needs and dosages. Seniors will now be better informed about various drug side effects, and the high price of careless or sporadic prescriptions and over-the-counter drug habits.

I assure you, Mr. Chairman, it is my intention to see that this information gets the widest possible circulation in my State of Iowa.

Chairman HEINZ. I imagine we all have an innumerable number of questions for all of you. I have one or two I would like to put in myself.

Mr. Flaherty, you have done a very interesting study of misuse, and what you have given us, in a sense, are averages. An average does not fully describe the kind of case that a Mrs. Zimny might be involved with. We referred earlier in this hearing to the fact that there were as many as 14 medications taken by an elderly person, on the average, during the course of the year, and Mrs. Zimny took in excess of 20, and indeed, a little commonsense would tell us that in order to get an average of 14, it is indeed an average of 20's and 25's, maybe a few 30's, and a few low ones. Is that your experience, that there are some tremendous numbers of drugs being used?

Mr. FLAHERTY. Yes, Senator, it is. Our figures, I would say, are on the conservative side from what we believe to be out there. Most of the subjects studied were able to walk to us in Allegheny County. In the Beaver County study, it was more door to door, and that is why the figures there are almost double. And I think we would have found that consistently had we gone door to door.

I might point out also that Mrs. Slade, who is with us this morning, was at 30 prescriptions at one time. She did not testify this morning, but she is here in person and can attest to that.

Chairman HEINZ. In your experience, were the prescriptions clearly labeled, first, as to what they were; and second, as to their directions?

Mr. FLAHERTY. Well, insofar as you or I might be reading them, but given the fact that one out of four of the people said they could not read or understand the prescriptions, or the directions after they got the bottle open, if they could, no. From their subjective point of view, no, they could not manage, read, or understand the prescriptions. They were going on color.

Chairman HEINZ. One out of four. Let me ask Mr. Hall, what is your experience with respect to the clear labeling of both the content of the bottle and the frequency of use, the directions for taking the medication? Do you have any particular experience on that?

Mr. HALL. We have to rely, of course, on a telephone conversation, so we do not often see the actual bottle, but it is perhaps more important that we ask, particularly in the case of a senior citizen calling, to read us the label. Just the difficulty that they have reading the label to us over the phone is certainly an indication of the difficulties that they have in reading it for themselves, or even understanding it.

Chairman HEINZ. How much of that is a text that does not make sense, how much of it is related to the size of the print, and how much of it is related to a state of confusion on the part of the color?

Mr. HALL. I believe it is a combination of those areas, and perhaps the lack of a standardized form to which a person could become accustomed. Too often, special instructions are added by a little stick-on label on the side, around the bottom, and those points are often missed.

Chairman HEINZ. "Take with food."

Mr. HALL. On the bottom, yes

Chairman HEINZ. Dr. Lieff, let me ask you the same question.

Dr. LIEFF. Well, I think it is just very hard to take so many medicines. I do not know if anyone here has ever tried to take medicines four or five times a day. It is hard to remember. One just does not remember the exact time to take it. Attempts to remember five, six medicines at the same time are really impossible. In order to sit and explain how to take five medicines four times a day, the doctor will need to sit with the patient 10, 15, or 20 minutes, and explain it in great detail. The studies show that anyone does not remember everything that you tell them, and most people remember the first couple of things and then forget the rest.

Congressman Bilirakis mentioned technology. One little gadget that came out of Harvard recently is a pill box which tells the patient when to take medication. In other words, a bell rings, and it says, "Take this pill" at this time. That is one little device which might help. But it really is very, very difficult. You have the problems of vision, the problems of hearing, but in-depth explanations have to be made, and it could take a half an hour, and very few doctors are going to sit and spend a half an hour with a patient in this way. Perhaps nurses can do that. However, often patients, will only listen to the doctor.

One added problem is that some people only feel that they are getting proper attention if they get a pill from the doctor, so they go to the doctor demanding some kind of pill. The doctor may want to try to change their diet, but instead, the patient wants a pill. The communication is a very difficult one. And just giving informa-

tion is part of the answer, but also, we need help in coordinating the actual care in some way.

Chairman HEINZ. I note that the experiences that you have all described are indicative of an enormous problem.

You, Dr. Lieff, mentioned the difficulty even the doctors have keeping track of the indications for drugs, and before I return to you, I want to ask Mr. Flaherty, in his experience at St. Francis General Hospital, which is a very fine hospital, which specializes in care for the elderly and people who are frail and have other problems, whether he has experienced the same difficulty, or have the doctors at the hospital experienced the same kind of difficulty, in keeping track of medications.

Mr. FLAHERTY. Oh, indeed, it is a problem. The pills begin to look alike after a while, and when a person is subjectively taking them, they are taking a red, green, or blue pill, and pretty soon they have run the spectrum of colors, so they are getting their colors mixed up, and they are forgetting what color to take at what time. Many of these pills are taken at 2-hour intervals, some at 4-hour intervals, so there is that factor, to take into consideration.

Chairman HEINZ. In 1981, the Food and Drug Administration started to issue a rule for patient package inserts that would be noticeably different from the absolutely terrifying and confusing insert that is included on the label distributed with the medication from the industry for the benefit of doctors and pharmacists.

An example of such an insert was published in the Federal Register on September 12, 1980, this for a drug, Digoxin. It is fairly easy to read. I could understand it. It is in reasonably large print for anything published in the Federal Register. And my question to the panel is: Would the publication of fairly easy-to-understand patient inserts be of significant help? Would you like to respond to that?

Digoxin
(pronounced: di-JOX-in)

Summary

Digoxin helps the heart beat more strongly and, sometimes more regularly. This helps the blood circulate better throughout the body. Keep taking digoxin exactly as directed even if you are feeling better. Check with your doctor before making any change in the dosage schedule.

While taking digoxin look for the warning signals of too much digoxin in your body. This is often referred to as digoxin toxicity. Call your doctor immediately if you have any of the following symptoms: a loss of appetite, nausea, vomiting, diarrhea; blurry vision, seeing spots, halos (rings), yellow vision, or weakness.

The rest of this leaflet gives you more information about digoxin. Please read it and keep it for future use.

Why Take Digoxin?

Digoxin is commonly used to treat heart failure and to slow the heart rate. Heart failure occurs when the heart cannot pump enough blood through the body. Symptoms of heart failure are fatigue, difficulty breathing, swelling (especially in the legs and ankles), and rapid or "galloping" heartbeats. You may have had some of these symptoms before taking digoxin. They may return if you stop taking digoxin.

Digoxin may be used for fast or irregular heart rates. It increases the strength of the heartbeat and may slow down the heart rate. This allows the heart to pump blood more regularly.

> Digoxin should never be used to help you lose weight. Using digoxin for this purpose is dangerous and may cause death.

How To Take Digoxin

There is a narrow range between the helpful and harmful amount of digoxin in your body. If you have too much you may have toxic signs. If you have too little, you may have signs of heart failure or too rapid heart beat. That's why it is so important to follow the dosage directions carefully.

Digoxin *does not cure* heart failure but helps control it. Therefore, you must take it even when you are feeling better. When you first start taking digoxin, the dose may be changed to find the right amount for you. Make sure your doctor knows if you have liver, kidney, or thyroid conditions or if you are taking any other drugs.

Try to take digoxin at the same time every day. This may help you to remember to take it. Do not skip any doses. If you miss a dose, take the tablet as soon as you remember it that day. If you do not remember until the next day, do not take two doses. Take only the dose scheduled for that day. If you forget to take two or more doses in a row, contact your doctor.

Warning Signals

Call your doctor immediately if you notice nausea, vomiting, diarrhea, loss of appetite, change in vision ("halo" effect, spots, blurred or yellow vision) or weakness. You should watch for such signals particularly after starting treatment or when your doctor increases the dose.

Pulse rate: Changes in your pulse rate are a good way of telling if you are taking the right amount of the drug. Every day before taking digoxin check your pulse while resting. If you do not know how to take your pulse, ask your doctor. Call your doctor immediately if you have an increase or decrease of 20 beats or more a minute from your normal pulse.

Cautions

Other drugs: Other drugs may change the amount of digoxin in the body. For example, antacids can prevent the digoxin from being absorbed by the body. Laxatives can cause the drug to be removed from the body faster than normal. If you start taking any new drug while on digoxin, be sure to tell your doctor and pharmacist.

Diuretics: Your doctor may tell you to take diuretics ("water pills") with digoxin. Diuretics may cause your body to lose potassium. Signs of excess potassium loss are leg cramps, muscle pains, fatigue or nausea. If these appear, tell your doctor. You may need to eat more foods containing potassium or take a potassium supplement. Foods rich in potassium are bananas, oranges, tomato juice, and dried fruits.

ECG/lab tests: You may need to have tests while taking digoxin. These include an electrocardiogram (ECG) and may include blood tests to make sure the drug is working properly and safely.

Other illnesses: Any illness that causes vomiting, diarrhea, or other fluid loss for more than a day or two should be reported to your doctor.

Possible Side Effects

After you start taking digoxin, you may need to urinate more often. Other side effects occur rarely. If a side effect occurs or becomes bothersome, call your doctor.

Other Information

The safe and effective use of digoxin depends on your taking it as directed. This drug has been prescribed specifically for you. Do not give this drug to others who may have similar symptoms or use it for any other reasons.

In the event of an accidental overdose, contact you doctor, poison control center or nearest hospital emergency room immediately. Keep this and all drugs out of the reach of children.

If you would like more information about digoxin, ask your doctor or pharmacist. They have a more technical leaflet (called a package insert) they can let you read. You may need their help to understand it.

Dr. LIEFF. I think absolutely, it would. One of the problems with the constant amount of malpractice litigation is that a physician has to explain all the adverse side effects. Those inserts are very scarey. If you read them, the medicines seem to do anything. For almost any pill, one could have a list of almost any problem. So regular physician inserts are very scarey, and patient inserts has to be a realistic and simplified version. NIA had some inserts which were in very large print and seemed fairly good. I think it would help a lot.

I just want to throw in one other, little comment about why people are hoarding. We had a grant from the Administration on Aging to help with difficult patients in the Boston Housing Authority, and we were able to visit many homes of the people living in the housing authority. We saw whole pharmacopeias in drawers. People literally collected enormous drawers of pills over the last 10 years, and would trade them or give them to their friends.

One problem I noticed was that if one pays $40 for a bottle of pills—some of these pills cost $30 or $40 for a bottle—one is not going to want to throw it away. If a poor person pays this amount of money, they are going to want to give them to someone, so they keep them, and hold onto them even long after they are useful, and they give them out to people.

Chairman HEINZ. I suspect if we all looked in our medicine cabinets, we would find pretty much the same thing.

Mr. FLAHERTY. May I comment also on that, please?

Chairman HEINZ. Just one point. I think in addition to that, we would have to do something to shore up the personal contact, because once the elderly person reads the directions, they really do not trust their own judgment, and they are going to check that out with somebody else. Now it is usually a friend.

For example, now, many of the pharmacies are operating on a quota system, where they have to fill so many prescriptions per hour, per day, to keep their operations going. And this restricts the pharmacists from coming out and giving them the kind of information they were used to as children. This kind of thing would allow the pharmacist or the doctor to give a little more personal information, or allow the elderly to call someplace where they can check out what they are taking, in addition to reading this information. It is a two-step thing.

Yes, Mr. Hall?

Mr. HALL. Senator, also on the prescription information, we talk a lot about information and education, but we are ultimately concerned with behavior. Perhaps one of the more successful means of providing information to patients about their medication would occur not necessarily at the pharmacist, where they are receiving the prescription, but in fact, at the doctor's office, where they are receiving instructions. The AMA, incidentally, has prepared a series of patient information slips, just like the prescription pads——

Chairman HEINZ. Well, while you are on that point—and my time has expired—maybe you could just answer this. You run a service agency. People call you. Why would they call you, rather than their doctor?

Mr. HALL. An excellent point. We receive calls which often we lead the client to return to his doctor with questions But ofttimes they call us, first, because we are an anonymous service, and they do not have to be identified or, most importantly, embarrassed by asking a question that they are not certain requires their physician's attention.

What we often attempt to do in our consultations is to help the person identify the problem that they are really asking about, and to help them put that into language, or a question, that they then can go to their physician to ask.

All too often, particularly our senior citizens, are so apologetic, even when they call our service. "We do not want to bother you." But we try to emphasize to them, that our service is there indeed to help them and that the ultimate goal is really to improve the patient-physician communication, and to help them in those skills. So a lot of what we are doing is just helping them to formulate the questions that they in turn, then, give to their doctor.

Chairman HEINZ. Thank you, Mr. Hall.

Congresswoman Oakar, and then I will call on Senator Burdick. I also would like to recognize that Congresswoman Geraldine Ferraro is here.

Representative FERRARO. Thank you very much, Mr. Chairman.

Representative OAKAR. Thank you, Mr. Chairman, and I want to thank the panel.

Ms. Powell mentioned that she took all of this medication, and she had terrible side effects, and almost died, and so did Mrs. Zimny. We heard a lot about the doctors not being instructive, and so on.

I am wondering, should those medications have been on the market to begin with? Dr. Lieff, Mr. Hall, or Mr. Flaherty, you know, a lot of times, in prescription drugs, they do not even put down what the side effects are. When you do have them, as the Senator pointed out, they are so hard to read, and usually, when you are a little older, you have some visionary problems.

I am wondering if putting even side effects gets pharmaceutical companies and FDA off the hook, for drugs that, perhaps, should not have been on the market to begin with?

Dr. LIEFF. It is a very difficult question that you are asking. Some have said that we only need about 50 of the medicines, total, that are now available, and that a lot of the medicines are unnecessary. Clearly, the laws of getting medications through are now much more stringent than they were, and there are many medications that are hanging around from a previous era that probably would not pass today or would not be allowed today. It is very hard to get medications off once they are on.

Representative OAKAR. Why is that?

Dr. LIEFF. Well, one has to prove all kinds of side effects. Almost any medication has side effects, unfortunately, and the problem is monitoring them, and finding out when it is optimal to have the medication, and when it is not optimal to have the medication. I think you raise a difficult point, but I think it is certainly true that we could get away with a smaller number of the medications than we now have.

Representative OAKAR. You mentioned that it is hard to keep up with all the drugs. How do you get that kind of training when you give prescriptions? Do you just read the printouts from the pharmaceutical companies or FDA?

Dr. LIEFF. Most doctors do learn from detail men who follow them around and hound them, giving them papers, and trying to convince them what to use. I hear ads now for the Pharmacists' Association. Unfortunately, pharmacists make money selling drugs—often they own drugstores—so often, they are not the perfect ones, either. It is quite a difficult problem. What you have to do is to scout through the literature, and have a lot of clinical experience, and talk with a lot of other doctors. It is not an easy thing to stay up on. And most doctors I know are expert on only one or two medications; cardiac specialists are expert in their cardiac medicines, and psychiatrists are expert in psychiatric medicines. It is so hard to keep up. There are so many journals, and so many articles, and so many studies going on, that you really need to work very hard to keep up in one little area. In geriatrics, which I specialize in, we have to keep up in a lot of different areas, because they interact—neurological, medical, psychiatric. And we try to train the doctors together as a group, but it is not easy, because doctors resist being interdepartmental. So the best we have been able to come up with are teams of doctors who work together in some way and have real communication. Also useful would be a way to simplify the information and get the relevant interactions. I think that this simplification may have to happen at some agency, that is, to sift through the massive information, and to have it come out of some central source, where there is some really simplified information that a doctor can remember.

Representative OAKAR. What do you do, for example, when they know a drug is of very little help? Do you write the FDA about it?

Dr. LIEFF. Do you mean when I see another physician prescribing medication that he should not be?

Representative OAKAR. Yes, when you see a drug that you know has very little value—I am sure you have come across a few like that——

Dr. LIEFF [interrupting]. Yes.

Representative OAKAR [continuing]. A lot of drugs like that—what do you do? Where is the vehicle for people to get drugs off the market that should not be there?

Dr. LIEFF. Well, I think this is not a question that I can really answer. It sounds like more of a legal question, or a question for Congresspeople to answer. All I can see is that I see many medications that are not effective, that are prescribed, and do have side effects. In other words, a lot of the medications cause sleepiness, a lot of them cause dizziness, a lot of them cause insomnia, a lot of them cause constipation. So you get certain vicious cycles going with medicines, where there is more confusion, and then you take another one, and there is more confusion, and then you take the medicines more inaccurately. So a lot of them are additive in the wrong direction. And over-the-counter medicines are just as bad. One of the major side effects is called anticholinergic. That is a category of side effect involving the choline secreting nerves—it is a

fairly important side effect because it causes constipation, it causes confusion, it causes blurry vision.

All cough medicines, all cold medicines, most sleeping pills, almost all psychiatric medicines have this same side effect, as well as many of the cardiac medicines. If one takes two, three, and four of these medicines, and one becomes pretty confused and dizzy, and then it is hard to remember after that what pills one is taking.

So I think the over-the-counter prescriptions have to be controlled, too. One can easily kill themself with over-the-counter prescriptions. One does not need to have doctors prescribe.

Representative OAKAR. Mr. Hall, let me ask you about over-the-counter drugs, because we really have not gotten into that very much.

Our office has had some complaints about drugs that contain something called phenylpropanolamine, PPA, that is found in diet pills and things of that nature. Have you had any complaints about this PPA?

Mr. HALL. We deal with PPA on several different levels. First, the legitimate use, or at least, the use in over-the-counter products and also in prescription medications. First of all, it is a decongestant, so therefore, it is a very popular ingredient in many over-the-counter cold remedies, and it has also been approved by the FDA for use in OTC weight reduction aid products. That is one area where we deal with PPA. We also deal with PPA as a key ingredient in the illicit drug scene, in what are referred to as "look alikes" or "act alike" stimulant pills. These were pills that were introduced in the early seventies, and technically, were being sold through the loopholes, I like to say, in the drug laws, but as stimulants, to look like real amphetamines, or controlled substances. Though they are not that substance, they provide an "act alike" action. I think their popularity, particularly in the diet or weight reduction aids, is related to that stimulating effect that PPA does have. It is often used in combination with ephedrine or caffeine.

Acting like a stimulant, will have a tendency to reduce the appetite. It is related basically to the adrenaline system in the body. In an emergency, when adrenaline is released, the body will shut down nonvital functions, and the digestive function is a nonvital function in an emergency. So the use of a stimulant to reduce appetite is a pharmacological reality. However, there are probably more effective ways to lose weight.

Representative OAKAR. Thank you very much.

Chairman HEINZ. Thank you, Congresswoman Oakar.

Senator Burdick.

Senator BURDICK. Thank you, Mr. Chairman.

I would refer this question to Dr. Lieff. We have heard much about the problems that older Americans face dealing with medications and drugs. My question is, what can we do about it? I have long advocated that geriatric medicine be incorporated into curricula of schools of medicine. I was pleased that we were able to get a small amount of funding in the 1983 HHS budget to encourage schools to start such programs, and I am even more pleased at the administration's willingness to increase this funding for fiscal 1984. I would like to know if you think teaching more geriatric medicine,

incorporated into the basic medical school curriculum, is a solution to the problems we have heard about today.

Dr. LIEFF. Well, I think that is a very critical point. All those in this field, all specialists in the field of geriatrics know that that is a critical problem. I guess even a number of years ago, we tried to train the number of doctors who could specialize, or knew about this area, to be adequate to deal with the problem. Right now, we are so hopelessly behind that all one can hope to do is have some specialists at each university so that they can be consultants for the other people. Even one-third of the patients are in this elderly group, most doctors do not recognize themselves as geriatricians. It is an uphill struggle, though. As the director of a geriatric fellowship program at one of the universities—and I teach at two of the other universities in the same problem—the studies show that doctors enter the university with a prejudice against old people, and it gets worse as they go through medical school, and as they come out of residency. It is commonplace to call old people who are ill, and do not have exotic illnesses, by names, such as "gomers" and "crocks." Teaching hospitals deal with the most difficult patients, and yet in the teaching hospitals, the prejudice against old people is probably the worst.

It is a very serious problem We have to get the medical students, really, in the first and second year—any medical student who sits with an elderely patient learns some appreciation. All medical residents at Boston University go through a geriatric unit which we have, and some come with very, very negative attitudes, and others come with a positive attitude. Any doctor that we can get early enough to sit with old people and simply get to know them, become much more sensitized to the problem, and then learn more as they go through school, and later on, deal with the problems.

I think it is a critical problem. A study recently showed that 56 percent of universities do not have any training in geriatrics whatsoever, and programs, such as you are mentioning, are critical to change that.

Senator BURDICK. Is it a fact, then, that, relating to all the medicines and dosages we have heard about this morning, that older people react differently to the same medicines than young people?

Dr. LIEFF. Absolutely. There are noted pharmacological differences. The ratio of fat to lean body mass changes dramatically. The water compartment goes down. They are sensitive to much more medicines The receptor sensitivity changes. The kidney changes. The metabolism in the liver changes. So they are much more sensitive to almost every medicine, and the medicine stays around in the body longer. For example, some sleeping pills stay for weeks. The typical half-life of one of the metabolites Dalmane is 3 weeks in many elderly people. That means one takes one pill, and 3 weeks later, one still has half of it in the blood. This is true for many of the antianxiety medicines, it is true for many of the psychiatric medicines. They stay a lot longer in the body, and then each day, if one takes more, it adds and builds up.

Senator BURDICK. I assume from your answer, then, that you do not think we have done enough to encourage this area in geriatric medicine?

Dr. LIEFF. Nowhere near enough, no. There is a tremendous amount of education needed, both in the medical profession and for the general population, or it is just going to increase. The problem is only increasing every year.

Senator BURDICK. Do you think it would help to teach geriatric medicine in schools of nursing and schools of pharmacy, that we should extend Federal help to help start up geriatric education programs in those schools, as well as in schools of medicine?

Dr. LIEFF. Absolutely. Nurses are critical. Nurses deal with the patients a lot more than the doctors do, and they have to know about the medications. Very often, it is the nurse who brings to the attention of the doctor when they are on too many medicines; it is very often the nurse who catches that. Pharmacists can be a very critical source. Of course, they have a little bit of a split interest, unfortunately, so one has enlightened pharmacists and you have pharmacists who want to sell medications.

Senator BURDICK. I cannot resist a plug at this point. The University of North Dakota is advancing on this area of geriatric medicine.

Dr. LIEFF. I am delighted to hear that.

Chairman HEINZ. We follow a modified early bird rule, so Congressman Bilirakis—if I have pronounced that right—is next.

Representative BILIRAKIS. Coming from the part of Pennsylvania you come from, sir, you should not have trouble with names like that.

Chairman HEINZ. And coming from the part of Pennsylvania you come from, you are quite right. [Laughter.]

Representative BILIRAKIS. Yes. I am very proud to say that I come from the Pittsburgh area originally. That is where my upbringing was and where I received much of my education.

Dr. Lieff, you interpreted, I believe, a question of Congresswoman Oakar's a certain way, but apparently, she did not mean it that way, and so you got away from it. But I believe you repeated the question something like, paraphrasing, do you mean where another doctor has written a particular prescription that you feel is a mistaken one. But you never did really answer that issue. Do you run into those situations?

Dr. LIEFF. Could you repeat the question for me?

Representative BILIRAKIS. All right. I will ask it in my own way. When you have a patient, and there is an indication, in your mind, that a wrong prescription was written by another doctor—when I say "wrong," I mean dangerously wrong—what do you do?

Dr. LIEFF. I call the doctor and I argue with him. I argue with a lot of doctors. I would rather deal with it that way, because we need the doctors that we have, and it would be nice if we could educate them all. So I usually get on the phone and argue about it, and sometimes those arguments go on for half an hour or an hour.

Representative BILIRAKIS. What are some of the results of these arguments?

Dr. LIEFF. Most of the time, education. Most of the time, I can give them some articles or send some information that will be helpful. Some doctors get very annoyed. With a number of doctors it gets difficult. But for some, I have to force the issue sometimes, and force a workup. For example, I will see a patient who is get-

ting worse, and they will not do the necessary workup, so I will force the issue.

But most doctors do like to be educated, and like to keep up. I do most of my lecturing to general practitioners, and they are very eager for the information.

Representative BILIRAKIS. Do you find that you are incorrect at times?

Dr. LIEFF. Definitely.

Representative BILIRAKIS. This is very prevalent in my district. We have a lot of doctor-shopping that takes place down there.

Dr. LIEFF. Everyone makes mistakes. And when you talk about whether I am wrong, I try to keep up as best I can, and we have a team of people keeping up. But sometimes the information is wrong, sometimes the state of the art is wrong. I mean, if you look back at the turn of the century, the practice of medicine involved giving mercury to a lot of people, and now we know that that is dangerous. So the fashions in medicine change, and the information changes. We find that several years later, what we were doing is not correct. That is an inherent problem in science, and there is no way around it. But as human beings, we make mistakes every day, and the most important thing is to recognize that, and to correct them, and to go out and call the person, find out, make sure everything is rectified.

Representative BILIRAKIS. Are there organizations similar to Mr. Hall's Up Front, Inc., program, in the Boston area?

Dr. LIEFF. No. That is really an excellent program, and I commend this concept of having a place to go and get good information. In Boston, it is a real maze. You are in-between all the teaching hospitals, and people wait in waiting rooms. Boston is one of the major medical centers in the world, and we have established one of the only evaluation units for the elderly. We get referrals from all the major teaching hospitals. But interest in geriatrics is slowly increasing in some units and in some places. But by and large, when you get a patient who is very sick medically, then becomes psychotic, has neurological problems, it gets very complicated including their behavior and the medical problems, very few physicians want to deal with it, and that is the kind of patient that we get routinely.

Representative BILIRAKIS. Well, Mr. Hall, the Senator asked me if you were one of my constituents, and when I see your program, I wish you were. Is your program a nonprofit or private——

Mr. HALL. We are a nonprofit, private foundation. But we do receive some funding through the State of Florida HRS programs, and of course, we cover the entire State of Florida in our service.

Representative BILIRAKIS. So is all of your revenue derived from funding from——

Mr. HALL. Not all; just a portion.

Representative BILIRAKIS. There is no charge for your services?

Mr. HALL. No; it is free. The only charges we would have would be on certain literature requests, but usually, that is nominal, or often, free.

Representative BILIRAKIS. Are you limiting your service at this time strictly to the geographical area surrounding Miami?

Mr. HALL. Oh, no. We cover the entire State of Florida, in our "800" service for input. But actually, just as a point of interest, we have received inquiries this year from 48 States and about 16 foreign countries. We have become a repository of some rather unique information, particularly on illicit drugs, and the illicit drug-using patterns, and have been active in providing that information to a number of other——

Representative BILIRAKIS. If you do not mind, you are going to get a call from my office and from me before very long.

I would like to ask you one final question, sir. Do any M.D.'s call your firm?

Mr. HALL. Oh, yes. We have not had a great number calling for specific drug information, but we do provide that service. One of the things that we have is a very extensive library, and we consider it, without any real study, probably one of the most extensive libraries on the subject of drugs that is open to the public in the country. Many libraries of pharmaceutical information are locked behind doors of med schools and not available to the public. Of course, that information is also available just by calling our service.

Representative BILIRAKIS. Thank you very much.

Thank you, Senator, for the opportunity.

Chairman HEINZ. Thank you very much.

Congressman McCain.

Representative MCCAIN. Thank you, Mr. Chairman.

Mr. Hall, I also am impressed with your organization. Could you tell us how you got started?

Mr. HALL. We started from the interest of one family, who was concerned about an individual's use of an illicit drug. In an attempt to find out more information on that particular substance, to begin aid and treatment of the person, the family ran into brick walls, and unavailable information—"Why do you want to know that?" After they researched enough on their own, they identified that factual, accurate information is an important need for others involved in the tragedy of drug abuse. Up Front's philosophy is to present information on a nonjudgmental basis. If someone calls us and tells us that they are smoking marihuana and they want to talk about that issue, we do not throw up our arms and say, "Oh, you drug addict." We get into a discussion of why they are doing it, what they are seeking from it, and try to provide them with accurate information, so they can make their decision.

Representative MCCAIN. Do you make use of volunteers?

Mr. HALL. We do. However, our telephone lines are maintained by only trained staff members, operating under the direction of our staff pharmacists, or consultants.

Representative MCCAIN. And the size of your budget?

Mr. HALL. About $100,000 annually.

Representative MCCAIN. And the number of staff?

Mr. HALL. We have five full-time staff members, and that is supplemented by occasional part-time people.

Representative MCCAIN. If you cover the entire state of Florida, that must keep you very busy.

Mr. HALL. We keep hopping; but we can do a lot on the phone in a few minutes. And we are able to provide the lowest per-client

cost services of any Florida HRS program. For between $2 and $3 per client contact, we are able to run our entire program.

Representative McCain. You seem to have received a lot of inquiries. I think it certainly would be an excellent pilot program, or something that the other States should certainly look at.

Mr. Hall. We are anxious to help anyone who is interested in it, and we are even willing to spread our network.

Representative McCain. Good. I just have one more question. You mentioned a new concern that has recently been added to your list, and that is tamperproof packaging. And you indicated that many of our seniors say, "I would take it, if I could get into it." We see this problem more and more, and not only with the elderly—I seem to have difficulty myself from time to time. Do you have any ideas as to how to cure that problem?

Mr. Hall. Perhaps not as much just with the tamperproof packaging, but a problem that we have known for several years for seniors has been with child-resistant packaging, which one of our callers once referred to as "senior-resistant packaging." Most senior citizens do not have to worry about having child-resistant packaging in their home, or if they do, they can perhaps store their drugs in an area where they would be kept away from children and should request from their pharmacist not to have child-proof packaging. Certainly, the tamper-resistant packaging can be made to demonstrate that the product has not been opened. We should keep in mind, as those different techniques are applied, that it need not be difficult to remove the tamper protection in order to indicate that, in fact, the product may have been fooled with.

Representative McCain. Thank you.

Thank you, Mr. Chairman.

Chairman Heinz. Congressman McCain, thank you.

I think Congressman Daub was next, and then Congressman Ridge, and Congresswoman Ferraro.

Representative Daub. Thank you very much.

I have so many questions, I will not get it all done in 5 minutes, but I want to start. We have two teaching hospitals in Omaha, Nebr., the University of Nebraska Medical Center and Creighton Medical School, and we are very involved with this whole area of geriatrics, drug use and abuse with the elderly. We have five nursing schools in that area, and a VA hospital. I have had some experience with NDA's, new drug applications. I have had some experience with the overseas, or other country uses, and regulatory processes of drugs. Indeed, from patent delays, to getting drugs from there to here, to drugs that are there that are good that we cannot get here—there are a whole field of problems, particularly as they relate to elderly drug availability.

I appreciated, Rose, your very vivid description of your problems through your daughter, and we appreciate your being here today, and indeed, Ms. Powell, your helpful illustration of the problems. It is always one thing to get experts like Mr. Flaherty, Jim Hall, and Dr. Lieff here, but when we can have some real life depiction of what has happened to someone, it makes it easier for everyone to understand.

I am concerned about principal focus—what should Government do? Does any one of you on this panel have an answer to that ques-

tion? Should there be a national clearinghouse established? Should we use computers for the side effect problems which many, many doctors know about, but which are only gathered in one or two places, most often unavailable, when they are needed at a very instant? What should the answer be for the Federal system, and should there be a role?

Dr. LIEFF. Well, I think all the things you have mentioned are true. I think there has to be a major education campaign somehow, and programs, such as Up Front, are very valuable.

I think in terms of the medical profession, there has to be an effort made to simplify the information and give the doctors clear, up-to-date information as it exists right now. The other point is, there have to be incentives put into the reimbursement to have doctors work together rather than separately. In other words, right now, there is very little incentive for a doctor to spend the time on the phone talking to the other doctors, and there is very little incentive to coordinate any teams. One finds different doctors working separately, and giving out all kinds of pills that the others do not know about. So there has to be an incentive built in the system to have doctors communicate with each other, and there has to be simplified information given to the doctors, as well as the public campaign which you are talking about, and the information to the consumer.

Representative DAUB. So a covered item of an insurance policy ought to be drug followthrough consultation?

Dr. LIEFF. That would be one. Another one would be teamwork, somehow, having the internists talk to the psychiatrists, and talk to the neurologists—in other words, having all the relevant doctors in the case communicate, so it is clear what they should be prescribing together and what they should not be prescribing together.

I mean, there is usually one identified doctor, the attending doctor, but that is really not enough, because it is very hard for that doctor to keep up if he does not stay on the phone all day with all kinds of other people.

Representative DAUB. Is there a data bank available anywhere that can be accessed?

Dr. LIEFF. There are various data banks, but it is not coordinated in any way. The AMA is working on a computerized system, but again, it is not easy for a doctor to get that information now.

Representative DAUB. Mr. Hall, how many organizations are there, to your knowledge, like yours, in this country?

Mr. HALL. There are other organizations, particularly serving metropolitan areas, that provide information—drug hotlines, primarily, on illicit drug use. To our knowledge, there are not available to the general public, services similar to our own, where people can anonymously call and seek information about pharmaceutical products that they are taking.

In answer to your question about what Government can do, certainly, calling attention to the problems is one of the key areas that Government can do, and alerting consumers of their need to act as consumers, as they do when they are shopping for an automobile, an appliance, but to be informed and to get the information that they need to know.

One area that I think is particularly interesting in the private sector that has occurred in just the last year is the formation of a National Council on Patient Information and Education. This is a cooperative venture of Government agencies; the FDA is an active participant in it; the pharmaceutical industry itself, who is, incidentally, I think, very supportive in the financial operations of that organization—and of organizations like ourselves, the consumer groups, and the professional medical associations. There is emerging right now a strong emphasis across the board of cooperation on the need for patient information and education.

Representative DAUB. Thank you very much.

Mr. Flaherty, did you have a comment you would like to make?

Mr. FLAHERTY. Yes. Some of the areas where I think the Government could really help—the first is, we need a geriatric dose. If you take a prescription or an over-the-counter medication, nowhere in the directions will you see a geriatric dose. There is a pediatric dose and a normal dose. A normal dose is a normal, 25-year-old person. As has been indicated already this morning, physiology changes. We need to further do research on the interactions of these medications and get that information out, both to the professionals and into the private community. The elders need a place to call, but so do the professionals, where they can call safely, and get it checked, and so can the pharmacists.

Third, we need education, not only for the elderly, but for the professional community. Fully 75 percent of the medications on the market today were not on the market when 50 percent of the doctors practicing today were in medical school. So it is not only getting our medical schools up to date, but getting new information to get our physicians further brought up to date with that information on the market.

Representative DAUB. Thank you. That is a good and helpful set of indicators for us to chew over to see what we can do to come up with some answers on our part. We appreciate all of you, and thank you for being here.

Thank you, Mr. Chairman.

Chairman HEINZ. Congressman Daub, thank you.

Congressman Ridge.

Representative RIDGE. Thank you, Mr. Chairman.

Dr. Lieff, probably the most disconcerting statement that I heard during the course of your remarks, and one that everyone on the panel has addressed is, that it is impossible to keep up with the information explosion. And recognizing that each individual drug has potential side effects, and recognizing that there is an infinite variety—an infinite variety—of potential side effects when we are mixing 1, 2, 3, 4, 17, or 18 drugs, in Mrs. Zimny's situation—are you satisfied with the amount and/or quality of research that is available to the medical community in terms of the potential side effects, when you are mixing—always, on the prescription or the literature, you may get that this will have such-and-such a side effect—is there enough information out there to help you when you start mixing them, when you do run into these combinations?

Dr. LIEFF. You raise a very, very important point. There is some information on drug A and drug B interacting together. If you add drug C and drug D to drug A and drug B, there is almost no infor-

mation on what happens, because they could totally change the way drugs A and B act.

There are a couple of systems that have been described, for example, the hepatic enzyme system, where one has five or six drugs that play into the same mechanism. There are one or two examples of that in medicine, and for all the rest of the medicines, the only information is drug A and drug B, with no information on adding 3, 4, 5, 6, 7, 8, 9, and 10. So you are targeting one of the critical research areas. I mean, there has to be research into drugs A and B, plus C, D, E, F, and G. This research could be done in typical groupings, the kind of typical drugs that people are going to get, and do that kind of research. It could be an FDA requirement.

Representative RIDGE. I know the last thing that the medical community wants to do, or anybody else dealing with the Federal Government, is fill out more forms and send in more paperwork, but in your personal medical experience, it seems to me, you have done much of what, hopefully, other physicians would do, and would assist the pharmaceutical companies and the FDA, and I think it goes along with something that Ms. Oakar mentioned. You get back to the treating physician, and you discuss the adverse effect, or you get back to the treating physician, and you discuss the ineffectiveness of this particular drug or prescription. Would it serve the elderly people and the FDA, whatever, to put the burden on the medical profession to not only discuss it and resolve it for that particular patient, but to report it to somebody, so that in your experience, it can be shared with somebody in California, or you can share it with Mr. Hall's group in Florida?

Dr. LIEFF. Well, I think it is a very good point which you are raising. The problem in research on the side effects of drugs is very complicated. Let me give you an example of a patient who came in, an 86-year-old lady living alone, taking an antiarthritic medicine for 5 years. Suddenly, she started seeing kaleidoscope visions on the walls and was actively hallucinating. We brought her into the hospital, and I stopped the medicine, which I tend to do. I tend to stop medicines as much as possible. The visions went away. I discharged the patient, sent her back to her local doctor. He started up the medicine again, and the visions came back. I stopped the medicine again, and they went away again, and they have never come back, 4 years later.

To me, that is evidence that this particular medicine, which is not noted to cause hallucinations, definitely caused hallucinations in this case, and I see many instances of particular, idiosyncratic reactions of almost any medication. Just about any medication can cause severe psychiatric side effects, and that is not listed in every case. It has to be on a case-by-case basis, and one has to look very carefully. Now, that is not scientific evidence. I have not given you scientific evidence that this drug caused it, but I am absolutely convinced that it did. So that is not acceptable as double-blind evidence. So I think you need both the real, hard science done at the research level, and you need the reporting. The reporting gets very complicated, because very often one gets side effects, where they have 5 or 10 medicines, and the physicians stop 3 of them, and the symptoms goes away—but which one did it, which one did not do

it. It gets very, very complicated. There has to be some basic scientific research on the interactions of these medicines.

Representative RIDGE. Mr. Hall, would you enlighten us as to how you go about training these obviously very capable and very dedicated staff members? Is it a continuing education process? You are dealing primarily with volunteers, and you have them answering the phone. How do you keep them informed?

Mr. HALL. The people who are answering our phone are not volunteers; they are staff members. They are trained under the supervision of our staff pharmacist.

We work in several areas—basic pharmacology information, and of course, reference retrieval, because we have the information at hand, and to have that available. But also, we work very carefully in the whole area of telephone consultation skills. Often, the caller starts with a question that is not the concern that they are actually calling for, and it is our job to talk with them, to give them a comfortable environment in which they may then express their actual concerns. As well, we use an ongoing staff training program, yes, and relate it also with nursing students and med students.

Representative RIDGE. Mr. Chairman, I presume that the red light is not only for the witnesses, but for me, so I yield back, and thank you.

Chairman HEINZ. Thank you very much, Mr. Ridge.

Congresswoman Ferraro.

Representative FERRARO. Thank you, Mr. Chairman.

Mr. Chairman, I would ask that my prepared opening statement be made part of the record, and I want to apologize to the panel for being late. I did leave my home in sufficient time to get down here, but the only shuttle I have seen take off on time is the one I watched from the Kennedy Space Center 2 weeks ago. I am going to suggest, perhaps, that Eastern hire a few Sally Rides to ride along in the cockpit.

Chairman HEINZ. Without objection, the prepared statement of Congresswoman Ferraro will be inserted in the record at this time.

[The prepared statement of Representative Ferraro follows:]

PREPARED STATEMENT OF REPRESENTATIVE GERALDINE FERRARO

I would like to commend Chairmen Heinz and Pepper for holding this important hearing this morning on the use and abuse of drugs among the elderly.

It is estimated that about two-thirds of all older Americans use drugs prescribed by their physicians, and roughly 70 percent use over-the-counter products.

What often gets insufficient attention is that many drugs taken with alcohol produce new symptoms which are often quite serious. According to testimony that our House subcommittee received several weeks ago, nearly half of the elderly use drugs in combination with alcohol. In fact, of the 100 most frequently prescribed drug products, over half contain at least one ingredient that is known to react adversely with alcohol. This combination of drug and alcohol can cause reactions which range from minor drowsiness to termination of central nervous system functions or death.

When one considers that those over 65—10 percent of the population—consume about 25 percent of the medications in the United States, the importance of both public and physician education in the substance abuse area becomes obvious.

It is important, Mr. Chairman, that when we consider the use and abuse of drugs among the elderly, that we do not differentiate alcohol from other drugs.

At this time I anxiously look forward to hearing the testimony of our distinguished witnesses.

Representative FERRARO. I was listening with great interest to your comments, and Dr. Lieff, in particular, to your response to

Senator Burdick with reference to dosages, and how drugs in the body of an elderly person will remain a longer period of time, because of the variance in body waters, and things like that.

Mr. Flaherty has, I think, approached the problem in the way that it should be. You do have dosages for children. You do have dosages for different body weights in some medicines, and it is part of the label, even on over-the-counter drugs. Is that not a direction that should be taken?

Dr. LIEFF. Well, it is slightly more complicated than that, although I agree completely that that is a good direction. One of the problems is that when we talk about the geriatric doses, they often refer to what I would call a frail elderly. A robust person who is 85 or 90, has bodily changes which are not as extreme as other people—in other words, these changes can occur at any age, between 50 and 110. A doctor may have to gradually increase the dose into a normal range, in order to get any kind of beneficial effect. To me, the worst case would be to take a medicine and get no positive benefit and only get side effects. That is the most terrible scenario. For example, giving a hypertension medicine, and not lowering the blood pressure.

So it is necessary to start at these low doses and then very carefully increase. Most people will stay in the small doses, but probably in a third, you will have to go up into the normal higher doses. That involves careful observation. There is no way around it.

Representative FERRARO. That differentiation would come through the specific doctor, looking at the individual patient and saying, "Therefore, you would take a larger dose"—just like you do with kids. I mean, if they are chubby sometimes, they need more medicine than a frail child.

Dr. LIEFF. Yes. It involves targeting the family, it involves targeting the nurses, it involves a lot of back and forth communication with the people.

Representative FERRARO. And that would compensate for the fact that these are not people who are experienced in gerontology, and that you cannot expect every doctor to be experienced——

Dr. LIEFF. Right. If you start with the small doses and then carefully monitor them, then you can gradually raise them. Now, one other problem, and let me just throw this in, that doctors deal with the issue of overutilization of in-hospital stays and very often we get into a problem where, in order to properly treat an elderly person, we have to keep them in longer, because you need to carefully watch the five or six medicines, and that gets to be a problem. There is a pressure to get them out as fast as possible, which of course, is cost-saving on the one hand, but on the other hand, it is more expensive when they are sent out, and then they have serious side effects later.

Representative FERRARO. That is what I want to follow up with Ms. Zimny on, if I might. I read the testimony that you have given to the committee.

Was the doctor to whom your mother went, one, an individual doctor—was it a private physician, or was it someone connected with the hospital?

Ms. ZIMNY. He was a doctor working for the hospital, but he prescribed all the medicines on his own.

Representative FERRARO. And did she continue to go back to the same doctor, or——

Ms. ZIMNY. She went to him for about 1 year.

Representative FERRARO. Was she seeing any other doctor at the same time?

Ms. ZIMNY. No; she only saw him for about 1 year, and he gradually said that she was getting more and more problems, different things were wrong with her, and each time she had a problem, he would prescribe another medication.

Representative FERRARO. What are all those things in the bag, there?

Ms. ZIMNY. These pills are medications that he prescribed for her within 1 year's time.

Representative FERRARO. That is 1 year's medications by this one individual doctor; is that correct?

Ms. ZIMNY. Yes.

Representative FERRARO. They obviously were not meant to be taken at about the same time.

Ms. ZIMNY. About 10 or 12 of them were. You see, she had become—for instance, she was on a drug called tributyline—if I am not mistaken, I think it is a steroid—and it was giving her an allergic reaction, where all her muscles, fingers, elbows, and joints would tighten up to extreme pain. So he took her off of that medication and prescribed another one. When she started taking the prednisone, which—and I am not a doctor—but from what I have seen about how my mother has reacted with that particular drug, it should be taken off the market completely; they are just using it for anything. They are using it for colds, they are using it for asthma, they are using it for anything that they find wrong with somebody. They think it is a miracle drug. It stopped her from walking, completely. It caused facial swelling from here, under, so that she felt that she was drowning in her own fluid.

Representative FERRARO. Let me ask Mrs. Zimny; could you tell us how you felt, taking all those drugs?

Mrs. ZIMNY. I did not want to take them.

Representative FERRARO. But why did you?

Mrs. ZIMNY. The doctor told my daughter that if I did not take them, I would die.

Representative FERRARO. Did you trust the doctor?

Mrs. ZIMNY. No, not after that, because I used to see things climbing upon the wall. I used to see little devils, about this big, on the trees, and they had the two little horns on them.

Representative FERRARO. And when you were taking those drugs, did you go to your daughter and tell her?

Mrs. ZIMNY. My daughter noticed it, and she got another doctor on it.

Representative FERRARO. Dr. Lieff, let me ask you, why would her doctor prescribe those drugs, especially when she was hallucinating, obviously?

Dr. LIEFF. Well, he starts with the drug for asthma. Then, adds a couple more. Then, an increase in the heart rate starts, and then a swelling develops, so a cardia med is given, and then a diuretic for the swelling. Then, she starts to get a little dizzy, she is given vertigo medicine. Then, she gets real anxious and upset, she is given

an antianxiety medicine. Then she starts seeing things, so she is given an antipsychotic medicine. Then, she cannot sleep, so she is given an antidepressant.

Representative FERRARO. Do they keep records of what they are giving? I mean, I assume that he has a whole list of all these drugs he is giving, does he not?

Dr. LIEFF. Well, I cannot really speak for this doctor, but——

Representative FERRARO. Is that not common practice, though?

Dr. LIEFF. It is absolutely common practice to keep a total list of everything that one does with a patient, not only a list of what you do, but goals of treatment—in other words, dividing things up into what you are trying to accomplish.

Representative FERRARO. Let me ask one more question, because my time has run out. That is, would that situation be exacerbated for a clinic patient who is going from doctor to doctor to doctor?

Dr. LIEFF. Oh, absolutely. This is one of the biggest problems, is that there are so many doctors involved, and they have to coordinate, because each doctor gives two or three pills and does not know what the other—and it is very hard for a person to remember to bring all these pills every time they go see a doctor, and have a list of all the pills to give to the doctor. If the medical profession does not do it, it is very hard to ask the people to do that. And then, on the other hand, all the over-the-counter medicines. People rarely report over-the-counter medicines to doctors. If you ask, "What pills are you taking?" they will rarely tell you all the cough medicines, and the aspirin—which has 25 interactions.

Representative FERRARO. Thank you very much.

Thank you, Mr. Chairman.

Chairman HEINZ. Thank you, Congresswoman Ferraro.

I want to put into the record the testimony of Dr. Ruth P. Kane, who is the daughter of Nettie Apple Powell. Dr. Kane was introduced earlier this morning, and I want to thank her for her testimony.

[The statement of Dr. Kane follows:]

STATEMENT OF DR. RUTH P. KANE

I am Dr. Ruth Kane, the daughter of Nettie Apple Powell, an elderly citizen, whose distress and suffering over a 7-year period brought to my attention the serious drug-medication problems of the elderly. She married my father, a widower, 15 years ago, bringing much happiness to his saddened life. About a year after I knew her, Nettie developed a heart problem for which she was in the hospital. The doctor, who has since retired, prescribed medication for her heart, indural. Nettie faithfully took this medication, but soon began complaining of pains which traveled from her chest to her head and neck and would leave her very anxious. She was in constant fear of a heart attack. Her doctor who retired, referred her to a younger physician, who indicated that these problems were due to Nettie's "nerves." My experience as a psychiatrist and physician told me that Nettie was not the nervous, neurotic type, but not wanting to interfere, I let her consult with her physician. The second physician, in addition to the indural, prescribed librium to be taken only for her nerves. Nettie is a careful person, disliking to take any medications, and only took these following these attacks. She'd complain about these to me and didn't know what to do.

Known to me, Nettie felt ashamed of being considered a nervous person, and was upset about this. Problems still continued, however. My father's having a stroke 5 years ago, with his inability to get around very well by himself, compounded Nettie's distresses. At the suggestion of another family member, Nettie sought the care of still another doctor. This doctor indicated that indural had a side effect which was causing her pains in her knees, had them X-rayed, and was found to have ar-

thritis for which the, yet another doctor, prescribed motrim. This medication gave gave her stomach pains, and she discontinued this herself, feeling that the pain in the knees would be preferable to the one in the abdomen.

Since the disappearance of the attacks, Nettie has not needed to take librium and has been bright and cheerful. She no longer considers herself to be a neurotic mess, and suffered 8 years of great distress for these problems. Her nature is a cheerful, happy, helpful person and we have a close relationship.

Thank you very much for listening to the testimony.

In addition, I would like to say that the problem was forcefully brought to my attention that elderly are at a greater risk for side effects, more likely to be diagnosed as psychosomatic, and have difficulties communicating with their physicians.

Chairman HEINZ. Before we close, I just want to ask Mrs. Powell one final question.

Mrs. Powell, as you have been sitting here, listening to this discussion, a lot of thoughts must have occurred to you about the medical profession, drugs, the Congress. What do you think you have learned from listening to all of the discussion, and what is it that you would advise us, and anybody who cares to hear, look at, or sees this hearing; what should we emphasize to them?

Mrs. POWELL. Well, first of all, it was very, very interesting to me, and second, they really should watch the pills that they take—and not overmedicate.

I agree with all of them.

Chairman HEINZ. You went to three doctors.

Mrs. POWELL. Yes, sir.

Chairman HEINZ. Each of them changed your medication.

Mrs. POWELL. No; the first one gave me something, and that is what caused my so-called "sneak attack"—I gave it that name myself. It was a terrible feeling. And when I talked to him, he did not know what caused it. Then, the second one also did not know what caused it, and I still took this one medicine. But the third one changed it, and after he changed it, I felt much better, and I did not get these sneak attacks. And that lasted about 7 years, from 1973 to 1980, and really, it upset me for a couple of hours all the time, and it really made a nervous wreck out of me, because I was anticipating the next attack at all times.

Chairman HEINZ. That suggests to me that doctors should not only keep careful lists of medications and explicitly state what the medical history is on the patients, what medications are supposed to accomplish, the goals that Dr. Lieff suggested, but that doctors should also make an extraordinary effort to learn from their patients, particularly their older patients, what medications they have and use. Doctors should go into some detail with patients about the possible, very adverse side effects that they may expect or look out for in taking medication. I think we have learned one other thing here about drugs, and probably our next panel could testify to it, and that is, that although a particular drug may have a particular, unique set of side effects, there is no guarantee that a drug will not have a unique side effect on an individual human being. Doctors must be more alert to the fact that notwithstanding that AMA medication insert, which mentions everything in the world that can go wrong, does not mention everything. There is still a tremendous need to educate the medical profession about drugs. It is probably not the only thing we need to do, but when it comes to such basic things as we, the consumers of medicine, we

tend to assume that doctors know more than they do. They are a profession, and they are supposed to know everything, but obviously, nobody can know everything. But doctors can be well-advised to be cautious and understand the limitations of their knowledge.

One example that I am always struck by is that there is very little in the way of nutrition education in medical schools today. There has been a movement to recognize that problem. And here is just one more element of something that is internally conceived and a good deal more potent, although not necessarily more important, than the food that we eat and the beverages that we drink.

I think this panel has been extraordinarily helpful to the committee, both committees, in giving us an understanding of the kinds of problems, and I not only thank all of you for your journeys from Massachusetts, Pittsburgh, and Florida, but I thank the members of the committees for their excellent questions, that have helped draw out from you, what I think, is a very helpful and indeed, an outstanding hearing record.

We thank you very much. You are excused, as well as commended.

Our next panel consists of Dr. Peter Lamy, director of the Center for the Study of Pharmacy and Therapeutics for the Elderly, School of Pharmacy, the University of Maryland at Baltimore; Dr. Jerome Avorn, assistant professor, Department of Social Medicine and Health Policy, Division on Aging of the Harvard Medical School; Jack Christy, legislative representative of the American Association of Retired Persons; and Dr. F. Gilbert McMahon, director, Clinical Research Center, Tulane University, New Orleans, La.

The first witness is Dr. Peter Lamy.

Dr. Lamy.

STATEMENT OF PETER P. LAMY, PH. D., DIRECTOR, CENTER FOR THE STUDY OF PHARMACY AND THERAPEUTICS FOR THE ELDERLY, SCHOOL OF PHARMACY, UNIVERSITY OF MARYLAND, BALTIMORE, MD.

Dr. LAMY. Senator Heinz, Congresswoman Oakar, I am pleased to be here. I have prepared testimony on the premarketing of drugs.[1] Before I go into that, I was impressed by the prior panel. I could add to it that one of the major things the elderly look for is to whom they can talk and who will not look at them as hypochondriacs and complainers.

I once wrote a very short article in the Washington Post, which generated 3,000 letters from elderly; a television appearance in Baltimore for 5 minutes generated 750 phone calls. My mother-in-law was a patient in a hospital. She went went in with 8 drugs and came out with 16. They need somebody to talk to. But it is a cascade of problems, and I think one of the reasons is that we do not test drugs sufficiently in the elderly.

You have numbers here, and let me add some numbers to it, Senator, if I may. Elderly account for 79 percent of all antiarthritic drugs that are being used, and 86 percent of all cardiovascular drugs. New and refill prescriptions have risen from 14 to 19 per

[1] See appendix, item 5.

year. Five years ago, 57 percent of all prescriptions were for chronic care use; now, it is 69 percent. And in the VA, outpatients, instead of two prescriptions per outpatient visit, now get three.

We know very little about these drugs. Drug use is heavy, and we know extremely little if drugs are given for prolonged periods of time. We know even less when drugs are given in a complex therapeutic regimen. We test drugs in young people for 3 months; we give them to old people for 15 years. Drug toxicities may accumulate, and not only may drugs interact with each other, and we have heard that, but they will interact with other diseases. An eyedrop given to an elderly, two drops in each eye twice a day, can destabilize a previously stable elderly asthmatic or diabetic patient.

Disease states and poor nutritional state can alter the actions of drugs, as can the patient's status, such as when the patient is dehydrated. In turn, a drug can affect the patient's nutritional status adversely by chosing vitamin and mineral deficits.

In short, we know that all drugs can be hazardous to the elderly. They can adversely affect the patient's physical, physiological, mental, nutritional, and functional status. Drugs can decrease the patient's quality of life if used incorrectly, and in geriatrics, unfortunately, sometimes, even if they are used correctly by today's knowledge. We do know, and it has been testified to, that as we age, drug effects become increasingly difficult to predict. Elderly patients tend to respond to drugs much more individually than do younger patients, and average findings, as we get from studies, are often not applicable. Particularly important is that the elderly are more sensitive to drugs, particularly the brain, so central nervous system drugs should probably be given in lower doses. Usually, women are underrepresented in drug studies. Women in the community outnumber men 2 to 1, and in nursing homes, 3 to 1. Moreover, women are older than men, live alone more often, are poorer than men, and make more medication errors. The study population quite often does not reflect the user population. Drugs are usually tested in comparatively healthy populations, yet elderly present, more frequently, with more than one disease, and polymedicine is pervasive.

Current testing procedures often do not account for these facts. We have seen that the GAO reported that the FDA is unable to respond quickly to adverse drug reaction reports. Last February, it was noted that in 1982, that 42 percent of adverse drug reactions do not reach the FDA.

It might be argued that new procedures would add immensely to the cost of drugs, and that may well be true, and perhaps we should look for correlated, premarketing, and postmarketing testing. We should not forget about educational programs, and in this respect, I would like to add, that Congressman Lantos had said that industry does make a contribution. I would say that we, at Maryland, have a major drug education program that is currently funded by industry, and that Parke-Davis has launched a nationwide effort with pharmacy and elder care, with our cooperation. I just came from Chicago, where the Lieutenant Governor and the mayor are supporting this program greatly. The Commission on Aging in New York City is doing the same thing.

It was a pleasure to testify.

Thank you.

Chairman HEINZ. Dr. Avorn.

STATEMENT OF JEROME L. AVORN, M.D., ASSISTANT PROFESSOR OF SOCIAL MEDICINE AND HEALTH POLICY, DIVISION ON AGING, HARVARD MEDICAL SCHOOL, BOSTON, MASS.

Dr. AVORN. Thank you, Mr. Chairman, and Congresspeople.

I am an internist with a specialty in geriatrics, with particular interest in the use of drugs in the elderly patient. This is my main area of research at Harvard Medical School, where I am on the faculty.

At a time when new, powerful, and expensive drugs are being introduced at an unprecedented rate, the way in which drug information is disseminated to physicians should come up for renewed and careful scrutiny. Medical schools have been quite lax, as has been noted earlier today, in their provision of geriatric education for students, and the same could be said for their provision of training in pharmacology as well. But in fact, the drug industry has been very effective in moving into this educational vacuum. Education about new drugs is presented graphically, appealingly, and concisely in lavishly produced drug advertisements that call out for attention from the pages of virtually every medical journal.

Traveling salespeople, representing drug companies—the detail men—visit doctors with great frequency to encourage them to prescribe more of a particular company's products. In a study I published with Drs. Chen and Hartley in the July 1982 issue of the American Journal of Medicine, we demonstrated that what doctors know or think they know about drugs is often shaped more by these advertising approaches than by the scientific literature, which often presents quite a different view.

Many advertisements for drugs which appear in medical journals highlight the elderly, since this is a population of great interest to prescribers and the industry alike. Often, however, the impressions conveyed of the elderly are rather negative stereotypes, suggesting that they are combative, demented, and in need of sedation. The solution to the clinical problems posed in each of these ads is generally prescription of a drug, which should not be surprising. Sometimes, as in the case of the so-called cerebral vasodilators, advertised for the treatment of senility, the drugs are totally ineffective.

A critically important new development is about to occur on this front, with the scaling up of the drug industry to promote prescription drugs directly to laypeople. This could be a step forward or a giant step backward for the vulnerable population that we are concerned with. .

I want to move on to some proposed solutions to these problems, but first, I also want to acknowledge that there are enormous benefits resulting from drug therapy in the elderly, a fact that we should not lose sight of today. Many aged Americans would be either dead or in a state of severe disability, if it were not for the medications they take. We should not make the assumption that the minuses outweigh the pluses in this area, for they do not. Nonetheless, there are some very definite areas in which enlightened public policy decisions are needed.

The first, as Dr. Lamy has said, is the question of new drug testing. The fact that it is standard practice to test new drugs primarily on young subjects, that is, under 65, prior to marketing, even though, in fact, in practice, the elderly are going to be the largest recipients of that drug, is, I think, irrational and definitely needs to be changed. Discussions that have been going on at FDA are moving in this direction, and I would hope that they would be accelerated.

Next is the area of drug promotion. In the edition of the New England Journal of Medicine that was published 2 weeks ago—June 16, 1983—my associates and I reported on a new, Harvard-based "undetailing" program, an innovative means of presenting accurate, unbiased drug information for physicians in an attempt to provide a more neutral voice in the cacaphony of claims that reach physicians about the drugs they prescribe. In short, what we did was we put out our own "unadvertisements." Since most of the information flow, as has been noted, tends to be from industry, medical schools and specialty societies have more or less abdicated any responsibility for going out to physicians, while the industry has been very effective in going out to physicians. We felt that it was time for people who were not trying to sell a product, but were simply interested in good medicine, to also go out to teach physicians in their own offices. We created some "unadvertisements." This one, for example, says, "Mrs. R is doing fine without vasodilators," and it goes on to explain some of the physiology of her condition, and on the back, explains why these medicines do not work and why she does not need to be taking them.

In another "unadvertisement" that we prepared——

Chairman HEINZ. Who was your advertising agency?

Dr. AVORN. We actually put these together ourselves, with the help of some graphic artists.

Chairman HEINZ. Thank you.

Dr. AVORN. Another "unadvertisement" addressed this question of vasodilator therapy for senility, which most geriatricians agree is not an effective means of treatment. It does not work, but these drugs are very widely sold. So another one of our "unads" says, "Are you skeptical about vasodilators? You have every reason to be," and goes on and explains to the physician why these drugs do not work, and what, in fact, the doctor can do if he or she wants to do something for a demented patient—namely, do a number of studies that might reveal a treatable condition that might be reversible, rather than simply prescribing pills which are both expensive and ineffective.

We also sent out a series of people we called undetail men and women who were trained by us to go door to door, much as industry has been doing, but their mission was not to sell products, but rather, to say, "Here is a drug that is used commonly in this population. We think it is a little bit dangerous. Why don't you try something else?" We also prepared materials for patients that, unlike many of the materials that are put out by other sources, say, "Maybe you should not be on this drug at all. Maybe, for example, if you are having trouble sleeping, what you should do is avoid coffee and tea at bedtime, and that might be all you need instead of Dalmane or another drug," which may, as Dr. Lieff said

earlier, stay in the system a couple of days after the patient takes it, causing him or her to take a nap the next day, not be able to sleep the next night, and so forth.

What we found, to make a long story short, as we reported in the New England Journal, was that you can improve the way doctors use drugs by this kind of method. It is unusual, it has not been done before, but one of the things that gives us hope is that it also is a way of saving money. We found that the medicaid program was able to reduce its expenditures on many of these unnecessary drugs by a sum that was greater than the cost of putting out the program. We are now interested in exploring, as Mr. Daub asked earlier, what kinds of activities along these lines might be appropriate for Government. Government might choose to say, "We are paying a lot of drug bills, and we would like to see whether there is some way that we could get an unbiased, noncommercial, non-sales-oriented, flow of information to the doctor, who is, in many instances, trying desperately to keep ahead, but has to rely on sources which are not always quite as unbiased as they might be."

Other things that are being done and can be done to try to sound a somewhat more hopeful note this morning—Dr. Lieff mentioned the silicon-chip pill bottle top that has been developed by some people at Harvard to enable the elderly people to remember what medicines they are taking.

Representative DAUB. Excuse me. What did you call it?

Dr. AVORN. It is called Med-Tymer®. It is a silicon chip embedded in a pill bottle that sounds a loud beeper at predetermined intervals to enable an elderly person to remember when to take their medicine.

Representative DAUB. Meaning a high-tech alarm box, pillbox.

Dr. AVORN. Exactly, but inexpensive.

Chairman HEINZ. If Congressman Daub will permit me to interrupt, I got a high-tech Christmas card last year, with a little silicon chip, and you open it up, and it says, "Merry Christmas to you, and a happy new year, as well." And I checked the cost, and it is about $1.25, and that is with all the markups included.

Dr. AVORN. Yes, it is inexpensive. This is the whole point, that this is something which we are hoping will be available——

Chairman HEINZ. What would you estimate the silicon chip costs?

Dr. AVORN. The device itself, I think, is about $5, and it has a replaceable battery that can go on forever.

Chairman HEINZ. You can just about get a calculator for less than that. I am sure the cost will come down.

Dr. AVORN. Right.

Representative FERRARO. Is that reusable, by the way?

Dr. AVORN. Yes.

Something else that we are doing in more of a high-tech vein, as well, at Harvard, is using a data base that has been developed by FDA in conjunction with medicaid and health information designs. It enables us to look at the vast numbers of people in the elderly community who are on medicaid, taking medicines, and to see what side effects are associated with what medications, and what kinds of linkages between drugs and adverse effects might not have been detected previously.

In addition, the area of information for patients, I think, needs to come up again. The American Association of Retired Persons has developed a very solid series of patient package inserts about various prescription drugs. This kind of approach really ought to be encouraged in coming years, as we try to get a more appropriate level of information to both doctors and patients.

Finally, there is one proposal I make in a sincere but somewhat cynical way, because I am not at all sure it is politically feasible. It seems to me that it would not be a bad idea if we were to expect physicians who are prescribing drugs to their medicare patients, and who are being reimbursed by the medicare program, to be able to show competency in the way they use drugs in the elderly. I am suggesting that physicians should be able to pass a rather simple, straightforward test that would show that they know something about dosage, about drug interaction, about the special properties of the elderly patients that have been described this morning. It would seem perfectly appropriate that if a physician cannot demonstrate such a minimum level of competency, perhaps we should reassess whether he ought to be a participant in part B of the medicare program. Now, I realize that in the past, that would have been an unthinkable solution, and that the lobbying power of the profession, of which I am a member, has in the past been rather strong. I think what we need to consider is whether, in the course of the doctor glut which we are about to experience in this country, and changing relationships between the medical profession, Government, and increasingly vocal patients, we might reassess whether the profession is in less of a position to block this sort of basic competence testing around the use of drugs in the elderly. If it looks as if that is a viable legislative option, perhaps that may be something the committee may want to consider.

Thank you.

Chairman HEINZ. Thank you, Dr. Avorn.

[The prepared statement of Dr. Avorn follows:]

PREPARED STATEMENT OF DR. JEROME L. AVORN

Mr. Chairman, I appreciate your invitation to testify before this committee on this important issue. I am an internist and faculty member at Harvard Medical School, where for several years I have been studying the area of medication use in the elderly patient. I chose this area of research shortly after completing my training because it appeared to be a vital, yet terribly neglected field of study. My work, and that of others in the field in the last several years, has borne out both of these initial impressions. At this point, I would like to briefly review some of the clinical and pharmacological issues that contribute to the importance of this problem, and then suggest some possible solutions that might be helpful in dealing with it, particularly from the Federal level.

Members of this committee are well aware that those over 65 currently comprise about 11 percent of the U.S. population. What is less well known is that this 11 percent consumes about 25 percent of all prescribed medications, and an even larger proportion of over-the-counter preparations. Most drugs are broken down and eliminated from the body by the kidneys, liver, or both. Research in geriatrics has clearly shown that even in healthy elderly people, the function of these two organs decreases dramatically with advancing age. The loss in ability to metabolize drugs is, of course, even greater in ill elderly people, who are often at highest risk of receiving multiple medications. In addition, we have learned that the relative proportion of muscle to fat in the body changes with advancing age, and this also causes important differences in the way drugs are distributed throughout the body. Finally, there is exciting new evidence on the sensitivity of drug receptors in the elderly—those molecules which are "turned on" by drugs and cause their ultimate effect at the

cellular level. For many widely used drugs, it has been learned that these receptors themselves are more sensitive in the elderly, so that even at reduced dosages, a 75-year-old patient may experience an exaggerated effect from a drug when compared to that of a 35-year-old.

All of these factors interact with the large number of medications taken by many elderly people to create some very important clinical problems. First, there is much less margin for error in administering medications to the elderly patient. A dose that is slightly too high (which may be identical to the "correct" dose for a younger patient) is much more likely to result in toxicity. This may manifest itself as an overt overdose or other acute symptoms. More insidious, and probably much more common, are the subtler effects that often escape detection. Chronic excessive doses of various medications administered to an elderly patient can result in fatigue, confusion, loss of energy, and a whole host of symptoms which may either go completely unrecognized, or be written off as "the natural decline of old age." In numerous instances, patients seen by myself and my colleagues at the various Harvard teaching hospitals in Boston have come in with the diagnosis of irreversible senility, or were stated to be in need of nursing home placement, when the only problem was that they had been taking excessively high doses of various medications. The coexistence of other medication in the system, as well as other diseases, conspire with the physiological changes mentioned earlier to place the elderly at great risk for this kind of problem. The fact that education for medical students in geriatrics is still very spotty means that most physicians in practice today have never been systematically educated about the effects of drugs on the elderly body. I will return to consideration of this dangerous information gap shortly.

Problems associated with drug use in the elderly probably reach their height in the nursing home setting, where 50 percent of all nursing home residents nationally are being given some kind of tranquilizer. In the nursing home setting, the doctor-patient relationship is often dismal or virtually nonexistent, and attempts to impose some kind of regulatory review on the use of medications, while sometimes helpful, have not fully addressed the problem. For elderly living in the community, there is another important problem associated with the medications they take, and that is cost. Drugs are currently the second highest out-of-pocket health care expense for the Nation's elderly. For the chronically ill geriatric patient afflicted with several illnesses, but not covered by medicaid, the monthly drug bill can be staggering. For those who are covered, or can afford to buy all of their medications, adherence to the doctor's orders is often an additional problem. We know that the more pills a person is required to take, the greater is the likelihood that he or she will fail to take some of them correctly—a problem that any of us who has been required to take something as simple as a four-times-a-day antibiotic can identify with. The corollary of missed doses is double doses, also common in an elderly patient on expensive, complicated drug regimens. It is all the more tragic when these medication-taking errors occur because the patient is somewhat confused on a chemical basis, because of the very drugs that he or she is instructed to take!

I referred to the information gap that exists on the part of both patients and physicians. At a time when new, powerful, and expensive drugs are being introduced at an unprecedented rate, the way in which drug information is disseminated should come up for renewed and careful scrutiny. Although medical schools have, as I noted, been lax in their provision of geriatric education to their students (and the same could be said for their provision of training in pharmacology as well), the pharmaceutical industry has been very effective in moving into this educational vacuum. Information about new drugs is presented graphically, appealingly, and concisely in lavishly produced drug advertisements that scream out for attention from the pages of virtually every medical journal. In addition, traveling salespeople representing drug companies (known as "detail men") visit doctors with greater frequency to encourage them to prescribe more of a particular company's products. In a study I published with Drs. Chen and Hartley in the July 1982 issue of the American Journal of Medicine, we demonstrated that although physicians tend to deny that they are affected much by these sales approaches, their beliefs about several drugs were, in fact, shaped by these commercial messages more heavily than they were shaped by the scientific literature, with which they felt they were keeping up.

Many advertisments for drugs which appear in medical journals highlight the elderly, since this is a population of great interest to prescribers and industry alike. Often, however, the impressions conveyed of the elderly are rather negative stereotypes, suggesting that they are often combative, demented, and in need of sedation. The solution to the clinical problem posed in each of these ads is generally prescription of a drug, which should not be surprising. No one is out there (or at least was not until recently) using these effective and sophisticated communication techniques

to advocate nondrug ways of approaching these problems, which are often very effective, and certainly safer. Finally, we should not leave this topic without mentioning the huge amount of so-called "cerebral vasodilators" that are marketed and sold in large volume for the treatment of senility. These vasodilators are not effective for this purpose; the inability of the Food and Drug Administration to curtail their use, after literally years of fruitless effort, provides an important case study in the way in which drugs are promoted and prescribed in this country. A critically important new development is about to occur on this front with the scaling-up of the drug industry to promote prescription drugs directly to laypeople. This could be a step forward or a giant step backward for the vulnerable population with which we are concerned. Discussions currently underway between Federal agencies and the industry will help determine the future of this unprecedented approach in the coming years.

So much for my very brief overview of the problems associated with medication use and the elderly. I do not want to move on without acknowledging that there are, of course, enormous benefits resulting from drug therapy in the elderly, many of whom would be either dead, or a state of severe debility, if it were not for the drugs which they take. We should not make the assumption that the minuses outweigh the pluses in this area, for they do not. Nonetheless, I have seen it as my responsibility to focus on the areas of difficulty that we currently face in order to help this committee to consider ways in which these problem areas can be most effectively addressed. I would now like to consider some positive actions that can be taken, particularly at the Federal level, to begin to address some of the issues I have just outlined.

First is the question of new drug testing. Up until now, it has been standard practice to test new drugs on primarily young (that is, under 65) subjects prior to the widespread marketing of a new medication. However, this is potentially quite dangerous, both because of the physiological changes in the elderly that I described earlier, as well as because many of these drugs (such as those sold for arthritis or heart disease) will be used primarily by the elderly once they are marketed. The Food and Drug Administration is currently considering ways in which to insure that the elderly are well-represented in such premarketing drug testing, and these efforts, if successful, may help to prevent the recurrence of tragedies, such as those associated with Oraflex (benoxaprofen), which has been linked to lethal side effects, particularly in the elderly, and has since been removed from the market.

Next in the area of drug promotion. In the edition of the New England Journal of Medicine published 2 weeks ago (June 16, 1983), my associate, Stephen Soumerai, and I, reported on an innovative means of presenting accurate, unbiased drug information to physicians, in an attempt to provide a more neutral voice in the cacophony of claims that reach physicians about the drugs they prescribe. Supported by a grant for the National Center for Health Services Research, we conducted a randomized controlled experiment to measure the effects of having a medical school sponsor its own crew of "detail people" and produce its own "unadvertisements" to provide drug information to physicians that was not linked to a desire to sell more of that particular product. It worked, and we found that the physicians who had been visited by our Harvard-based pharmaceutical educators markedly reduced inappropriate prescribing. The savings were so great to the medicaid program alone in the four States in which we conducted the experiment, that the program could have paid for itself through the reduced drug bills charged to medicaid. We think that this kind of medical school-based noncommercial program of disseminating drug information is a very promising and cost-effective approach to the information gap that I alluded to earlier, particularly since it looks as if such a program could go on in an economically self-sustaining manner if initiated by an agency such as medicaid, the Veterans Administration, or any other health program which pays for drug charges.

Ours was a totally nonregulatory, noncoercive approach, and this may make it even more appealing in the current political climate. However, there is no way that we, as a Nation, can escape the need for certain kinds of regulation in this area, and one of them has to do with the information that is presented to physicians in package inserts and advertisements concerning drugs widely used in the elderly. There has been an encouraging trend in the last few years to include for the first time specific prescribing recommendations for the elderly in the materials published for physicians by drug manufacturers. This healthy trend should be encouraged, and probably expanded to make cautions about the use of drugs in geriatric patients more prominent than they now are in all published materials.

In the area of compliance by patients, an interesting new device has been developed by researchers at Harvard Medical School that uses silicon-chip technology embedded into a conventional pill-bottle top to sound a buzzer at preprogramed inter-

vals, to remind patients to take their medication. The device can be set for a variety of common dosage schedules, and it is automatically reset when the patient opens the container. It is this kind of use of technology on an affordable scale that we should encourage, so as to prevent the need for much more costly cure-oriented technologies that are required to treat the consequences of drug-related mishaps.

Continuing to focus on what we can do for patients themselves, there is still a great need for informational materials for the elderly that discuss commonly used drugs in language that is accessible to laypeople. Despite the plethora of self-help books dealing with medicine that are now on the market, I know of none that specifically address the question of drug use in the aged. Three weeks ago, an exploratory meeting was held at the National Institute on Aging at which such a project was discussed. The American Association of Retired Persons is currently putting out a very good series of patient package inserts for participants in their own extensive pharmacy program, and such products could serve as a very useful model for all further activities of this sort. On a much smaller scale, we have put out our own modest series of brochures, which attempt to teach patients that side effects such as drowsiness, forgetfulness, or constipation are not normal consequences of aging, but rather may be subtle side effects of medications that they are taking. If so many physicians are unaware of this, it is staggering to consider how many patients must be in the dark about side effects they are experiencing from the pills that they take.

Let me now turn to the more troubling arena of the nursing home, where the sickest subgroup of our parents and grandparents live, and where drug use is at its most prolific. We have yet to learn how to insure the wise and careful use of medications in this frail population. A critical evaluation is needed of the federally mandated program requiring inspection of drug utilization patterns by consultant pharmacists, which has now been in place for about a decade. If research reveals that this program is not successfully addressing the entire problem, then additional strategies must be considered. Some of these might involve the kind of noncoercive educational programs that we have developed, on the assumption that physicians want to practice good medicine, but often lack the information base they need to do so effectively. However, in the nursing home setting, which is a world apart from most of the rest of health care in this country, other measures may be necessary. Considering that there are now more people in nursing home beds than in acute care beds in the United States, and in view of the enormous expenditure of Federal funds on this form of care, it is high time that nursing home medicine be taken "out of the closet" and subjected to much more careful scrutiny.

This brings me to my last conclusion which, while eminently sensible, is probably totally unworkable. Nevertheless, as a veteran of the turbulent times of the late 1960's, when anything seemed possible, I will put the concept on the table for consideration by this committee. It seems to me perfectly fair that medicare should expect a certain minimum level of competence in relation to drug prescribing in order for physicians to participate in reimbursement through part B of its program. When the Federal Government contracts with a builder for the construction of an office building, it has a right to expect that the materials used will be of sound quality, and that they will be assembled with due care. If this is not the case, then stringent penalties are appropriately brought to bear. I contend that measures at least as stringent should be brought to bear in the reimbursement of professionals who are assigned the responsibility for preserving human life. Drugs have become such a central part of modern medical therapy that it is unconscionable to continue to support practitioners who cannot pass a basic competency test in their use. Knowledge of pharmacological therapy also has the advantage of being more easily quantified and standardized than other kinds of clinical knowledge, especially if one avoids the more controversial gray areas (such as what kind of patients should be taking Valium). The justification for implementing such a program through medicare is analogous to the grounds on which the medicare program itself was initially proposed: It will meet the needs of the most vulnerable portion of society, and do so in a way that will be reasonably uniform and equitable across the entire Nation. I would favor setting the knowledge level that is required rather generously at first, providing several years' leadtime before the implementation of such a requirement, and support the development of numerous preparatory programs in all parts of the country, whether through medical schools, frankly entrepreneurial organizations, hospitals, medical societies, or specialty boards. A physician should have several chances to pass what would initially be only a slightly demanding examination, and standards could be reassessed periodically. Recertification need not occur more often than every 3 to 6 years. Physicians who pass would continue to receive reimbursement under medicare part B; others would not until they had successfully demonstrated their competence in the use of drugs in the elderly. Other alternatives, such

as differential rates of reimbursement for those who pass and those who do not, are also possible.

Logical and plausible as this idea may be, veterans of the Hill will dismiss it out of hand, pointing to the enormous political clout of the American medical profession, which has thus far powerfully resisted any attempts at quality control that appeared to threaten the livelihood of its constituency. I am not naive to this historical reality, but would point out that as we used to say, "The times, they are a-changin" and that the profession faces an unprecedented surplus of physician manpower in the coming decades. This, as well as the increasing voice of the patient-consumer, and other changes, will make for a very different situation regarding physican-Government relationships throughout the rest of this century—a trend which has been very well documented by my colleague, Paul Starr, in his recent book, "The Social Transformation of American Medicine." It seems to me only a matter of time before the citizens of this country gain the right to expect that the physicians that care for them—and who are supported in large measure by their tax dollars—do in fact possess therapeutic credentials other than having once attended medical school, perhaps many decades in the past. The States have thus far not shown the ability or the will to address the problem of quality assurance in any but the most egregious cases; this task must be undertaken by the Federal Government if it is going to be undertaken by anyone. Whether such an approach would make the medicare program more of a nuisance than it is worth in the eyes of many physicians is an important problem to consider. Whether this occurs will depend more on the level at which the reimbursement rate for particular services is set, than on the requirements that are attached to such reimbursement. If a small number of physicians decide that they are unable or unwilling to demonstrate competence in drug therapy for the elderly, than perhaps we are all better off if such physicians are not participants in the medicare program in any case.

I have laid a number of issues before the committee and hope that at least some of them have been informative as well as provocative. I thank you for your interest, and will be happy to answer any questions.

Chairman HEINZ. Jack Christy.

STATEMENT OF JACK CHRISTY, WASHINGTON, D.C., LEGISLATIVE REPRESENTATIVE, AMERICAN ASSOCIATION OF RETIRED PERSONS; ACCOMPANIED BY NANCY OLINS, AARP PHARMACY SERVICE

Mr. CHRISTY. Thank you, Mr. Chairman.

On behalf of the 14½ million members of the American Association of Retired Persons, I want to thank the Senate Special Committee on Aging and the House Select Committee on Aging for this opportunity to state our views concerning drug misuse in the elderly.

My name is Jack Christy and I am a legislative representative for AARP. Accompanying me today is Nancy Olins, a member of the AARP Pharmacy Service. Our testimony today will focus primarily on the elderly's needs for greater information about the drugs they take.

Drug issues are a major concern of our membership because those over age 65, while representing only 11.3 percent of the population, account for over 25 percent of all expenditures for prescription drug products. For the elderly, prescription drugs represent over one-third of their total out-of-pocket health care costs. This situation is compounded by the increasing incidence of chronic debilitating conditions among the elderly, the relatively greater utilization of multiple prescription drugs and an increased tendency among physicians to overprescribe prescription drugs or to prescribe with inadequate knowledge of their patient's current consumption patterns and experiences. Clearly, older Americans have a large stake in the area of prescription drugs.

Drug misuse is a complicated phenomenon resulting from many factors. It is estimated that 70 to 75 percent of drug misuse among the elderly is underutilization, most often because they cannot afford the medicine prescribed. Preliminary indications from a recent AARP poll show that 40 percent of the elderly cite side effects and adverse reaction as the leading reasons for not taking prescription medication after buying it. Correcting the problems causing drug misuse among the elderly requires a multifaceted effort. Obviously, the degree of knowledge necessary to make an informed consent to take a particular drug must be shared at the time of prescribing. Physicians and patients must fully discuss the benefits and risks of potential drug therapy before a patient agrees to take it or not. The burden of this discussion falls most heavily on the doctors. But correcting drug misuse among the elderly requires a great deal more than just improving physician-patient communication. Doctors, nurses, pharmacists, drug manufacturers, trade associations, and the Government—all of us concerned with drug issues—must participate in informing patients about drugs. Printed information and instructions about how and when to take a particular drug, side effects, and what to do about them, are fundamental elements of a patient drug information standard.

The safe and effective use of drugs requires knowledge. Spreading that knowledge should be a priority of the Federal Government. It is a priority at AARP. For the past year, the AARP Pharmacy Service has been distributing easy-to-understand information about drugs. We call the program "medication information leaflets," MILS for short. We brought some examples which the staff has for the committee's examination.

[The following was received for the record:]

39

Important Information about You and your Medication...

Triamterene and Hydrochlorothiazide (HCT)

Provided by AARP Pharmacy Service, with the assistance and cooperation of the U.S. Food and Drug Administration, and experts in geriatric medicine and pharmacy.

24-861 O—83——5

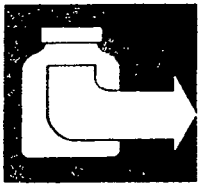
Name of your medication:

Triamterene and Hydrochlorothiazide (HCT)

Other names: Dyazide

What is it?

This is a combination of two diuretics (water pills), a thiazide and a drug to prevent loss of potassium.

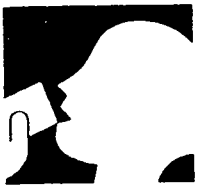


What is it for?

- It is used to lower high blood pressure and to get rid of extra fluid in the body.
- It is also used to decrease shortness of breath, swelling of your feet and ankles from extra salt and water caused by heart, liver and kidney disease.

How long will you have to take it?

- Probably for the rest of your life.
- This medicine cannot cure high blood pressure, but if taken as directed, it can help control it.



How should you take this medication?

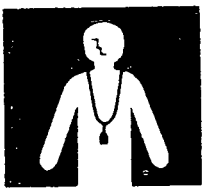
- Take it as directed, preferably in the morning after breakfast.
- Try to take it at the same time each day you are scheduled to take it.
- Some people take Triamterene and HCT every other day.
- If you take two doses a day, take the second one in the evening before dinner.
- If you miss a dose, take it right away, but do not take two at the same time.
- Do not take after dinner. It may interrupt your sleep and cause you to urinate (pass water).
- When you take this drug, you usually will not have to take any extra potassium supplements or eat large amounts of food rich in potassium (bananas, oranges, grapefruit, apricots, peaches, prunes, or figs).
- Do NOT stop taking if you feel better.

Things to remember:

- Do not rise quickly after lying down or sitting. You may feel dizzy or lightheaded.
- If you feel dizzy, sit up slowly, put legs over the side of the bed, and stay there for a few minutes.
- Some people think because this medicine is taken to remove fluid from the body, they must restrict fluid or water intake. This is wrong. Continue to drink normal amounts of fluid.
- When you first take your medicine, you may urinate more often. If this is very inconvenient, do NOT stop taking the drug. Call your doctor. Perhaps it can be taken at a different time.
- Triamterene and HCT may make you more likely to sunburn. Avoid too much heat, sunlight, saunas, or hot baths.

Check yourself:

- If you have shortness of breath or swelling of hands or feet, call your doctor.



Information your Doctor needs:

Do you have or have you ever had:

- An allergic reaction to sulfa or Dyrenium?
- Diabetes, kidney or liver disease?
- Gout?
- Lupus erythematosus?

Are you taking:

- Any heart medicine (Digoxin, Digitalis)?
- Lithium carbonate or phenobarbital?
- Medicines for diabetes?
- Narcotic pain medicines?
- Alcohol?

Possible side effects:

These can be bothersome at times. But do not stop taking your medicine unless your doctor tells you.

(continued)

- You may experience confusion, weakness or clumsiness especially when standing, when you first take Triamterene and HCT.
- You may find that you are allergic to this drug and get a rash, hives and an increased sensitivity to sunlight (severe sunburn).
- You may have reduced appetite, excessive thirst, indigestion, stomach cramps, diarrhea, vomiting, headaches or blurred vision.

If these or other side effects bother you, call your doctor.

Call your Doctor:

If you have diarrhea or vomiting.

Please remember:

- If you want more information about this drug, ask you doctor for a more technical leaflet, the professional package insert.
- Tell your doctor *all* medications you are currently taking, whether they are prescription or non-prescription drugs.
- Keep this and all drugs out of reach of children.
- If there is a chance you are or will become pregnant or breast-feed a child, please contact your doctor before taking this drug.
- Keep this leaflet for further reference.

Mr. CHRISTY. To date, 45 MILS, representing more than 150 drugs, are being distributed through AARP pharmacies around the country. Prepared in conjunction with the Food and Drug Administration and experts in geriatric medicine and pharmacology, the leaflets tell the various names of the medication, what condition it may be taken for, and how it should be taken, possible side effects, food and alcohol interactions, and the information patients should tell their doctors before taking the drug.

Judging from the comments of our pharmacy service customers, the leaflets provide valuable information. More than 90 percent of those who responded to a recent survey conducted jointly by the pharmacy service and the FDA reported they found the information contained in the leaflets useful. Seventy-six percent of those responding said that they talked about the leaflets with their family and friends. When asked whether the leaflet made the people feel better, worse, or had no impact on taking medications, 42 percent reported feeling better about their drugs, while 56 percent said the leaflets did not change their opinion about taking their medication.

In June, the AARP News Bulletin published an article describing the MILS program and its evaluation. At the end of a two-column article buried in a 16-page paper, members were invited to write for copies of MILS by specifying the name or names of the medications in which they were interested. Over a 13-day working period, the pharmacy service received more than 5,600 requests for prescription information. We have made some of those letters [1] available to the committee, so you can see the type of mail we are getting on the issue.

The writers were interested enough to read the News Bulletin article——

Chairman HEINZ. We will try and get you a larger table next time. [Laughter.]

Mr. CHRISTY. We know this group takes prescription drugs, and probably is likely to take more than one prescription at a time. On average, each writer requested information on seven different medications.

A great deal more research is necessary before any definitive statement can be made about this data. Nevertheless, this outpouring of letters show that our members want prescription drug information and are not receiving it. When given the opportunity to request such information, they do so in great numbers.

Some say the prescription drug leaflets scare people so they stop taking their medications. Just the opposite is true. AARP members not only like the leaflets and read them, but armed with additional information, tend to feel better about the drugs that they take.

Beyond comprehensive patient drug information, AARP has long advocated more basic research and more educational courses on drugs and the elderly. Health professionals need to know more about geriatrics and pharmacology——

Chairman HEINZ. Mr. Christy, could you have your assistant share a few of those with the members of the committee?

Mr. CHRISTY. Yes, we will pass these out.

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[1] Retained in committee files.

Health professionals need to know more about geriatrics and pharmacology, more about the effects of drugs on people with diminished liver or kidney functions, or central nervous system sensitivity. AARP supports the FDA's efforts in developing Federal guidelines for testing drugs on the elderly. We urge the FDA to report those guidelines promptly.

Finally, Mr. Chairman, like the health care sector in general, the drug industry is characterized by inflationary costs. High-cost drugs are particularly painful for the elderly because they use more drugs than the under-65 population, and medicare does not pay the cost of outpatient drugs. This glaring gap in medicare coverage added over $110 to the elderly's per capita out-of-pocket cost in 1978.

AARP urges the Congress to close this glaring gap and reduce the cost of out-patient drugs to the elderly. But there are other ways to reduce the cost of prescription drugs. The AARP Pharmacy Services encourages members to ask their physicians to prescribe generic, rather than brand-name drugs, whenever possible. Consumers can realize significant savings from prescriptions that are written with generic equivalents. Unfortunately, the FDA has yet to propose final guidelines for approving generic drug equivalents to brand-name drugs coming on the market since 1962. This delay is costing American consumers millions of dollars in additional drug costs. AARP urges Congress to correct this situation, by legislation, if necessary.

Again, thank you for this opportunity to testify on this important subject. Our members are grateful for the efforts of both the Senate and House Aging Committees in behalf of the elderly.

Chairman HEINZ. Thank you, Mr. Christy, very much.

Dr. McMahon.

STATEMENT OF F. GILBERT McMAHON, M.D., DIRECTOR, CLINICAL RESEARCH CENTER, TULANE UNIVERSITY, NEW ORLEANS, LA.

Dr. MCMAHON. Thank you, Senator Heinz and ladies and gentlemen.

I am visiting here, or attending your committee this morning as a member of the American Society of Clinical Pharmacology and Therapeutics. It is a society founded in 1900, and made up of many scientists and physicians in the pharmaceutical industry, at the National Institutes of Health, the Food and Drug Administration, and primarily every medical school in the country has representatives in our society. We have over 1,400 members.

For myself, I am an internist. I am a clinical professor of medicine at Tulane Medical School, and since 1953, I have been studying drugs in man. So, for most of the last 30 years, I have been interested in primarily the evaluation of new drugs in people.

I agree with the general thrust and applaud the general thrust of your committee, that old people are different and need to be studied and treated specially. I was particularly impressed by the previous two speakers, representing the American Association of Retired People, but I can go even a step farther and claim membership in that organization.

I also was on Senator Kennedy's Commission on Post-Marketing Surveillance of Drugs for 3 years, and learned a lot about how drugs must be monitored after they are on the market.

I was also chairman last year of the Scheuer-Gore Commission, making recommendations to the Congress on simplifying some of the Food and Drug Administration's procedures.

I have a brief statement and would be happy to try to answer questions afterward.

Patients over 65 years of age constitute 11 percent of the U.S. population and consume 30 percent of prescription and at least 40 percent of all over-the-counter drugs. These data are from the 1982 New England Journal of Medicine.

Drug therapy in the aged is often complicated because of the consequences of aging per se, plus the frequent presence of multiple illnesses in the same patient. Therefore, it is not unusual for a patient to take five or six drugs at a time, that is, in 1 day.

Ideally, I believe a family member or neighbor ought to orchestrate and monitor such multiple drug therapy in the old people. I have heard a lot today, and you have, too, about polypharmacy, and the complications of old people taking a lot of drugs. I believe one way to monitor that accurately—and it is extremely important and very complex; a lot of my physician patients goof on how to properly take their drugs. It is easy to make mistakes when you take several drugs a day, around mealtime, or not around mealtime, some drugs four times a day, and some drugs twice a day, et cetera. But I think ideally, if there is an old patient taking this volume of drugs a day, that some younger member of the family or some benevolent neighbor can best monitor the drug consumption.

Mind you, I do not criticize people taking five or six drugs a day. The truth is, after 50—and certainly, after 65—one's body begins to deteriorate, and you have multiple diagnoses, and you need multiple drugs. I am mostly critical of people using drugs when not necessary. I believe that for many complaints, patients need no drug therapy at all, but obviously—I hope obviously—to every member here, particularly the Commissioners, drugs do more good than harm, by and large.

A female baby born today can live to be 82 years old; at the turn of the century, life expectancy was 42 years. A young male child can live to age 74 or 76 today; 40 years ago, it was more like 45 years of age. Drugs do more good than harm, so I am not here to condemn them, although I am here to caution about their use.

Elderly patients often require—in fact, usually require—smaller doses of drugs. Indeed, sometimes the usual adult doses may be harmful to geriatric patients. The Food and Drug Administration and industry ought to encourage the development of long-acting, simple-dose regimens, for example, once-a-day dosages of drugs. One of the new blood pressure pills we are studying in my group is a little patch, where you can give the patients antihypertensive medication once a week, not by mouth, but by a simple little skin patch. This is something that is going to happen in the future, and I think such developments that make treatment of old folks easier, must be encouraged by industry and by the FDA.

Packaging for elderly patients ought to be kept simple, and it is not. It is more complex today than it was a year ago. Non-child-

resistant caps ought to be used routinely for old folks' medicines, instead of vice versa. At our University Hospital at Tulane, old folks have to sign a release not to get a safety cap on their medication. It ought to be just the opposite for people 65 and older.

I brought a supply of caps, and of pills, and packaging with me. I was going to ask Senator Pepper to open one of the pill bottles if he could, because I find, personally, at my age—and I am almost 60—but I find old people have great difficulty opening the caps that are childproof, but also old people-proof.

Chairman HEINZ. You may have picked the wrong subject. I found there is very little that Senator Pepper cannot do. [Laughter.]

Dr. MCMAHON. I believe that. I agree with you. But I think he might need a knife to open a lot of the present packages. And also, the white-on-white labeling on the top of the cap is ridiculous, because as has been said so often, older people have difficulty in vision, and white on white is the wrong way to do it. At least make it black on white, so you know where the arrow is pointing.

Some clinical studies, I believe, of new drugs which are intended for use primarily in geriatric patients, ought to be required—in late phase 3—if they are intended for geriatric-patient use. So premarketing, I would encourage the Food and Drug Administration and the pharmaceutical industry to do more studies in old folks.

The public needs to be educated about drugs in general. The expectation that a drug is completely free of side effects, or that the Food and Drug Administration would permit only safe drugs on the market is terribly naive, and I have heard it implied this morning, and so have you. People can die of too much salt and too much water. Drugs are permitted on the market by FDA, and correctly so, when their benefits exceed their risks. Obviously, a cancer chemotherapy agent that can get on the market and cause a man or woman to lose their hair may well be acceptable if it kills cancer cells, but obviously would be totally unacceptable if it is for arthritis or for bursitis, or something relatively benign.

So, you cannot go just by side effects of the drug. All drugs that ever will come out will have side effects, and I think it has been overly exaggerated in the discussions this morning that drugs have awful side effects. Let us look at both sides of the coin. They are not allowed on the market in the United States unless the benefits exceed the risks. That does not mean some doctors do not misuse them. There is probably no one in this room who has been sued for getting a quack out of his State medical society for misusing drugs other than me. I have defended good medicine all my life. I have defended the Food and Drug Administration, but I have also sometimes been a critic of FDA. I think we have the best system, however, in the United States at the FDA than any other foreign system, and I have visited an awful lot of them, a few months ago in India, and in South America, and in Ireland, and all around the world. But we have the best system of judging whether drugs are beneficial and should be on the market or not.

As far as information about drugs, obviously, patients need more information. There are already good sources of drug information. The American Association of Retired People have excellent prescription information pamphlets. I would like to leave with you

what the American Medical Association has done. These are just a few. I have 20 with me. There are 60 of these patient medication instruction sheets produced by the AMA that will be available in another month, and they are clearly written for people who do not have a college diploma to understand something more about their drugs, and I think they are very helpful.

[The following was received for the record:]

PMI 037

Quinidine/Procainamide

Patient Medication Instruction Sheet

For: _____

Drug Prescribed: _____

Directions for Use: _____

_____

Special Instructions: _____

Please Read This Information Carefully

This sheet tells you about the medicine your doctor has just prescribed for you. If any of this information causes you special concern, check with your doctor. **Keep this and all other medicines out of the reach of children.**

Uses of This Medicine

Quinidine (KWIN-i-deen) and **procainamide** (proe-kane-A-mide) are most often used to restore irregular heartbeats to a normal rhythm and to slow an overactive heart. This allows the heart to work more efficiently. Do not confuse quinidine with quinine, which is a different medicine used for other purposes. Take this medicine only as directed by your doctor.

Before Using This Medicine

BE SURE TO TELL YOUR DOCTOR IF YOU...

- are allergic to any medicine;
- are pregnant or intend to become pregnant while using this medicine;
- are breast-feeding;
- are taking any other prescription or nonprescription medications, or if you have any other medical problems.

Proper Use of This Medicine

DOSAGE

Take this medicine with a full glass (8 ounces) of water on an empty stomach 1 hour before or 2 hours after meals so that it will be absorbed more quickly. However, to lessen stomach upset, your doctor may want you to take the medicine with food or milk. If you have any questions about how you should be taking this medicine, check with your doctor.

Take this medicine exactly as directed by your doctor even though you may feel well. Do not miss taking any of the doses and do not take more medicine than ordered.

This medicine must be taken every day in regularly spaced doses. If you miss a dose of this medicine and remember within 2 hours of the missed dose, take it as soon as possible. Then go back to your regular dosing schedule. Do not double doses.

(continued on reverse side)

Precautions While Using This Medicine

It is most important that your doctor check your progress at regular visits.

Before having any kind of surgery (including dental surgery) or emergency treatment, **tell the doctor or dentist in charge that you are taking this medicine.**

Some people who are extra-sensitive to quinidine may have side effects after the first dose or first few doses. Check with your doctor right away if the following side effects occur: breathing difficulty, changes in vision, dizziness, fever, headache, ringing in ears, or skin rash.

Side Effects of This Medicine

SIDE EFFECTS THAT SHOULD BE REPORTED TO YOUR DOCTOR

Less common

- Breathing difficulty
- Pains with breathing
- Change in vision
- Dizziness, lightheadedness, or fainting
- Fever
- Headache
- Joint pain or swelling
- Ringing in ears
- Skin rash
- Itching
- Hives

Rare

- Rapid heartbeat
- Sore throat and fever
- Mouth or gum sores
- Unusual bleeding or bruising

SIDE EFFECTS THAT MAY NOT REQUIRE MEDICAL ATTENTION

These possible side effects may go away during treatment; however, if they persist, contact your doctor.

More common

- Bitter taste
- Nausea or vomiting
- Stomach pain or cramping
- Diarrhea
- Flushing of skin with itching
- Loss of appetite

Less common or rare

- Mental confusion
- Unusual tiredness or weakness

Discontinuing This Medicine

Do not stop taking this medicine without first checking with your doctor, in order to avoid possible worsening of your condition.

The information in this PMI is selective and does not cover all the possible uses, actions, precautions, side effects, or interactions of this medicine.

This PMI is produced by the AMA, which assumes sole responsibility for its content. Appreciation is acknowledged to the other organizations that provided assistance and information to the AMA and, in particular, the U.S. Pharmacopeia.

HDA: 83-113(37): 1/83: 10M

Dr. McMAHON. There are a variety of sources of information about drugs, and people need more and more information, including physicians. I would agree they need to know more about drugs. But by and large—I am not negative about drugs—by and large, I think drugs are doing more good than harm, and if we try to look back 40 years and see the few drugs doctors had, how sparce their little black bags were—they were awfully generous with tender, loving care, and with housecalls, but their therapy was lousy. There were no antibiotics on the market before World War II. There were no tranquilizers, no antidiabetes drugs, except insulin. There was no treatment for tuberculosis, no treatment for mental disease, and there was very little other than tender, loving care in 1940. Today, tremendous therapeutic breakthroughs have occurred, and tremendous therapeutic advantage. Doctors can make people live longer and better lives. I think part of the team that should be and is involved in giving information to patients are societies like the American Association of Retired People, but do not forget the pharmacists. They do a tremendous job of helping educate patients, under sometimes difficult circumstances in crowded drugstores.

In our hospital, patients get their drugs from a pharmacist, and sit down and ask questions about their drugs, and are explained about their drugs by the pharmacists at the Tulane University Hospital before they are dismissed.

Anyway, I believe patients have a right to know about their drugs, and it is a complex issue, but thank you for having invited us.

Chairman HEINZ. Dr. McMahon, thank you very much.

We are indebted to all of you for some very expert testimony. I note that the AMA's drug information pad is somewhat different from the AARP approach to the same problem, which is, in turn, is somewhat different from the draft regs that FDA has proposed.

In looking over the AARP handouts, they seem to be a little easier to understand, a little clearer about the specific medications. The AMA handout does not appear to be as clearly laid out. Have you examined one of the AARP handouts?

Dr. McMAHON. Not in-depth. I have examined two I have here. But I think the challenge is how much information should you give. And the American Medical Association has listed a great many—in fact, all the common side effects of drugs, I believe, in the categories I have seen. Even more complex, of coures, is the physician package insert, referred to earlier—which, incidentally, is one of the five largest used books in the New York City Library, the PDR. All that information about the Physicians' Desk Reference, it contains tremendous information about drugs. I think it is accurate, and it is nonpromotional; and it must contain all the information, all the possible side effects.

Chairman HEINZ. I want to ask the panel about the PDR in a minute, but more to the point, is there any reason, as far as you or any other members of the panel are concerned, that the FDA should not proceed and draft final regulations that would require that these kinds of materials are available?

Dr. McMAHON. Yes, I would oppose that stringently, and we did.

Chairman HEINZ. Why would you oppose that stringently?

Dr. McMAHON. I do not believe the Federal Government is the source of all information, nor should be the answer to all medical problems in the United States. I think it is much better handled at the bedside by physicians. It is much better handled locally. Not all patients are made better by someone handing them a list of all possible adverse effects of drugs. A lot of patients would pin this—probably, my mother would do it—on the refrigerator, and check off the side effects as they appear, and perhaps develop side effects simply because of the suggestion here. Not all patients want to know.

Chairman HEINZ. Would you look at the AARP handout and see if you think it would have the same effect, of scaring people to death?

Dr. McMAHON. Yes, sir—I think they are good. I think patients have a right to know.

Chairman HEINZ. I know what you mean when you talk about inserts scaring people to death. I have sore knees, condra malasia patellae, and I was once prescribed some indocyne, and I read the package insert, and I immediately thought I was going crazy, because it said that one of the things that would happen was that I might—and in this line of work, you always wonder. [Laughter.]

Dr. McMAHON. I understand. Well, I think these are both commendable, but I would like not to see the Federal Government try to solve the problem and indeed, this is, I think, the present posture of the Food and Drug Administration and of the Executive.

Chairman HEINZ. Your view is that the Federal Government should do nothing?

Dr. McMAHON. No, sir.

Chairman HEINZ. What should they do?

Dr. McMAHON. The Federal Government should encourage, as I think the FDA does, education of patients. They do provide information, they do educate patients. I think they have made, and Dr. Hayes has made, great strides in public announcements to protect the public.

Chairman HEINZ. What should we who are in Congress do?

Dr. McMAHON. I do not think the Congress should be looked to to solve all problems in medicine. I think you ought to commend and encourage the production of new drugs. I bemoan the fact that people are dying of metastatic cancer, even in my family right now, and many other people around the world. But I believe in 40 years, if you encourage medical research and development, not discourage drug companies from scientific research and ethical medical research, but if you encourage it, I think in 40 years, cancer will be cured largely in America.

Chairman HEINZ. But does it discourage medical research to give consumers accurate, factual information about their drugs?

Dr. McMAHON. Of course not. Those who want it, I believe, have access and can get access to information. There are excellent sources of it. I think anyone could go to a library and get it.

Chairman HEINZ. What about drug labeling? The FDA's guidelines on drug labeling for medications state, as I understand it, that the directions for use only have to be put on the label if the doctor decides to give them to the patient. I have medication

here—Washington, D.C., being where we live—a prescription or medication that says, "Use as directed." In other States——

Dr. McMAHON. Right. That is probably because a doctor wrote, "Use as directed," and he probably explained it. Now, I suspect that is not cancer chemotherapy. It is probably not a potent drug. It is probably a cough medicine, or something. And he probably explained to the recipient of that prescription drug how to use it. If it is a potent, unusual drug—I believe there ought to be clear labeling on all bottles.

Chairman HEINZ. My point is that if you look at the labeling requirements in the 50 States, they vary all over the lot.

Dr. McMAHON. They do. And I think the States have monitored the way they are done in their States, and I think some States are a little behind. But does that mean the Federal Government should step in and tell each State how to do it? I do not agree.

Chairman HEINZ. I understand.

Now, let's talk about the PDR.

Dr. McMAHON. Please.

Chairman HEINZ. One of the most commonly prescribed medications, as I understand it, is Lanoxin, which is a form of digoxin. It helps strengthen the beating of the heart, slows it down, strengthens each beat, as I understand it. And apparently, it is a very useful medication.

Dr. McMAHON. Yes, sir. I have taken it.

Chairman HEINZ. In the PDR, there are sections on pregnancy, nursing mothers, adults, infants, and children; nothing on senior citizens, frail elderly, a population that, I think we can presume, is as much at risk as pregnant women or infants and children.

Now, Dr. Avorn and Dr. Lamy have suggested that there should be much more explicit testing and incorporation of indications for senior citizens. Do you think that is a good idea?

Dr. McMAHON. Yes, sir. My No. 7 recommendation is that some studies, particularly kinetic studies, of new drugs ought to be undertaken routinely on all new drugs intended for use in geriatric patients. Digitalis is a drug for the failing heart, primarily, and for certain cardia arrhythmias. People's hearts fail, by and large, in old people, not young people; people who use Lanoxin are generally geriatric patients.

Chairman HEINZ. Now, do you think there should be a Federal requirement along those lines?

Dr. McMAHON. Well, I think when most pharmacology departments and most medicine departments teach the subject of the use of digitalis and digoxin, and they demonstrate on the wards and with patients in the clinics, the proper dosage in geriatric patients becomes evident. Nevertheless, I think the renal excretion of digoxin diminish in elderly people, and they often need smaller doses. So I would concur, as I did in the statement, that drugs ought to be studied when they are intended for old folks; they ought to be studied in old folks more often.

Chairman HEINZ. But should the Federal Government require that they be studied?

Dr. McMAHON. I think there ought to be some requirements for drugs intended for old people to be studied before they are marketed for old people, yes, sir.

Chairman HEINZ. Let me ask our other medical experts, with no less respect to Jack Christy, who does not happen to have an M.D. after his name, if they have any comment either on the use of consumer literature or on the requirements for labeling of prescriptions given to individuals. Would you care to comment on that?

Dr. LAMY. Yes, Senator. I have a comment. I want to point out I am not an M.D., I am a Ph. D.

Chairman HEINZ. I apologize. So is Dr. McMahon.

Dr. LAMY. I like the AARP's program better because it is clearer. The influence of the FDA was very beneficial in helping get the data base together, but if you turn it around, you see that at the end of it, the FDA insists that the AARP list a statement which says, "If you become pregnant or intend to breast-feed a baby, be careful with the drug," and that is something that is directed only to elderly. Under that kind of system, we still work.

At the School of Pharmacy of the University of Maryland, we assign each incoming pharmacy student to an elderly individual living in the community, and they must follow them for 3 years. They like the kind of information, such as given by the AARP. It is clearer. I think the AMA message is a bit more scary than the one from the AARP. The elderly want information. I think they need information. We ought to give it to them, and if it takes something to encourage the FDA to do it, we should do so.

Chairman HEINZ. Dr. Avorn.

Dr. AVORN. The Rand Corp., at great expense to the Government, did an enormous study on the effect of patient package inserts on the way patients use, think about, and feel about their drugs, and one of the conclusions of this enormous study was that they do not seem to get scared and stop taking their drugs when given package inserts with them. When we talk about public policy, it is one thing to armchair what may or may not happen; it is another to go and do some good scientific research and find out what actually does happen, and I think Rand has done that for the Government, and has shown that it is not as scary or dangerous an affair as some people would claim. So I see no problem with it. I think that what it might do is open up more channels of doctor-patient communication. It is not at all a bad thing if one of my patients calls me up and says, "This pill you gave me last month—the leaflet I got with it says that it can make me nauseous. I just started throwing up; what should I do?" I would rather do that, than have to take care of the patient in the middle of the night in an emergency room, because they did not recognize the nausea is the sign of digitalis overdose, and ends up in a severe state of ill health because of it.

So I am in favor of that, and I do not think that we should be reluctant to say that the Federal Government ought to encourage, and in fact, mandate such kind of activity.

However, on the physician side of the equation, I would not take too much comfort in having a couple of lines about the elderly in the PDR, because as you can tell from leafing through it, this would not be something which really jumps out of the page at you. We need to think of more creative ways of getting information out of the doctors.

Chairman HEINZ. No. It would be very difficult for something to jump out of the page at you here, and I think one of the difficulties

is, if you kept this reference manual around, there are clearly an awful lot of drugs, a lot of information in it, and I for one am glad that I am in politics and not in medicine, even though sometimes what we prescribe is more far-reaching.

Dr. LAMY. Nevertheless, Senator, one out of three elderly we have talked to buy the PDR because they want information.

Chairman HEINZ. One out of three buy the PDR.

Dr. LAMY. Yes; they want information.

Chairman HEINZ. That is a remarkable statistic. How much does it cost?

Dr. LAMY. Is it $18 now—somewhere in that neighborhood.

Representative FERRARO. You qualify that with one out of the three that you have talked to?

Dr. LAMY. That we have talked to, yes.

Representative. FERRARO. All right.

Dr. LAMY. And we get 12 to 20 calls a day, I think, from elderly.

Chairman HEINZ. Well, my time has expired. I have some additional questions I would like to submit in writing.[1]

Congresswoman Oakar.

Representative OAKAR. Thank you, Mr. Chairman. Mr. Chairman, with your permission, I would like to just make a few comments and then reserve my time and add it on to the time I have with the FDA, because I think some of the material that you gave us in your testimonies today was very, very significant.

Dr. Lamy mentioned that he thought that at times, drugs are not adequately tested, and that there is not enough research done with respect to women. He cited a GAO report that verifies that whole area. Dr. Avorn, you mentioned some points about the advertisements versus scientific research, and the new drug testing. Jack Christy mentioned that he was concerned about the delay in the guidelines for generic drugs, which have been on the market since the early sixties, and we still have not seen any. Dr. McMahon said that we raise too much concern about side effects at this hearing. I do not know that too many of us have raised that. You mentioned that we have the best system in the world and that drugs would not be allowed to be on the market if they were not safe. Is that——

Dr. MCMAHON. Just the contrary. I warned you not to take that point of view. Drugs are not put on the market, I said, because they are safe. They are put on the market because the benefit appears to exceed the risk at that point of medical or scientific information available, which I hope you understand is a continuum. Science progresses, and 10 years from now, something safe today is shown not to be entirely safe later on.

Representative OAKAR. Oh, I see. But you think that of the drugs that are on the market, that the good that they do outweighs the risks?

Dr. MCMAHON. Yes, ma'am, I do.

Representative OAKAR. We should encourage more drugs to be on the market, particularly in areas of cancer.

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[1] See appendix, item 2.

Dr. MCMAHON. Yes; I think it is important that we have continued encouragement for medical research and progress in the treatment of heart disease, cancer, and mental disease, particularly.

Representative OAKAR. Well, I will tell you that I disagree with you that not all patients want to know. I think that is part of the problem, that they do not know, and that they wish they did know, especially after they have acquired some of the problems that relate to some of the drug abuse and the side effects. But I am going to reserve my time, with the Chair's permission, for the next witness, because they are last but not least, in my opinion, and I really would like to ask them some questions.

Thank you, Mr. Chairman.

Chairman HEINZ. Very well.

Congressman McCain.

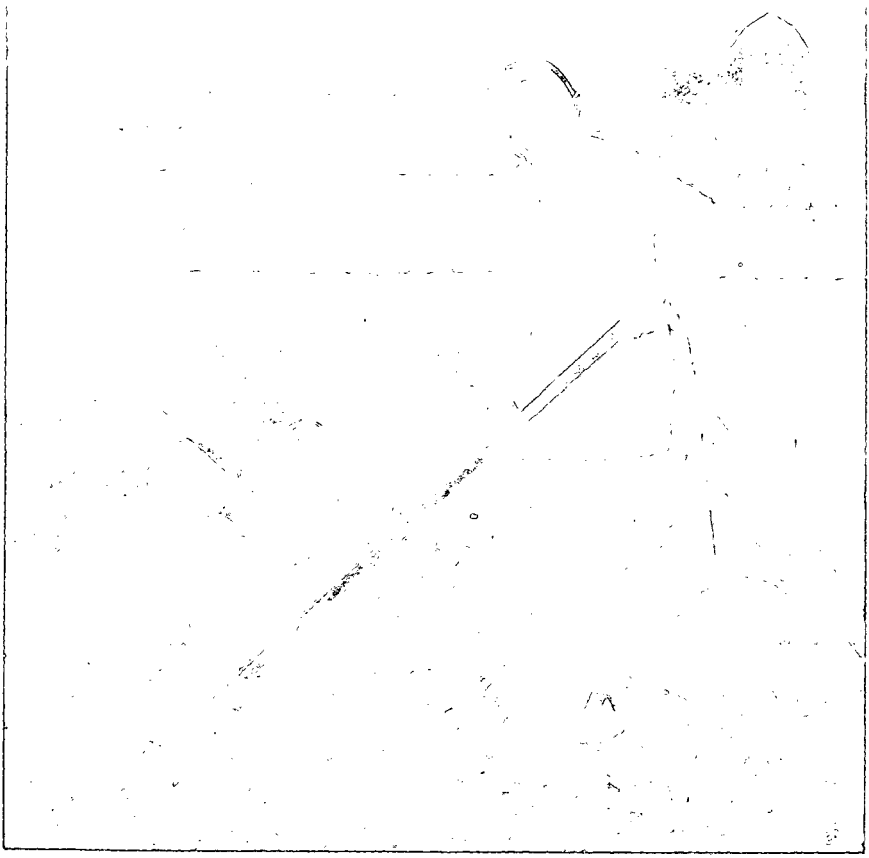
Representative MCCAIN. Thank you, Mr. Chairman.

Dr. Avorn, would you make available to my office your "unadvertising"? We would very much appreciate copies of that.

Chairman HEINZ. And to the committee record, so we can distribute it to members of the committee on both sides.

[The following was received for the record:]

Mrs. R is doing fine...
without vasodilators



Intermittent claudication is a familiar clinical problem facing physicians with large geriatric caseloads. "Peripheral vasodilators" nylidrin (Arlidin), cyclandelate(Cyclospasmol), papaverine (Pavabid, Cerespan, etc.), isoxsuprine (Vasodilan) and others have long been promoted for use in the management of this condition.

However, recent clinical evidence indicates that **vasodilators are not effective in the treatment of intermittent claudication,**[1-8] while regular exercise **has** been shown to improve symptoms somewhat.[3,9]

Peripheral vasodilators can't dilate vessels narrowed by atherosclerosis: cholesterol deposits and stenotic areas are major causes of peripheral insufficiency, and they are not affected significantly by these drugs.[1,2]

Ischemic muscle is its own best vasodilator: the build-up of metabolites from poorly-perfused muscle causes these vessels to dilate maximally (and automatically) with exercise. Drugs add little or nothing to this natural response.[1,2,4,5]

Vasodilator drugs could actually decrease flow to ischemic areas:
because they act systemically, such drugs would dilate many vascular beds, potentially further reducing flow to the highly resistant vessels supplying ischemic limbs.[2,4,5]

While short on therapeutic effect, the "vasodilators" can cause side effects,
such as hepatoxicity [papaverine(Pavabid, Cerespan, etc.)], postural hypotension [isoxsuprine(Vasolidan)], drowsiness [cyclandelate (Cyclospasmol)], and palpitation [nylidrin(Arlidin)].[1,2,4]

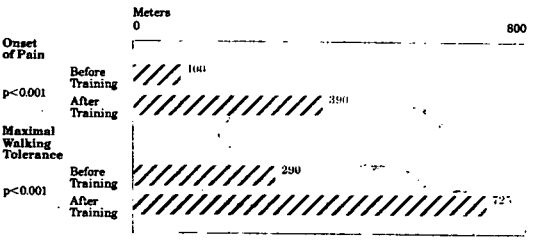
"Review of the clinical studies of vasodilator drugs in obstructive vascular disease reveals little substantive evidence to support their use. They are not effective in the treatment of either intermittent claudication or ischemic symptoms or signs at rest ... No drug has been shown to increase muscle blood flow during exercise when patients with intermittent claudication experience symptoms."[5]

(Coffman JD: Drug Therapy: Vasodilator drugs in peripheral vascular disease. New England Journal of Medicine 300:713-717, 1979.)

What's the Alternative?

Reports have appeared in the last few years demonstrating that **exercise can significantly improve symptoms in patients with intermittent claudication.**[3,9] One team of Swedish physicians studied 148 subjects with peripheral vascular insufficiency.[9] Patients took part in individualized programs of walking, running, dancing, and sports for 4 to 6 months. During training, exercise was stopped only for an excessive rise in pulse rate or anginal symptoms, **not** for leg pain. Here are their results:

Walking Tolerance in Patients with Claudication Before and After Exercise Training Program



Patients on the average **doubled** their walking tolerance. Improvement was independent of size or nature of vascular lesion, or presence vs. absence of diabetes.

Consider switching your claudication patients from vasodilator drugs to a program of graded, supervised exercise. Their symptoms (as well as their general health) may well improve ... and you'll be saving them up to $200.00 per year. That buys a lot of sneakers.

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- 2 SIDES -

This information has been prepared by the Drug Information Program of Harvard Medical School, under the direction of Jerry Avorn, M.D. A brief pamphlet for laypersons, "Exercise and 'Bad Circulation,'" has been written for physicians to distribute to patients in explaining the material presented above. For copies (specify number desired), and for additional information, please write to the Drug Information Program, Harvard Medical School, 643 Huntington Avenue, Boston, MA 02115. The Drug Information Program is supported in part by grant No. HS03880 from the National Center for Health Services Research of the Public Health Service, Health.

Representative McCAIN. Mr. Christy, I would like to take this opportunity, on behalf of thousands of people in Arizona, to thank you for the very valuable contribution that you have provided through the MILS program. I have seen it in action, and I have talked to many people who have a clear and concise understanding of the side effects and possible hazards of drugs that they are taking. It has, in many cases, been their only source of information. I would like to thank you for that.

I still am concerned about the tamperproof problem with prescription drugs and over-the-counter drugs, such as aspirin. Many of our senior citizens are deeply concerned and are even reluctant to buy some products because they cannot get them open—not only the white on white, but the entire process. Has the AARP addressed that problem at all?

Mr. CHRISTY. Yes, Congressman; first of all, thank you for your kind comments about the MILS program. We are very proud of the pharmacy service and the leadership role they are taking in drugs and the elderly.

About 90 percent of the customers who use the pharmacy service request that their prescriptions be filled in non-child-resistant packaging so that they can get to them. So this has been a priority of AARP for quite a while. Earlier this year, when we had the tragedy with the Tylenol case, we went early on to the FDA and started working with them to try and work out what might be tamper resistant yet elderly accessible. It got off to a fast start, and I am not sure where that program is now, but the FDA was moving on it to our satisfaction at the time, and I know the pharmacy service is continuing to work with them on the subject.

Representative McCAIN. Dr. McMahon mentioned that people have to sign a release in order to receive a non-tamper-proof prescription. Would you go along with his recommendation that it be just the opposite?

Mr. CHRISTY. Well, I believe that is Federal law, that you have to sign that release.

Representative McCAIN. But would you recommend a change so that they are not required to do that?

Mr. CHRISTY. Let me ask Nancy Olins, who works for the pharmacy service, how they are handling it.

Ms. OLINS. Well, as it is now, when people get their prescriptions from us primarily through the mail, they do have to check off a box when they are getting their prescription, saying that they do not want child-resistant packaging. We are, of course, concerned, though, about packages that might come into a home if a grandchild is there. We do not want to start saying, "No more child-resistant packages," and then have further problems.

So, if some kind of packaging can be designed—and we have been working with manufacturers, thinking about it—that is easier for older people to open, yet can still protect other members of the population, that is what we would ideally like to see out there.

Representative McCAIN. Well, I am sure it is very minor, but first of all, doing away with white on white is——

Ms. OLINS. I agree with you. That is a tremendous problem, and our own private-label packages take that into consideration, and the whole issue of tamper-resistant packaging, we are beginning to

see so many of these different packages come down the pike now—we do not like very much of what is out there. Every one of them that has come to us saying, "Gee, we think we have found something that the elderly can get into," we are not particularly enthusiastic about it and have urged everybody to go back to the drawingboards and keep working on this. We would like to see some kind of a pull tab that has a contrasting color, as you suggested, because we think that will be easier for them to open.

Representative McCain. Thank you. I just have one more question.

Dr. McMahon, why weren't generic drugs on the market earlier? Statements have been made here suggesting that they have been available since the early sixties. Yet, there has been some major obstacle to people obtaining them.

Could you comment on that, please?

Dr. McMahon. I think generic drugs ought to be permitted—and our commission made the recommendation to the Scheuer-Gore subcommittee. My attitude and feeling is that generic drugs ought to be permitted on the market only after they have been identified as being therapeutically equivalent or biologically equivalent to drugs that are on the market.

I do not want to economize on important drugs. When I lay in the coronary care unit at Tulane University, I was given quinidine sulfate, after I had just sent a book in to the publisher and was under a lot of stress a few years back. But I was getting quinidine every hour, and I was not responding. I asked the nurse, "What kind of quinidine am I getting?" She mentioned, "Phillips-Roxanne quinidine." I said, "Give me some branded quinidine. Do not save $1.98 when it is my heart, or my mother's heart, or my patient's heart—or anybody's heart." I like generic aspirin because you do not take aspirin, and I do not take aspirin, to save a life. But when it comes to important antibiotics, when it comes to heart medicine, or cancer chemotherapy, do not give me generics, unless they have been proven to be equivalent to the branded drug. That is my posture on generics. I think it is terribly important to save money wherever you can with medicines. But I think it is all of our responsibilities, and I think it is FDA's modus operandi, to require the proof of bioactivity, and too many generic drugs have been shown to be inferior. I do not want to save $1.98 and risk somebody's life. I think they are all entitled to the best medicine.

Representative McCain. Thank you, Mr. Chairman.

Chairman Heinz. Congressman Daub.

Representative Daub. Thank you, Mr. Chairman.

I really am fascinated by a thread of commonality in the witnesses who appear here. The Maryland program has its Elder Ed, the education program is one of the leading programs in the country. We have the Harvard folks talking about unhooking a lot of people from drugs, at least to explain and to educate them, and you have cartoon and picture types of leaflets that explain, I take it, to physicians as well as to patients.

Dr. Avorn. That is right.

Representative Daub. The Association of Retired Persons, in its MILS program—which I really do appreciate, and I know our elders in Nebraska do—is informing and educating, and the phar-

macologists, the pharmaceutical companies, the AMA, are developing handout fliers and education sheets on drugs and their side effects. FDA guidelines seem to play a little role in all of this.

With all of this going on—and I get back to the question I asked the previous panel—is there any one, central thing that the Federal Government ought to be doing?

Dr. McMAHON. That they are not already doing? I think the Federal Government is appropriately and necessarily involved in a function of policing the marketing of drugs, of labeling properly, drugs for safe use by the majority of people in this country. You complain about the size of the PDR, but your laws, the congressional laws, require that all information and all possible side effects be listed in the package inserts, and, therefore, in the PDR. That is why it is so bulky. I am glad it is there.

Dr. AVORN. I think, however, there are a number of things the Government could be doing. For example, if you look in the PDR, a large number of drugs that I think most pharmacologists would agree do not work, but were grandfathered in after the 1962 legislation, the regs now state that those drugs are to be labeled as not being as good as other drugs. But the wording that was agreed upon was possible effective. Now, it seems to me that possibly effective means maybe they work, whereas the National Academy of Sciences judgment for those drugs was that they do not work. I think that something very useful that could be done by the Federal Government would be to look again at the so-called desi drugs that have been on the market, despite repeated attempts to get them off the market, that sell very well, and are beloved by many doctors and patients, even though they are ineffective. We have no lower label than possibly effective. That is as bad a labeling as a drug can get in the current nomenclature. I do not think that communicates very well if the opinion of the National Academy of Sciences, upon reviewing it, is that it does not work; I do not think we ought to call it possibly effective. I think we should have some warning in there, somewhat analagous to the cigarette pack warning but, I would hope, more effective, that says, "This drug has been reviewed by the FDA and shown not to work," and then let the advertiser make whatever other claims they would like to make above that. Of course, it would be preferable to get such ineffective drugs off the market altogether.

Representative DAUB. Let me comment that in the House, if you heard some bells just a minute ago, we have a vote. So do not be offended, please, if a number of our colleagues here have to get up and go. I will finish before I do, and quickly, ask this last question.

Is it a multiplicity of responsibilities that are fixed, or is there a place where—a personal opinion from each of you, if you wish, very quickly—where we must place the ultimate responsibility for drug use, drug information, drug misuse? Is it the doctor, the pharmacist, the user, the consumer, the nurse, the hospital, or somebody in-between? Is there a primary place where we ought to put the responsibility for all of this?

Dr. AVORN. I think that would be an oversimplification. I think it is a pluralistic kind of situation, and we need to work at the level of the doctor, the pharmacist, the industry, and the patient.

Mr. CHRISTY. We would agree with that, and we would also say that the Federal Government has a primary role, especially in drug information. Patient package inserts is an important program that should be pursued.

Representative DAUB. Dr. McMahon.

Dr. MCMAHON. I agree it is a multifaceted responsibility.

Representative DAUB. I appreciate the opportunity, Mr. Chairman, and I thank the panel very much for their contributions today to this very good record.

Chairman HEINZ. Congressman Ridge, or Congresswoman Ferraro, do you have any brief points?

Representative FERRARO. I just have one comment, if I could. We just held hearings about 1½ weeks ago in my district office, on alcohol as a drug. I was wondering, in your research, if you have done any research on alcohol, as well, which I would like perhaps to have you share. Could you share that information with us, as well—not at this time—but in addition to that, any information you might have on whether or not prescription drug abuse is exacerbated by the use of alcohol, might also be something that this committee would like to look into.

I would like to ask all the doctors present—what we have done with this panel is deal with the problem of prescription drugs and labeling and finding out where things are coming from, but we never addressed the problem that Mrs. Zimny testified about. You have a doctor who is just prescribing this stuff and not paying attention to what he is doing, or the situation where you have a clinic patient who is going to several doctors and getting lots of prescriptions, and thinking that, if one is good, two must be better, and is taking everything that the man that she believes, or the woman she believes, knows more than she—those are things that we have not addressed, and I just wish that somehow you would be able to share, perhaps, in some sort of written comment, just what are your thoughts on that. I have got to run; I will be right back.

Thank you.

Chairman HEINZ. Congressman Ridge.

Representative RIDGE. Thank you, Mr. Chairman.

Mr. Christy, I sound a bit like an echo when I commend you and your organization for these informational sheets. I was thinking in personal terms about a grandfather, who is now deceased, who was similar to Mrs. Zimny, and had a variety of pills and medications. When you get into an elderly patient who is taking so much medication, and you give them one of these for each drug that they are consuming, based upon your experience and the letters—obviously, you get letters when you ask for information—but does your organization get a sense that, even though you are trying to do right by your people, and you are trying to do right by your senior citizens, that this sometimes could be counterproductive, when you get into a situation where you have an elderly person, when health is foremost on their mind, that is all they think about—that may be unfair, but I know in later years, my grandfather was particularly concerned about his health—at times, are these counterproductive, and are we putting a little bit too much of a burden on the elderly and maybe not enough focus elsewhere?

Mr. CHRISTY. I will turn that over to Nancy Olins, of the pharmacy service.

Ms. OLINS. Congressman, in questionnaires that we sent out, asking people if they have been helped by these leaflets, or if they thought the information was useful, we really found that they were very supportive of the efforts and appreciative of them.

I think we were concerned, really, before we really got into the whole program of doing these MILS, because a lot of people said, "If you give them too much information, they are not going to like it, and they are going to complain of every side effect, and you are going to get physicians who call you and say, 'Why are you giving my patient this kind of information?' "

We were really surprised to see that we did not get that kind of negative feedback, that when we have heard from physicians, they have been enthusiastic about them, and patients have, as well, and if anything, we have sought to educate them, not confuse them, and have not received any kind of communication saying that they have caused problems.

And I think, from looking at the number of letters there, that we would have heard from them if they did not like them.

Representative RIDGE. I am very pleased to hear that, because I think indeed, that just the educational role that you have undertaken with the senior citizens, when we talked about a pluralistic solution or involvement, is something that is commendable, and I again want to be part of that echo.

I was curious, and you did answer the question about whether physicians get more phone calls because of the listing of symptoms, and they are taking 8 or 10 medications; is it your sense that you are creating more communication—maybe that is good—more communication between the doctor and the patient?

Ms. OLINS. That is what we hope to do. You can see on everyone of them, there is a statement that says, "If these or other side effects bother you, consult your doctor." That is on there very specifically. In no way are we trying to replace that communication between the patient and the physician—only to enhance it.

Representative RIDGE. To encourage it, yes.

Dr. Avorn, you mentioned that we must come up with more creative ways to get information to doctors, about side effects, about whatever. I appreciate that the "we" being the private sector, the public sector, whatever, but do you have any specific suggestions—we could go into the high technology and maybe ask doctors and hospitals to put a computer bank in and have it all transcribed with what the potential side effects might be. Are you leaning in that direction? Is that when you are talking about creative ways? What are you pointing toward?

Dr. AVORN. Actually, on that front, my thoughts turn much more to a low-tech approach of using people and not machines.

When we set out to find out how we could, as part of a research project, get more information out to doctors, we took it as a rule-of-thumb that if the drug industry is doing it, it must work and be cost-effective, because otherwise, they would probably not be doing it. In the case of our own research, this amounted to sending individuals door to door to knock on doctors' office doors and say, "Hi, we think there is something you ought to know about drugs." We

modeled our program very much after the pharmaceutical industry, and that seemed to work very well. One would worry that it is expensive, but again, I do not think that if they were losing money on it, the industry would keep doing it. What we found, as I mentioned, was that one can show that the effect of this program, in terms of reduced expenditures by a program like medicaid, pays for the program. Here is one of those nice instances where you can improve the quality of care, and do cost containment, and save money at the same time, and chances like that do not come along very often.

Representative RIDGE. Thank you very much, Doctor.

I yield back the balance of my time, Mr. Chairman.

Chairman HEINZ. Congressman Ridge, I understand that you have a vote, and that you are going to have to really make tracks to make it.

One question that I have for Dr. McMahon regarding patient inserts. Presumably, patient inserts could easily be distributed by pharmacists. Your comment was that you think it would be a mistake for there to be a requirement that they be distributed, and as I understand it, you felt that that would be some kind of negative or harmful intervention of the Federal Government in the doctor and the patient, and that is why we should not do it. Is that the rationale for not doing it?

Dr. MCMAHON. I would like to phrase my reply a little differently than suggested. I think the Federal Government should not be interposed in the doctor-patient relationship. I think patients have a right to know. I think you have heard several systems described today by which patients can get information, and are getting information about drugs.

I think for the Federal Government to say, "This is the information they should get, and this is the way to do it and the only way to do it," is wrong. I think it must be tailormade and individualized.

I have had patients with cancer, working in a cancer hospital, who really do not want—and it was sort of the Congressman's implication about his grandfather over here, as I suspected anyway—they do not want the awesome burden of reading about all the side effects when they have serious diseases, and make the judgment that, indeed, this is what they want. That is a tough, tough thing when patients have malignancies, and they should not be dumped 10 patient package inserts where cancer therapy usually involves multiple drugs, often five drugs. Families should be involved, doctors ought to describe the details to the families, but not toss it on the patient unilaterally. I do not agree with that. I think that if the patient wants to know, they should be directly told. But I would leave those judgments not to the physician, but to the families, who are closer to those patients.

Chairman HEINZ. The Food and Drug Administration, as you correctly point out, uses an analysis of whether the benefits of the use of the drug outweigh the risks of the use of the drugs.

Why shouldn't we apply the same test to the dissemination of information about the drug to the patient, and what evidence do you have that the dissemination of information to the patient is in any way harmful?

Dr. McMAHON. All right. I might ask, before you create a system for universal use, the obligation of proving that the benefits exceed the risk for patient package inserts is on the people in the Congress, or whoever might dictate that—so I do not have negative information.

Chairman HEINZ. That is why I specifically asked you the question whether you have any evidence at all that information is hazardous to your health.

Dr. McMAHON. I would suggest it the other way around. Before you interpose a system on the whole American public, you ought to prove that it does more good than harm.

Chairman HEINZ. Dr. McMahon, I am not interposing anything. I am simply asking you for some information, so that we will have, as a start, a small piece of all the information we may need, and I will repeat the question.

Do you have any information at all that information is hazardous to your health?

Dr. McMAHON. No, no, sir. I have not done that study. I have not attempted to gather it.

Chairman HEINZ. But you have asserted, it seems to me, that somehow, it is not beneficial.

Dr. McMAHON. No. I think it ought to be individualized, and I think patients who want to know have a right to know, and I have said that in my prepared statement.

Chairman HEINZ. We have had on previous panels instances of patient-doctor relationships which, charitably, one might describe as less than ideal.

Dr. McMAHON. I suspect that is true of all professions, isn't it?

Chairman HEINZ. None of us in Congress have anything less than perfect relations with all our constituents. They agree with us 100 percent of the time, and we with them, with a few exceptions. [Laughter.]

Notwithstanding that, there are problems. You must recognize that. And my question is, what do we do about that? When I say "we," I do not mean we, the Congress; I mean we as a country, we as a medical profession, we as consumers, we as pharmacologists, we as people—what do we do? What should happen?

Dr. McMAHON. There are, unfortunately, as you said, a few people not deserving of their profession, and my illustration earlier was that we took the individual doctor's license away in Louisiana, who was doing more harm than good, and when indeed he, because he owned a hospital and was able to hire a great many foreign medical graduates, had a lot of money, hired a team of Chicago lawyers to come down and defend him. The Food and Drug Administration asked me to testify against him in Federal district court, and I was happy to. And the judgment of the 5th District Court in Louisiana was that this man should be banned, his hospital closed, and he be sent out of the State. That is what we did.

Chairman HEINZ. How much did that cost?

Dr. McMAHON. What did it cost? I do not know what it cost. I think I got $35 per day for 5 days in Federal court.

Chairman HEINZ. It is not easy to do, is it?

Dr. McMAHON. No, sir, but it is good to do, it is necessary to do occasionally, in the legal profession, the medical profession, even in the Congress, I understand.

Chairman HEINZ. If you were here, and I think you were—we, by the way, have a license renewal process that is set by the Constitution—you heard the testimony of Rose and Gloria Zimny.

Dr. McMAHON. Yes, sir.

Chairman HEINZ. What system, if any, should operate to slow down that kind of medical practice described? I would assume you would agree that that was not a very good example of professional medical practice.

Dr. McMAHON. I think Rose was describing malpractice, from what I heard, and I think the local medical society has a serious obligation to clean its own house, and I am disappointed they have not done it.

Chairman HEINZ. Well, we have a doctor from Massachusetts still at the table. Dr. Avorn, what is the matter? You are a member of the AMA——

Dr. AVORN. No, I am not.

Chairman HEINZ. You are not? [Laughter.]

Well, maybe I now know why—but why doesn't the medical society of Greater Boston, or whatever it is, do something?

Dr. AVORN. I think the track record of the profession in policing itself is terrible, and I do not see very much evidence that at the either State, local, or any other level, that the profession has been able to keep on top of the numerous cases that one hears about of people practicing bad medicine.

This case this morning was dramatic, but not, as Dr. Lieff said, at all atypical.

But there is another problem. I do not want to just catch the doctors who are doing that kind of thing to Mrs. Zimny. I think there is a lot of very inappropriate practicing that goes on that is not malpractice and does not require that somebody be disbarred from the profession, but it is just lousy care. And I would hope that we would come up with some way of correcting or improving that kind if mispractice that is far more widespread than the very widespread cases of disasters that one hears about. If we simply look back at history and see how well we have done policing ourselves, it is an embarrassing track record.

Chairman HEINZ. Would you agree or disagree with that?

Dr. McMAHON. Yes, and I would encourage the young Harvard physician to join his American Medical Association and do something about it.

Dr. AVORN. If I thought that joining the AMA would help, I would certainly do so.

Dr. McMAHON. I think your clear logic would help it.

Chairman HEINZ. I think that is a fascinating note to end on, and before we get you each trying to sign up the other, one for membership, the other for nonmembership, I think I will take this opportunity to thank all our witnesses who have come varying distances and, in every event, given us very thoughtful, provoking testimony. We thank you all for being with us.

Our next witness is Dr. Mark Novitch, Deputy Commissioner of the Food and Drug Administration. Dr. Novitch, before you proceed, would you please introduce your associates?

STATEMENT OF DR. MARK NOVITCH, WASHINGTON, D.C., DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY DR. ROBERT TEMPLE, ACTING DIRECTOR, OFFICE OF NEW DRUG EVALUATION; AND DR. LLOYD G. MILLSTEIN, ACTING DIRECTOR, DIVISION OF DRUG ADVERTISING AND LABELING

Dr. NOVITCH. Yes, I would be happy to, Mr. Chairman. On my left is Dr. Robert Temple, who is Acting Director of our Office of New Drug Evaluation, and on my right, Dr. Lloyd Millstein, who is Acting Director of the Division of Drug Advertising and Labeling.

Chairman HEINZ. Thank you. Please proceed.

Dr. NOVITCH. Thank you very much, Mr. Chairman. With your permission—I know the hour is late, and my statement is not very long, but I will try to summarize, and submit the entire statement for the record.

I appreciate this opportunity, Mr. Chairman, to discuss an issue which is of deep concern to all of us, and that is the safe use of drugs in older Americans. I would like to discuss four major areas in which FDA is playing an active role in improving the use of drugs in the elderly. In each of these areas, FDA has already taken what I think are important steps to deal with existing problems and to identify and deal with future ones.

The first is increasing our knowledge of the effects of drugs in the elderly. That problem has two aspects. One is the participation of elderly subjects in drug investigations. We need to be sure that any drug with potential usefulness in the elderly is, in fact, studied in that population, and that special parameters, such as decreased kidney function, which is common in the elderly, are appropriately evaluated. Second, we need to be sure that this information is included in drug labeling, so that physicians who treat the elderly will have it available to them.

There may be an impression, an impression, if it exists, I want to correct, that we have little actual knowledge derived from the use of elderly patients in drug trials. To the contrary, for some drugs—typically drugs used in angina pectoris, heart failure, or peripheral vascular disease—many, or even most of the patients studied will be 60 years old or older. On the other hand, there are certain impediments to the use of elderly patients in clinical trials. For example, these patients, as we have heard this morning, often may be taking, for valid therapeutic reasons, drugs other than the ones being tested, or they may have complicated or atypical disease states. Each of these factors limits substantially the utility of such patients as the subjects of clinical trials. I should note that we have underway a survey of recent new drug applications to document the age distribution of subjects in clinical trials conducted on these drugs. We expect to complete that study shortly and we will submit it for the record.[1]

[1] See letter from FDA in appendix.

Our existing guidelines on drug investigations specifically note the need to study drugs "in all age groups, including geriatric, for which they will have significant utility," but we are expanding these guidelines to provide more detailed recommendations for the study of drugs in the elderly.

Our current guideline is entitled, "General Considerations for the Investigation of Drugs." It already includes several directives that concern the study of drugs in the elderly, including requirements for the study of drug interactions, which has been mentioned this morning; drug metabolism; enzyme production; and protein binding—all areas of study that can signal potential age-related problems. But this guideline will be modified to deal with additional problems. Although the revision is still only in a preliminary stage, I think it would be useful to give you an early idea of the kinds of changes we think ought to be included. First, that it is of primary importance that the elderly not be excluded from the clinical testing of new drugs, particularly when the drug will have important use in that population. Exactly when in the development of new products it would be appropriate to include older patients needs further discussion, because of the many variables one faces with an older age group. The current guideline needs greater emphasis on that point.

Second, it is essential in analyzing the results of clinical studies to examine elderly subjects separately, to see if either effectiveness or safety differ by age group. That is sometimes done in drug investigations, but not always.

Third, drugs excreted by the kidneys should be studied in patients with varying degrees of kidney malfunction, so that the effects of such impairment on excretion can be defined, and appropriate dosage adjustments made. This requirement is pertinent to all patient populations but is especially important to the elderly, who often have some degree of kidney impairment.

Finally, we are considering a new screening approach called a "pharmacokinetic screen," under which we can detect potentially important differences among people in how a drug is metabolized. It will reveal, quickly and rather inexpensively, whether most subjects cluster around similar values, or whether there are marked variations that need further study. These variations could be due to age, to liver dysfunction, kidney dysfunction, or many other factors. While this concept bears wider discussion, we believe it has promise in allowing the early detection of these kinds of differences among people that can turn a useful drug into a dangerous one.

As I mentioned, obtaining data on how drugs affect the elderly is only part of the problem. We need also to convey what we learn to physicians who treat the elderly, as to well as the pharmacist. Here, the agency is giving increasing attention to the elderly in programs which relate to the professional labeling of prescription drugs. We are increasingly aware of the effects of age on metabolism, disposition, and adverse reactions, and we are engaged in a comprehensive program under which drug labeling for products in the marketplace—that is, drugs that have already been approved—is now being revised by manufacturers. As the revision program progresses to completion, increasing numbers and types of drugs will be carrying specific messages for use in the elderly. A look at

labeling for drugs often cited as problems for the elderly, I must add, already have distinct cautions or specific instructions for geriatric use. Others of the drugs that you looked at in the Physicians' Desk Reference—PDR—Mr. Chairman, would have special cautions and special instructions for either dosage or the other considerations in treating the elderly with those drugs.

We have other sources of drug information on the elderly apart from clinical trials. Chief among these are postmarketing surveillance activities in the National Center for Drugs and Biologics. They include four general areas of activity: The spontaneous case-reporting system for identifying new, unusual, and rare adverse drug reactions. These case reports usually contain, at the very least, the patient's age, and I can tell you that we receive about 30,000 to 35,000 of these case reports each year. We have roughly 160,000 case reports from physicians and institutions and other sources in our files and being analyzed.

Second, the analysis of drug use based on information obtained from multiple data sources, such as the IMS America, which makes marketing data available to us, and from State medicaid programs which monitor the use of drugs in that population and report the data to us from at least two States.

Third, the use of epidemiologic methods to identify potential drug-related problems and provide supportive information on previously identified problems with drug therapy, such as information generated by the Boston collaborative drug surveillance program and the drug epidemiological unit of Boston University.

And last, the use of case reports from poison control centers that can identify potential problems resulting from poisonings or overdoses.

The information derived from these sources is used as a part of the FDA's regulatory decisionmaking process, and it also provides a means of furnishing updated information on drugs to the medical and scientific communities.

We report these findings and cautions and other important information in our Drug Bulletin, which reaches over 1 million physicians, pharmacists, and other health professionals. It is published four to six times a year, and each issue contains between 5 and 10 items of importance relating to some drug problem or issue.

Mr. Chairman, it might be useful to submit for the record some copies of the Drug Bulletin.[1]

Chairman HEINZ. The committee is pleased to receive them. Thank you.

Dr. NOVITCH. The information on drug safety developed as a result of postmarketing experience is relevant to all populations and can identify problems that are age-influenced. For example, in 1981, our surveillance bulletin, called "ADR Highlights," which I will also submit for the record,[1] focused specifically on the association of Clonidine, a potent antihypertensive, with hallucinations in elderly patients, and others of ADR Highlights do the same thing. Much of the information generated is either drug specific or medical problem specific, and insofar as the drug effect is accentu-

[1] Retained in committee files.

ated by age, the materials become extremely important to the elderly population.

In the past 2 years, we have begun looking at available data resources for drug reactions which may be specifically related to aging. Several projects are underway in the FDA to look at drug use trends in the elderly, and we are analyzing, by age, adverse reaction case reports already accumulated.

There is a third activity which we believe can also promote the safer use of drugs in the elderly, and that is patient education. We are just beginning a new approach to provide drug information directly to the elderly. In July, in fact, next week, an FDA patient education insert will accompany all social security checks that will reach as many as 36 million people. The insert will alert these people to the kinds of information that they should have about prescription drugs, and will advise them to ask their physician or pharmacist about their medication. The insert also offers a free brochure, entitled, "Here Are Some Things You Should Know About Prescription Drugs," if the patient writes to the Government's Consumer Information Center.

Chairman HEINZ. Do you have copies of that with you?

Dr. NOVITCH. Yes, we do. This is the insert that will go with the social security checks, printed on both sides, and I will summarize what it says.

Chairman HEINZ. Well, I would like to see it.

Dr. NOVITCH. Yes, indeed, and this is the brochure.

[The following was received for the record:]

A Message About Taking Medicines Properly—

From the Food and Drug Administration

Prescription drugs can do much to cure illnesses, maintain health, and relieve symptoms. But they must be taken correctly to do their job.

Yet studies show that as many as half of the people taking medicines aren't taking them properly. Often patients don't know enough about their prescriptions or how to take them.

If you are on a prescription drug, be sure you know—

- The name of the drug.
- Its purpose—what condition it treats?
- How and when to take the drug and when to stop taking it.
- What food, drinks, and other drugs to avoid while taking it.
- What side effects may result—are they serious, short-term, long-term, etc?

If you have any questions about your prescription, *ask your doctor or pharmacist.*

For a *free brochure* about prescription drugs, write to:

Rx Drugs
Department 62
Pueblo, Co 81009

Chairman HEINZ. I will share it with the other members of the committee. Please proceed.

Dr. NOVITCH. The insert also offers a free brochure entitled, "Here Are Some Things You Should Know About Prescription Drugs," if the patient writes to the Government's Consumer Information Center. We expect that the insert and brochure will receive wide readership and will result in more and more intelligent questions being asked of health professionals. The insert and the brochure will concentrate on four basic questions that should be discussed by patients with their physicians on each prescription that they use:

What is the name of this drug and what is it supposed to do?

How and when do I take it, and when do I stop?

What food, drinks, or other drugs or activities should I avoid while I am on this drug?

What side effects might occur, and what should I do if they occur?

To capitalize on the impact of this insert, we have planned a major public communications campaign. It will include a series of print ads that will be sent to 9,000 weekly and daily newspapers and magazines; a mailing that has, in fact, gone out to 120,000 physicians, mostly primary care physicians, but some cardiologists, informing them of the social security insert and the brochure; a letter to some 3,500 health editors of daily and large weekly newspapers and magazines, as well as the program directors of television stations in the top 50 markets in this country; and "live" copy to be read and sent to 6,500 radio stations at the end of the month—that is, the next couple of days. And in July and August, we plan to distribute to some 4,000 supermarkets a brochure on the theme, "Go Ahead—Ask Your Doctor or Pharmacist," and again, offering the prescription drug reprint through the Consumer Information Center.

We will be watching very closely, as I am sure you will, the effect of that advertising campaign and that mailing to social security recipients, and in my experience, I do not think any other agency has done anything quite like it before.

Another avenue of patient education is FDA's Committee on Patient Education, which was established in January 1982. Its goals are twofold: To coordinate the Government's efforts, to advise consumers about prescription drugs, and to serve as a catalyst for private sector initiatives in this area. In addition, FDA is a founding member, as you have heard, along with many medical organizations and pharmaceutical companies, in the National Council on Patient Information and Education, the so-called NCPI, which is chaired by former Congressman Paul Rogers. The council is a nongovernmental group whose goal is to stimulate patient education program development for the entire population, including the elderly.

I would like to mention certain efforts by private groups—efforts in which we have actively participated—to disseminate patient information. Information about drugs is now being distributed, as we heard in some detail, by the American Association of Retired Persons, through its pharmacy service, as well as by physicians, through the AMA's patient medication information program. We

have worked closely with both groups to encourage the development of these efforts, and we have been especially involved with the AARP in the preparation of what we believe are easy-to-understand leaflets which are available to their customers at the time prescriptions are filled.

There are some activities in the Department of Health and Human Services. The Department has an ongoing interest in health promotion and disease prevention, and is planning a major national campaign to promote "wellness" and encourage people to adopt healthier lifestyles. In addition, Secretary Heckler has formed a special task force on Alzheimer's disease and has directed all HHS agencies to share information and work together to speed the translation of research findings into policies and programs to improve the quality of life for the elderly.

Beyond that, the Public Health Service and the Administration on Aging are working together to develop recommendations for primary health promotion activities for the elderly, and a special group established to explore drug use and misuse, has completed its work. The group has reported several recommendations, most of which go along the lines that FDA has already engaged in; that there be concentration on specific physiologic and pharmacodynamic responses to drugs in the elderly; that there be increased drug surveillance studies in the elderly population; better drug testing in the elderly; studies of prescribing patterns by physicians to the elderly; and effective educational techniques with the elderly.

The working group concluded that many of the activities which could be affected by their recommendations involved existing PHS programs that will need special targeting and emphasis by agencies, including the Food and Drug Administration.

Apart from the drug use working group, the PHS will be working with a number of other agencies on several projects, such as accident prevention, injury control, nutrition, physical fitness, and exercise.

Despite these numerous and diverse efforts, clearly, more needs to be done. Not all drugs with potential use in the elderly are tested in them. Not all drugs contain in their labeling appropriate physician instructions on the proper use in the elderly. We can do more to provide useful and meaningful information specifically to elderly patients on their special problems. We are sensitive to the problem. We will continue our present efforts and develop new ones until we have the necessary solutions. We will have to make sure that testing includes elderly subjects when appropriate. We have to be sure that the labeling of both over-the-counter and prescription drugs is improved. We have to emphasize among physicians and pharmacists special care in drug use among the aging. We have to educate consumers, elderly consumers in particular, to ask the right questions about the drugs that they use. We have to expand post-marketing surveillance, and I can tell you, we are engaged in all of those activities.

Mr. Chairman, Ms. Oakar, that concludes my statement, and my colleagues and I would be happy to answer any questions that we can.

Chairman HEINZ. Dr. Novitch, thank you very much.

Certainly, you are doing a number of things, and in your concluding remarks, you certainly mentioned all the right things to mention—testing against the elderly groups where the drug is relevant; better labeling of the specific prescriptions for the user; special emphasis on making sure that pharmacists and doctors know more; education of the consumer; the senior citizen; and more postmarket surveillance. All of those are commendable. I suppose the real question we need to ask you is the extent to which those are effective.

Let us talk first about premarket clinical testing. You say you would like to do more research on relevant population groups, the elderly. Are you talking about a cross-section of the elderly, are you talking about that group of the elderly that is most at risk, which we often refer to as the "frail elderly"?

Dr. NOVITCH. Well, first, let me say in response to your earlier comment, Senator Heinz, I did not mention those in the abstract. We really are working, and I assume that you will go down each of those, and I would like to tell you what we are doing.

Chairman HEINZ. Yes, and if I run out of time, I am sure that my colleagues up here will continue to draw out every conceivable amount of information in each of those areas, one way or another.

Dr. NOVITCH. What I meant to say, and hope I said in my statement, was that the drugs are tested in the elderly. We have scanned a number of recent new drug approvals and found that patients over 60 or over 65 are well represented in the test subjects in which those drugs were tested. What we are saying, by developing——

Chairman HEINZ. At that point, because this is central to my question, we had testimony earlier that suggested that women are underrepresented in your testing, simply because there are so many more women over age 65 than there are men.

Dr. NOVITCH. Well, women have to be excluded in some of them. Pregnant women will be excluded in the testing of a drug, the effects of a drug——

Representative FERRARO. Not too many of those are over 65, though, are they?

Dr. NOVITCH. No. You were not talking about the aging; you were talking about women, generally, were you not?

Chairman HEINZ. I was talking about women over age 65, because females outnumber males considerably for the over age 65 population.

Dr. NOVITCH. I am not certain that women in the elderly age group are systematically excluded or diminished in their participation——

Chairman HEINZ. No; the question is whether you have a sample that is sufficiently representative.

Dr. NOVITCH. For any particular drug?

Chairman HEINZ. For a senior citizen population. That is my question.

Dr. NOVITCH. I think that in the testing of drugs, particularly where they are used by the elderly, we have sufficient representation of the elderly. Whether we have enough significant numbers of women and men, so that you could break out those populations separately, I am not sure. Perhaps Dr. Temple could——

Chairman HEINZ. Well, the question is whether the population of the elderly you have is representative of the elderly population. Your sample may not reflect the way things are in life.

I do not understand why that is such a difficult point to grasp.

Dr. NOVITCH. It is not a difficult point to grasp. I just believe that the representation of the elderly, both women and men, in drugs that are most commonly used by——

Chairman HEINZ. Why don't you get some information on that and submit it to us, rather than guess one way or the other? [1]

Let me get back to my question, which was this: A significant proportion of the 30 or 40 million elderly we have are so-called "frail elderly." There has been a lot of testimony—you have heard some of it today—that suggests that the effects of those drugs, the side effects of those drugs, are much more pronounced on more senior, more frail elderly.

Now, the Food and Drug Administration routinely administers a benefit-to-risk test. Is it your view that the Department is in the process—clearly, it is not, up to this point—in the process of adequately assessing the benefits versus the risks for senior citizens, who are going to experience more difficult, more dangerous side effects?

Dr. NOVITCH. I do not want to pretend that the testing in the elderly has been as adequate as you or we would like to see it—else we would not be developing and seeking to put in place more detailed and specific guidelines for the testing of the elderly.

Chairman HEINZ. You are relying mainly, now, on postmarket surveillance, are you not?

Dr. NOVITCH. Well, we rely on postmarketing surveillance, but we also rely, for the development of new drugs, on clinical data, as well as preclinical data. For the clinical data, at least, we rely on subjects in age groups for which the drug is intended. It stands to reason——

Chairman HEINZ. On those tests on the new drugs, do you know if that subgroup that we might classify as the frail elderly is broken out and looked at separately?

Dr. NOVITCH. I would be misleading you if I told you I had that information. I know they are tested on the elderly——

Chairman HEINZ. I see one of your colleagues shaking his head.

Dr. TEMPLE. No, it would not be broken out that way. I think you have to ask what you mean by "frail elderly." The reasons that an older person gets into trouble with a drug may not be that different from the sorts of reasons that cause a younger person with the same problem to get into trouble with a drug. We have heard a lot of testimony to this effect. But one of the things that makes an elderly person frail is that his kidneys tend not to work as well as a younger person. So, one of the things we often—but not often enough, I think—do look at is what the effect of impaired kidney function is on the handling of a drug. Now, once you know that, you have got a lot of important information that will help you use the drug in an old person, if you take the trouble to learn what that older person's renal function, kidney function, is like.

[1] See letter from FDA in appendix.

So I do not think the category of "frail elderly" is specific enough for anybody to have broken it out, but if you wanted to do so, you would look at people with impaired kidney function, you would or could look at people with impaired liver function. You could look at people who are unusually fat or unusually thin, to see if there are differences in the way drug is——

Chairman HEINZ. Do you do those kinds of breakouts?

Dr. TEMPLE. No, not yet.

Chairman HEINZ. Should you?

Dr. TEMPLE. Yes.

Chairman HEINZ. Why don't you do them, if you should do them?

Dr. TEMPLE. Well, we are developing at the moment guidelines which will, among other things, require that sort of thing. I can expand on some of the subjects we are thinking of.

In scanning the literature on what kinds of difficulties the aged get into, it is conspicuous that most of the drugs that cause problems do so because they are not excreted or metabolized in the elderly the same way as they are in younger people. It could also be that there are some drugs that, even with the same blood level, act differently in the elderly, but by far, the most prominent problem is that the drug levels in the elderly are different—that is, the elderly patient does not get rid of the drug fast enough, so more accumulates. What that means is that if you knew a great deal about the blood levels in the elderly, or in some cases just in people with abnormal kidney function, you would know a great deal of what you need to do to adjust the dosage.

There is no present requirement in any of our guidelines or regulations specifically to examine the effect of abnormal kidney function on blood levels. Now, that is not to say it is not done. For drugs that are known to be toxic, it is done, and in fact, I believe it is fair to say the best advice on how to adjust the dose of certain particularly toxic drugs like the aminoglycoside class of antibiotics—that is drugs like Kanamycin—it can be found in the package inserts that are developed now, with very specific guidance for adjusting the dosage for each level.

The example you gave before of Digoxin or Lanoxin—it is quite correct that there is no specific comment about age, but there are several column inches about what to do to account for the patient's renal status, which is probably the most important thing you need to do in an elderly patient. You need to make the correct adjustment. There is even a formula which many physicians, I think, probably do not know, for how to calculate a measurement called the creatinine clearance without actually doing the measurement, because it is a very difficult measurement that cannot really be done well unless you hospitalize the patient, so there is a way to take a simple measurement called serum creatinine and make an approximation of the creatinine clearance by adjusting for age and weight. I think one of the first things to emphasize in a new guideline is that information on dose adjustment in renal failure needs to be obtained for every drug that is excreted by the kidney. It is one of the most important things we can do. So that will be the number one thing. It is of general benefit to everybody with kidney problems, but it is particularly useful to the elderly.

Chairman HEINZ. I thank you. I think that gives us a better idea of what you are trying to do.

My time is long since expired.

Congresswoman Oakar.

Representative OAKAR. Thank you, Mr. Chairman.

First of all, Dr. Novitch, I want to submit for the record a New York Times article.

[The article referred to follows:]

[From the New York Times, June 28, 1983]

WARNING ON PROPER DRUG USE

(Special to the New York Times)

WASHINGTON, June 24.—Social Security beneficiaries may be surprised to find a message from the Food and Drug Administration with their July checks. "Prescription drugs can do much to cure illnesses," the F.D.A. insert says, "but they must be taken properly to do their job. Yet studies show that as many as half of the people taking medicines aren't taking them properly."

The F.D.A.'s advisory, which will reach 36 million people, encourages patients to question their physicians and pharmacists closely about medications. The mailing is part of a national campaign by Government and private groups to increase communication between patients and their physicians and pharmacists.

A December 1982 poll by Chilton Research reported that nearly 70 percent of the respondents were not told about the proper use of their medicine or possible side effects. Only 2 to 4 percent of the patients said they questioned their physicians.

In a survey of health professionals last month, Louis Harris & Associates found that physicians presumed patients were well informed because they did not ask many questions.

More than 90 percent of the physicians said they gave adequate instructions to patients. However, when questioned about their instructions on specific drugs, the physicians indicated that they failed to provide sufficient information. Only 7 percent of the physicians, for example, said they told patients they had to finish their prescriptions of tetracycline in order to complete the drug therapy.

"We're trying to resolve the communications gap," said Robert Bachman, spokesman for the National Council on Patient Information and Education, a nonprofit Washington group coordinating the campaign.

The Health Research Group, founded by Ralph Nader, has recently published a book about nonprescription drugs. "Over the Counter Pills That Don't Work" describes the causes, symptoms and cures of health problems ranging from coughs to weight loss. The 302-page book, principally written by physicians, suggests nonmedical treatments for various problems and gives advice on when to consult a health professional.

The book also recommends certain over-the-counter drugs and their generic equivalents that the F.D.A. has determined to be safe and effective. The consumer group, however, recommends against using many nonprescription drugs not yet approved by the agency.

The F.D.A. has not yet ruled on many drug ingredients because they were marketed before the 1938 Federal laws that require drugs to be safe. Only in 1962 did Congress tell the F.D.A. to require that drugs be effective as well as safe.

The F.D.A.'s advisory committees, which have reviewed test data on nonprescription drugs, have reported that only about one-third of the ingredients were proven safe and effective for their intended uses.

Edward Nida, an F.D.A. spokesman, said: "Major products tend to have both effective and ineffective ingredients. The F.D.A. permits continued use of ingredients which lack proof of their safety and effectiveness while companies perform tests to substantiate their claims. However, when safety problems have emerged, the F.D.A. has acted to remove the ingredients from the market.

Dr. Jere Goyan, F.D.A. commissioner during the last two years of the Carter Administration and now dean of the School of Pharmacy at the University of California in San Francisco, has endorsed the group's book stating that it is "an important contribution to consumer education and I recommend it to every concerned American."

The $7 paperback is available only by mail from the Health Research Group, Department 22, 2000 P Street NW, Washington 20036.

Representative OAKAR. What I am concerned about, and I have been not only through the tenure of this administration, but historically through other administrations, is the testing that is done and the postmarketing surveillance.

Let me ask you if this is my understanding of FDA's mission—that it is to assure the safety and effectiveness of drugs and that you address this responsibility with clinical evaluations before new drugs can be marketed, labeling requirements at the time of marketing, and postmarketing surveillance. Is that pretty much how you see your responsibilities?

Dr. NOVITCH. Basically, yes.

Representative OAKAR. I want to ask you specifically about a couple of drugs, just to highlight some points that I want to make. Let me ask you to submit for the record, if you will—I do not think you will have this information—you receive 30,000 to 35,000 adverse drug reaction reports per year, I am told, and if you could, I would like you to submit for the record of this joint hearing the names of the five drugs that have generated the most frequent complaints and the number of reactions reported for each drug. Would you do that for the record?[1]

Dr. NOVITCH. Yes, I would be happy to.

Dr. TEMPLE. Forever, or for the last year?

Dr. NOVITCH. Ms. Oakar, the question is for what time period would you like that?

Representative OAKAR. This year.

Dr. NOVITCH. OK.

Representative OAKAR. Within the past year. I think that will give us an example.

Just for the record, you have at FDA a drug experience file, and at times you receive voluntarily complaints from consumers. Is that not correct?

Dr. NOVITCH. That is correct.

Representative OAKAR. Now, with respect to an FDA-certified drug called Zomax, which was certified in late 1980—I know it is off the market now—you ruled or judged that that was safe and effective at the time for the treatment of arthritis. Correct?

Dr. NOVITCH. Right.

Dr. TEMPLE. Actually, principally, for the treatment of pain.

Representative OAKAR. How many people did you test?

Dr. NOVITCH. I think, rather than just switch the microphone back and forth, Dr. Temple is head of the team that evaluated Zomax and was responsible——

Representative OAKAR. Actually, you do not test them, do you?

Dr. TEMPLE. No.

Representative OAKAR. No. The drug companies do the testing, and you monitor what they say has taken place; correct?

Dr. TEMPLE. That is right.

Representative OAKAR. Is it pretty close surveillance?

Dr. TEMPLE. Well, we monitor what they do mostly by reading the reports, OK.

Representative OAKAR. Oh. I see.

[1] See letter from FDA in appendix.

Dr. TEMPLE. We read the reports that they make afterward. We look, to some extent, at what is called the raw data that is collected, the actual numbers for each patient, and we also have a field inspection for at least several of the principal clinical studies, the ones we deem most important.

Representative OAKAR. Well, in the case of this testing, how many individuals were tested?

Dr. TEMPLE. The number was something like 3,600. That is unusually large, and I should point out——

Representative OAKAR. Unusually what?

Dr. TEMPLE. That is unusually large.

Representative OAKAR. Large?

Dr. TEMPLE. Large. It is atypically large.

Representative OAKAR. Well, how many do you usually test?

Dr. TEMPLE. The normal number would be closer to 1,000 to 1,500, I would say.

Representative OAKAR. Oh. Just about 1,000 people, and if more people react favorably than less, it is on the market. Is that the way it works—you read the report, and——

Dr. TEMPLE. I do not think I would put it that way. There are studies that are carried out that meet standards for controlled trials, as required by the law.

Representative OAKAR. Maybe you would like to submit for the record the studies that were carried out for Zomax. Could you do that?

Dr. TEMPLE. Sure. I guess I have some questions about what form you would like them in.[1]

Representative OAKAR. Well, we will get together after the hearing, and I will be happy to tell you.

How many of these individuals who were tested were elderly?

Dr. TEMPLE. I cannot answer that.

Representative OAKAR. Wasn't it more typical that you tested 25-year-old, 175-pound, healthy men?

Dr. TEMPLE. No, that is completely wrong.

Representative OAKAR. What percentage was——

Dr. TEMPLE. The drug was tested for both pain and for arthritis, which is a kind of pain. Arthritics are more likely to be women than men, so that trials of this kind of drug tend to have a relatively large representation of women, and the people who have this kind of disease tend not to be young men.

I can tell you a little bit about the population that was studied with Zomax, I think—no, I cannot. I do not have a figure on that. Zomax is a member of a class of drugs called nonsteroidal anti-inflammatory drugs. The typical patient would be in the forties, fifties, or sixties, not in the twenties——

Representative OAKAR. Are you telling the committee that the typical individual tested was in the forties or fifties?

Dr. TEMPLE. For Zomax?

Representative OAKAR. Yes.

Dr. TEMPLE. I cannot speak to Zomax, because I am not looking at it. I can tell you some numbers on other drugs.

Representative OAKAR. I am asking about this one.

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[1] Not received by committee.

Dr. TEMPLE. You would like the age distribution?

Representative OAKAR. That is right, because you mentioned that you felt strongly that elderly should be included separately. And arthritis, pain-related arthritis, is a disease that is at times, at least, associated with being older. Is that not correct?

Dr. TEMPLE. Yes. I agree that the elderly should be represented in a study of that class of drug.

Representative OAKAR. Well, how do you reconcile the decision that the drug was safe and effective when thousands of individuals, more than 5,200 people, indicated that they had tremendous adverse reactions to this drug, and 40 deaths were associated with that?

Let me just submit for the record this printout. Now, these are just the people who voluntarily submitted to FDA the fact that they had some reaction. We know that GAO reported a 5-month backlog when we were trying to get this, and you are entering complaints last year. So we do not even have an up-to-date printout.

But if my colleague would help me, I just want to show you what we are talking about here. We got the names of the numbers of people who complained about this drug, and you indicated that you have a postmarketing surveillance requirement. How long did you survey this before you decided to take it off the market? I am going to submit the whole list for the record [1]—this is not all of them, but this is about 5,200 names.

How many did you decide that you had to hear from before you exercised your administrative authority to recall a drug?

Dr. TEMPLE. Well, actually, we did not recall the drug at all. The drug company removed it from the market.

Representative OAKAR. Oh, I see. You did not have anything to do with that decision?

Dr. TEMPLE. I would not say that, but it was their decision.

Representative OAKAR. Oh. Did you encourage them to take it off the market?

Dr. TEMPLE. To some degree.

Representative OAKAR. What degree?

Dr. TEMPLE. They did it voluntarily. We did not order them to.

Representative OAKAR. Well, did you alert them that all these people were writing and calling in, and doctors were telling you this is really a problematic drug that you considered safe and effective?

Dr. TEMPLE. We did not need to alert them. Most of those reports come to us through them.

Representative OAKAR. Oh, I see.

Dr. TEMPLE. They are fully aware of——

Representative OAKAR. Are you going to tell me that the drug companies always come forward with all that information?

Dr. TEMPLE. I will only tell you that it is the law that they submit everything they are supposed to. Whether they always comply with the law is another matter. But they have a clear requirement to do so.

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[1] Retained in committee files.

Representative OAKAR. Do you feel you have a responsibility to monitor more closely their activities when they are doing the testing? Have you ever seen——

Dr. TEMPLE. I do not understand the question.

Representative OAKAR. Well, do you know of any cases where people have died when they were being tested?

Dr. TEMPLE. People certainly have died in the course of clinical trials. Trials have been conducted, as you have urged, in people with serious illnesses.

Representative OAKAR. Well, during the clinical trials, if someone had died while they were being tested, would that not signal to you that that was a problem, and that drug ought not to be on the market?

Dr. TEMPLE. Well, it depends on why they died. If they died of something that the drug seemed to have done, that would be an important concern, of course.

Representative OAKAR. Have you ever not sanctioned a drug because you heard somebody died, and you thought that that was the reason they died, because of the clinical testing?

Dr. TEMPLE. Drugs are refused for a variety of adverse effects. We have refused drugs because they caused gastrointestinal bleeding, because they caused kidney failure, because they caused liver injury, all of those things——

Representative OAKAR. But that would not signal anything, that some people died while they were being tested—my question specifically is, do you know of any drugs where, during the course of testing, people passed away, and that there was a related connection to their being tested by this drug?

Dr. TEMPLE. There is no question that in any cancer drug, there will be some deaths that are properly attributed to the drug itself. It would be unusual for a drug intended to treat arthritis to continue to be of interest to anyone if deaths occurred during the clinical trials. If there were, for example——

Representative OAKAR. In other words, 40 people had to die, and 5,000 complaints, et cetera, et cetera, before they voluntarily took it off the market, right?

Dr. TEMPLE. Excuse me. Are you asking me about clinical trials, or are you asking me about postmarketing period? I can only answer one thing at a time.

Representative OAKAR. Take the former first.

Dr. TEMPLE. OK. Nobody died of something attributed to Zomax during the clinical trials of the drug.

Representative OAKAR. What about any other drug?

Dr. TEMPLE. Any other drug?

Representative OAKAR. Yes, that you have ruled safe and effective. My point is, I want to know how scrutinizing you are when you monitor the reports from the drug companies.

Dr. TEMPLE. Yes, and I am trying to give you a reasonable answer. Certain classes of drugs are potentially dangerous, and are known to sometimes cause death. For example, drugs that are used to treat cardiac arrhythmias are, on the whole, a relatively toxic group of drugs, and there is no question that sometimes, in an attempt to treat an abnormal cardiac rhythm, they sometimes make it worse. That is known for the entire class of drugs, including the

drugs which are already marketed. So for a drug like that, you would have to make a judgment as to whether the beneficial effects on the abnormal rhythm are sufficient to outweigh those matters.

If your question is does one look at every such event—of course—it is probably the most important thing that can happen——

Representative OAKAR. Well, looking at it and action are two different things. That is the point, isn't it?

I just want to, with the Chair's indulgence, get into one other drug, and that is Oraflex. In April 1982, the FDA approved a second arthritic drug, concluding that there was "substantial evidence of effectiveness"—and I am quoting—"and adequate scientific evidence of safety." Three months later, the drug was pulled from the market, and you had 1,146 individual reactions and complaints concerning this drug, and 100 deaths associated with this drug that there is some documentation about.

My point is, if you do not want people to think, quite honestly, that you are "in bed with the drug companies," then you had better start doing something about the manner in which you survey this testing, and your surveillance afterward——

Dr. TEMPLE. Excuse me. You will have to be more precise. What exact moves would you have had us make on the basis of the reports you presumably have evaluated here. I do not——

Representative OAKAR. Do you have the administrative authority to recall a drug?

Dr. TEMPLE. We have to take action on the basis of evidence that the drug is responsible for something and is doing it. One thousand reports may or may not be relevant to whether the drug needs to be removed from the market.

Representative OAKAR. Well, you are supposed to be protecting consumers.

Dr. TEMPLE. Yes, that is what we do full time. That is what we try to do, yes.

Representative OAKAR. Full time.

Dr. TEMPLE. Full time.

Representative OAKAR. And you are telling me that after 1,000 people take the time and have the sophistication—we do not even know how many more thousands there might be—in 3 months to complain about a drug, you are asking me what you should have done?

Dr. TEMPLE. I am sorry——

Representative OAKAR. Now, I am a lay person, and I know what you should have done.

Dr. TEMPLE. Excuse me. They did not complain about a drug. They reported what they thought was an adverse reaction or might be an adverse reaction.

Representative OAKAR. Well, what do they have to do?

Dr. TEMPLE. May I continue?

Representative OAKAR. Yes.

Dr. TEMPLE. OK. Depending upon what the adverse reaction is, the remedies vary. Certain kinds of adverse reactions require mention in labeling, warning of some adjustment to make, or something like that. Certain others, more severe ones, require that the drug be removed from the market. The answer is not the same for every reaction.

Taking Oraflex, we knew before the drug was approved that the frequency of rashes, especially in response to sunlight, was quite high with the drug. It was 10 to 20 percent in the trials that were carried out, and in some studies, was still greater. That fact was taken into account when the drug was considered. It was taken before an expert outside advisory committee, and the benefits of the drug were felt to outweigh those nonlethal adverse effects. They were adverse effects. One would expect to get many reports of them—and we did—but they are not a reason for removing the drug from the market. The drug was removed from the market principally because of findings in Great Britain, where patients had been on the drug——

Representative OAKAR. Well, good for Great Britain.

Dr. TEMPLE. Well, they had it for 2 years. They had longer to have those reactions. They found that in patients on the drug for a very long time—particularly in the elderly in this case, as a matter of fact—there was an unusual combination of kidney and liver disease that developed. It is not clear that such a combination of effects developed and was fatal in any patient in the United States. So that the reports that we have of deaths are a whole range of number of things. In some cases, they are people telling us that the patient had a heart attack. Whether or not that is due to the drug is not easy to tell.

Representative OAKAR. Well, what do you do—just sit back and wonder—or do you go out and get your caseworkers busy and find out specifically?

I mean, the burden of proof should not be on the consumer, when you hear and you have people relating adverse reactions.

I want to just submit one other point for the record. It is that since 1980, the number of administrative actions on the part of FDA has decreased by one-third. So you are not exercising the authority that we invested in you in terms of protecting consumers when you have good products. I want to stress to the Chair that I raised the same issues during the previous administration. I think we have not, as Members of Congress, contrary to what Dr. McMahon told us—stay out of it—we have not in Government done enough to monitor what you do, and to force you to do your job.

Thank you, Mr. Chairman.

Chairman HEINZ. Thank you, Congresswoman Oakar.

Congresswoman Ferraro.

Representative FERRARO. Thank you, Mr. Chairman.

Dr. Novitch, let me just speak to you about another thing that was said during the course of these hearings. I have a very large elderly population, and we have been dealing here with the number of drugs that people have been taking, and one thing we have not really been discussing in great detail is the cost of those drugs. I do not know if you saw what was on the table before, but not only was there a great variety, but I could not venture a guess on how much those drugs cost her in a year.

One of the things I do when I go to my senior centers—and I know a lot of people live on social security alone—is I say to them, "Look, if you can save money, save money, and if you can buy generic drugs, buy them." Now, you heard Dr. McMahon say that they are inferior. Are generic drugs inferior?

Dr. NOVITCH. No, we do not think so. And in fact, we have gone to great lengths to make sure that they are not inferior. We do considerable testing on drugs in the marketplace to make sure they meet current standards. We do bioavailability studies to see that, when they are administered, they produce the same blood levels that their brand-name counterparts do, and all studies that we have done show that, in general, brand-name drugs and generic drugs perform essentially the same. We have taken that information, and have worked with the Health Care Financing Administration, in a maximum-allowable cost program, for drugs supplied under State medicaid programs, so that the States can have assurance that drugs that we have examined and approved for the maximum limit will do the same as their brand-name counterparts. So we have a good deal of confidence in generic drugs, and we have made it progressively simpler for manufacturers who want to enter the market and compete, on the basis of price as well as quality, to market those drugs as simply and as easily as possible.

Representative FERRARO. When you do the testing, do you have the drug meet a minimum standard, or do you compare them as well to other drugs, the brand-name drugs?

Dr. NOVITCH. First of all, each drug, whether brand or generic, has to meet the established USP or other standard, the compendia of standards for that drug.

Representative FERRARO. So they have to meet minimum standards.

Dr. NOVITCH. That is right. There are laboratory tests that are done on each drug and are done regularly by manufacturers on each lot to assure that the drug meets that standard. That itself is a pretty good——

Representative FERRARO. Dr. McMahon did not say that they did not meet standards. He just said they were inferior. So that is the next point. Do you then compare them to the name-brand drugs?

Dr. NOVITCH. Yes. We do bioavailability studies, both ourselves and under contract, on drugs where we suspect there may be a bioavailability problem, where a drug is of very low solubility, and where there are other difficult formulation characteristics that make it more likely that a drug could behave differently when administered to patients—that is, a brand name and a generic drug. We subject those drugs to bioavailability studies, and by and large, they perform the same, at least the same to the extent that we have confidence in the quality of all of those drugs.

Representative FERRARO. You have made me feel a little better.

Let me just ask you one other thing and that is, you were talking during the course of your testimony about consumer education, and you talked about the efforts by private groups like AARP to inform consumers of what is in the prescription, and the efforts by the AMA to do the same thing. You said we have to train the elderly consumer to ask the right questions, and you said you dealt with the AMA patient information services. It seems to me—in a bit of a followup to Congresswoman Oakar's question—that what you are doing is putting all the onus on the consumer and none on the doctor, and both of those women who testified earlier today were complaining about doctors and actions, or poor actions.

What is being done to inform the doctors?

Dr. NOVITCH. We cannot lift the doctor's hand and guide it across the pad and his record, so that he behaves in a rational manner. What we can do is arm both physician and the patient with the kind of information they both need to make sound decisions; in the case of the patient, try to communicate the kinds of questions that patients ought to ask; assist private efforts in getting specific drug-related patient information in the hands of patients so they can stimulate the right kinds of questions of their physicians; and, in the case of the physicians, communicate the kinds of information they need to make sound prescribing decisions, and when information about a drug changes, to get that information in the hands of physicians so they can take it into account; and to make sure that the information in drug labeling, which is reflected in the Physician's Desk Reference and other references, is complete and up to date and relevant to the kinds of patients that they are seeing.

The most that we can do is try to make sure that physicians and pharmacists are informed so that they in turn can inform their patients.

Representative FERRARO. The AMA patient information service, you said you had dealt with. What, specifically, do they do with reference to the doctors or members of their association?

Dr. NOVITCH. I am sorry, I did not get that question.

Representative FERRARO. The AMA, you said you have dealt with the patient information service and have worked with them. What do they do, other than try to inform the consumer? What do they do as far as their own doctor members are concerned?

Dr. NOVITCH. What they are doing is providing leaflets, I think it is now up to 40 or 45 drugs, and by 1984, I believe they expect to cover double that number, some 75 or 80 drugs. They provide to their members, at cost, booklets of these leaflets so that the physician, during the patient encounter, and before the prescription is written, or at least, before the prescription is filled, have an opportunity to individualize the instructions on that sheet with the physician.

I must tell you that the AMA's view, and a number of people during the course of our deliberations on patient package inserts, a number of people felt—and the AMA was a leading exponent of this—that it is more important for patients to have information at the point of prescribing with the physician more than at the point of dispensing after a prescription has already been written, when it is too late to discuss that information, or at least, more difficult to discuss that information with the physician. They felt that interaction with the physician at the point of prescribing is the most valuable kind of specific drug patient information.

Representative FERRARO. Dr. Novitch, I would agree with you if we were dealing with younger people. But I think that what is being lost sight of here is the type of client or the type of patient you are dealing with.

I do not think Mrs. Zimny could sit down and really discuss in a great deal of detail with her doctor precisely what was going on, and from the testimony that her daughter gave today, I do not think her doctor is the type who would sit down and discuss it with her.

Dr. NOVITCH. No; I agree. I have two living parents—one is 92, and one is 86—and I can tell you that they would have a very, very difficult time remembering what they took yesterday, let alone what they take tomorrow.

Representative FERRARO. But they will remember that you gave their ages on television——

Dr. NOVITCH. I beg your pardon?

Representative FERRARO. Your mother will remember you gave her age on television, and she will let you know about it tonight when you get home. [Laughter.]

Dr. NOVITCH. In any event, I will tell you that the problems are very real, and they need surrogates to deal with the physician for them. But patient written information will be of no more help than the kind of interaction that they are likely to have themselves with the prescribing physician. It is a very difficult problem, both in terms of their ability to interact and their ability to retain and utilize the information that they get, and the numbers of drugs that they take.

Representative FERRARO. When you dealt with the testing on these drugs, was there any sort of testing done on the reaction of alcohol on the prescription drugs? Is there any research on that that you know of?

Dr. NOVITCH. I cannot be specific. I know that the influence of alcohol is taken into account in drug testing, but I cannot be more specific than that, unless Dr. Temple could——

Dr. TEMPLE. Not usually. Occasionally, a peculiar reaction will be observed when a drug is used with alcohol, and if it is observed, it is then put in the labeling. But it is not a routine part of testing.

Representative FERRARO. And I assume since alcohol is not one of the drugs that is tested in conjunction with another drug that it is not too frequent that you would get all those drugs that were on the table and kind of mix them all together and see what you come up with.

Dr. TEMPLE. Well, there is almost no rational way to test 15 drugs at once.

Representative FERRARO. Except in a person who is getting drugs from her doctor.

Dr. TEMPLE. Yes, and no one would do that on purpose. You cannot have a study where you give people a lot of drugs they do not need; it would not be right.

Representative FERRARO. Thank you very much.

Thank you, Mr. Chairman.

Chairman HEINZ. Thank you very much.

Dr. Novitch, I want to return to the patient package insert program. As I know you are aware, under the previous administration, FDA developed regulations that would have required patient package inserts for a group of 10 drugs. It was a pilot program—it was a test, as I understand it.

Dr. NOVITCH. That is right.

Chairman HEINZ. An example of the patient inserts to be used is for digoxin, a heart stimulant, as I understand it. [See pages 28-30.]

Earlier in the hearing, I had the opportunity to refer to this. It seems fairly clear, fairly easy to understand, not particularly threatening—similar in style, but a little bit different, but nonethe-

less similar in style to what the AARP has developed. This would have been made available by the pharmacist directly to the patient. Why—and I do not think this has been directly asked of you—why did the FDA cancel the pilot program?

Dr. NOVITCH. Well, as you know, it was quite a controversial program, and it caused a great deal of agonizing thought, because there was a great deal of support for it, and a great deal said against it.

There were those who thought that putting in place these regulations—this was not a voluntary thing; this would have been required and enforced—would be the precursor of a national program of patient inserts required for a large number, a much larger number of drugs, eventually, if not all drugs, and that it would stifle other ongoing efforts. There were a number of people who came forward. We held a hearing back in late September and early October 1981, and a number of people came forward and made us aware of private sector efforts, many of which we did not know about, that were aborning——

Chairman HEINZ. Who were the people who were afraid that if this program were successful, it might be more broadly used?

Dr. NOVITCH. Well, I do not think they were afraid of it. I think there was the general assumption, that if the program went into effect, that it would grow and become the standard system of disseminating patient information.

Chairman HEINZ. And if the pilot program were implemented, FDA, whether it was successful or not, would in fact expand the program?

Dr. NOVITCH. I think that—I am not——

Chairman HEINZ. You are the FDA.

Dr. NOVITCH. Yes, we are.

Chairman HEINZ. If it had been unsuccessful, would you have expanded it?

Dr. NOVITCH. No, probably not.

Chairman HEINZ. If it had been successful, would you have expanded it?

Dr. NOVITCH. Probably, yes.

Chairman HEINZ. Well, starting at that point, if some people came to you and said, "Don't test this program," and in effect what they are saying is, "If it is successful, we are afraid you might expand it——"

Dr. NOVITCH. No. I think what they were saying, Senator Heinz, was "Give us a chance." If you put in this program, many people will assume that the decision has been made, and there will be a lesser incentive for——

Chairman HEINZ. Why didn't you test it in a few States?

Dr. NOVITCH. Well, I am not sure that we could. You know, we do not govern State programs; we govern interstate commerce.

Chairman HEINZ. The Department of Health and Human Services runs all kinds of State-by-State tests.

Dr. NOVITCH. Well, in essence, Senator Heinz, an experimental program or two are going on right now. The AARP program and the——

Chairman HEINZ. No. That is not an FDA program. You are the FDA. We pay your bills, and we raise the taxes to pay them. We

want to know what you are doing, not what the AMA or the AARP is doing. We have had them before us. My question to you is, Why can't you test it in a few States?

Dr. NOVITCH. Well, we decided that before we put in place this required program, even as a test, that we would allow some time. There was considerable interest in private forms of patient education, and it was our decision that it was worth a try.

Chairman HEINZ. Let us try and understand something. You had gone to the point where you were almost ready to finalize regulations on a pilot program. People came to you and said, "If you go national with this program, we do not trust you. You will expand it whether it is a good program or not." That is what they said to you. What you did, I guess, is cave in to that line of argument, because if you really wanted to find out whether the program was good, and still give the private sector a chance to do what it was capable, they said, of doing, you could have tested it. Now, why did you reject the notion of testing it in a few States? I would like to know why you rejected that notion.

Dr. NOVITCH. I will tell you why. We were persuaded that there was enough private sector effort going on that would be stifled by a required program, and I think it has turned out to be——

Chairman HEINZ. How, if you tested something in 3 States, would it stifle something in the other 47?

Dr. NOVITCH. We did not plan to test it in three States. The regulations called for testing it in all States, in all States, on 10 drugs, and 10 classes of drugs. And what we were told is, and what has happened is, that there are voluntary efforts that are much broader than that.

Chairman HEINZ. Doctor, if I may say so, I do not believe you are being responsive to the question. When I ask you why don't you test it, you tell me, well, it would stifle initiative. And when I say how could it stifle initiative if you only test it in 3 or 4 out of 50 States, you say, "Well, we were going to go national." You are just not answering the question.

Dr. NOVITCH. Well, we did not consider testing it in three or four States, Senator.

Chairman HEINZ. Well, why shouldn't you today consider testing it in three or four States?

Dr. NOVITCH. Well, I guess we could consider it and——

Chairman HEINZ. Will you consider it?

Dr. NOVITCH. Yes, sir.

Chairman HEINZ. Will you let us know what you decide in writing?

Dr. NOVITCH. Yes, sir.[1]

Chairman HEINZ. We would appreciate that.

Now, one of the things that you said was that you wanted to wait and see and give the AMA and the AARP, and a bunch of very commendable private initiatives, some time. How much time do you want to give them?

Dr. NOVITCH. Well, I do not think we have set a date. I think that there are enough studies going on. There is a National Com-

[1] See letter from FDA in appendix.

mittee on Patient Information and Education, Congressman Rogers' committee, and——

Chairman HEINZ. Who appointed the Commission?

Dr. NOVITCH. It was a private effort initiated by the industry and 125 private organizations.

Chairman HEINZ. That is interesting, and I have a lot of respect for Congressman Rogers. I served on his committee for 4 years, the Health and Environment Committee. But that is not a publicly mandated commission. You are deciding as a public sector agency to wait for a private sector commission, which you had no point in appointing, and which——

Dr. NOVITCH. It is a private sector——

Chairman HEINZ. Excuse me, excuse me——

Dr. NOVITCH. I am sorry.

Chairman HEINZ. And which has some kind of a mandate to report at some point in time that is independent of anything you or the public might desire; is that right?

Dr. NOVITCH. It is independent of us. It governs itself, and we have no authority over it. We work closely with it, as you heard repeatedly during this hearing.

Chairman HEINZ. Does it have a reporting date?

Dr. NOVITCH. No. It may, but I do not—no, it does not have a reporting date.

Chairman HEINZ. So you are telling us that you are going to wait until a private sector commission, presumably composed of drug companies and the AMA, reports, and you do not know when they are going to report because they have not decided when they are going to report.

Dr. NOVITCH. I think that we should wait until we have had a chance to see what the existing efforts have accomplished, and studies are being done on them, both by their operators—the AARP is examining the effectiveness of its own effort; the AMA will do the same. We are looking ourselves at both of those efforts, as well as the results of the Rogers committee. I think that in a fair time—I cannot give you a date and an hour—but I think they will be able to make a report. I do not believe that you will let us forget to report on how we are doing, and I do not believe that other committees of the Congress will let us forget. I think we will be responsible to our own sense of need, as well as the Congress sense of need, as well as the private sector and the consumers' sense of need.

Chairman HEINZ. Well, I would love to believe that, and so would my constituents.

Dr. NOVITCH. You can believe it.

Chairman HEINZ. But one thing that they do not believe and that they are thankful for is that they get all the government they pay for. And sometimes they are right to be thankful they do not get all the government they pay for.

But how long, roughly, to the nearest year, do you think you want to give these private sector initiatives to prove themselves?

Dr. NOVITCH. I really cannot answer that. I would personally say that——

Chairman HEINZ. Are we talking about 2 or 3 years, 5 or 10, 10 or 20 years?

Dr. NOVITCH. No; 2 or 3 years.

Chairman HEINZ. Two or three years.

Dr. NOVITCH. I can only answer for myself, Senator Heinz, and if we did not have the information that we need to draw a conclusion on the adequacy of existing patient education efforts in the next year or two, I would be quite disappointed.

Chairman HEINZ. To what extent, if you know the answer to this, has the patient pad of information been used by members of the AMA who represent a portion of the doctors?

Dr. NOVITCH. My understanding is that it is being used by about 30,000 or 40,000 physicians and that some 4 million of those leaflets have been distributed to physicians.

Chairman HEINZ. 30,000 or 40,000 is what percentage of the AMA membership?

Dr. NOVITCH. Well, I do not know what the AMA membership is. I assume that it is around 200,000. So I would say that about 20 percent of the doctors are using it.

Chairman HEINZ. If the 20 percent figure is correct—we will attempt to verify it—it would be high compared to the information I have. I understand that only about 5 percent of the AMA members have requested the information.

Dr. NOVITCH. I can only give you my understanding.

Chairman HEINZ. But perhaps you are correct. My information may not be accurate.

Dr. NOVITCH. I am told by my colleague here that 20 percent is about right; 30,000 to 40,000 are using it, and that is in addition to physicians who develop their own information for patients. There are a considerable number of those

Chairman HEINZ. Well, there are undoubtedly a number of things we could continue to cover. Just one thing—and I apologize if any of my colleagues asked this while I was temporarily absent. You mentioned labeling, and labels vary all over the lot, depending on State law. Did any of my colleagues ask you, or did you state for the record at any point, what initiative you had in mind with respect to the labeling?

Dr. NOVITCH. Yes. We have begun—under regulations that were published a couple of years ago—systematically evaluating and revising the labeling of existing marketed drugs.

Chairman HEINZ. This is over-the-counter, as opposed to prescription?

Dr. NOVITCH. No. Both—but under different programs. You are talking about—well, there are two kinds of labeling that you are discussing. One is the labeling of drugs for physicians that appears in the Physician's Desk Reference——

Chairman HEINZ. Let me clarify my question. I was talking about the FDA regulations as they govern the labeling, minimum labeling requirement, by the pharmacist for the user.

Dr. NOVITCH. I am sorry. That is largely governed by State law, but it is also governed by us.

Chairman HEINZ. Yes. You have a minimum requirement.

Dr. NOVITCH. Right. That is correct.

Chairman HEINZ. Are you planning any change in those minimum requirements?

Dr. NOVITCH. Not that I know of, sir.

Chairman HEINZ. All right. Well, Dr. Novitch, you are clearly a very bright and able man. I have to tell you, I think there probably is more that you could be doing—I am not saying you are not doing anything. I do question the judgment of you and your associates, however, in abandoning totally even an attempt to test the pilot program on patient package inserts. But you have been forthright enough to say that you will get back to us with a policy decision on whether or not you will test that. I would strongly urge you to do so. I think your position of simply dropping it without any better analysis than you have given is totally indefensible, and at real variance with a lot of tests that we have made, in other, very difficult public policy areas. Let me give you one example.

We have going into effect this year prospective payment under medicare. Now, that is a dramatic change in the way we have done business here. Previously, it has been that whatever we are billed, we will pay. It was so-called retrospective, reasonable cost method of reimbursement. And yes, there were some outside limits, and in some cases, let me tell you, those outside limits set by HHS or medicare were utterly preposterous and ridiculous. We had doctors come before us and say, "You know, they pay us $3,000," or some figure like that, "to insert a pacemaker. We do it in 30 minutes. I refuse to accept the entire medicare fee. It is outlandish, and we do it for half-price and would not do it for more than that if you forced us to."

The fact is that there are all kinds of abuses of the medicare program we are trying to get away from, so we implemented, after some testing, not nationally, after some State-by-State experience, the DRG prospective method of reimbursement.

If you and your colleagues refuse to test something—as I believe you have done, either wittingly or unwittingly, you withhold from yourselves and the public, as well as Congress, information that may be vital. You are, I am sure, sensitive to the kinds of testimony we have received here today from people who have been victimized, either by bad medical care, or by lack of knowledge, or by their own fears. You certainly have to, as somebody who is in public service, want to do something about it, and where possible, do so with sensitivity to the opportunities of the private sector to be creative and to innovate, and that is, it seems to me, within what I think many members of the committee would take to be a testing ground.

Dr. NOVITCH. Senator, I do not want my testimony to stand as if to say I am opposed to patient package inserts, or that we, the FDA as an institution, are opposed. We are not. We think that written information for patients is a very valuable mechanism, and we have supported the efforts by AARP and others, as you heard earlier today. Nor do we think that it is to be abandoned, that by dropping this regulation, by withdrawing it, that we threw out that concept, never to return to it again.

What we felt was that there are other methods that deserve to be tested in an environment free for the time being of a regulatory program. We will examine—and I can assure you we will examine and get back to you—on your proposal for a limited test. But even if you had not suggested that, I want to assure you that we had not totally and forever dropped the idea that patient package inserts

are a good thing. I just could not let my own testimony stand in that respect.

Chairman HEINZ. One thing you learn in Washington, D.C., after a while, nothing is forever.

Thank you very much, Dr. Novitch. We appreciate your being here.

The hearing is adjourned.

[Whereupon, at 1:35 p.m., the committee was adjourned.]

APPENDIX

MATERIAL RELATED TO HEARING

ITEM 1. LETTER FROM ARTHUR HULL HAYES, JR., COMMISSIONER OF FOOD AND DRUGS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, TO SENATOR JOHN HEINZ, CHAIRMAN, SENATE SPECIAL COMMITTEE ON AGING, DATED JULY 29, 1983

DEAR SENATOR HEINZ: This is in response to your letter of July 7, 1983, requesting that the Food and Drug Administration (FDA) respond to questions for the hearing record subsequent to Dr. Novitch's presentation at the joint hearing before the Senate and House Aging Committees on June 28.

With regard to FDA's commitment to develop guidelines for premarket testing of drugs in the elderly, we have circulated a draft of these guidelines within the agency. Once comments have been received we will circulate these guidelines to interested parties outside the agency, probably in the early fall. Because actions after that will depend on the comments we receive, we cannot predict when a final guideline will be completed.

A guideline does not mandate specific actions but it does give a strong indication of the agency's views. Certainly, once a clear guideline is in place we will expect that NDA's for drugs used in the elderly will contain the information and analyses called for in the guideline. Whether an NDA should be rejected for lack of such information or approved on condition that further studies be carried out would depend on the importance of the drug, the necessity for its use in the elderly, and other factors that cannot necessarily be anticipated.

The current draft guideline calls for submission of certain information pertinent to use of drugs in the elderly for all drugs with potential use in these patients. We have not included in IND or NDA regulations any requirements for testing in specific populations.

I would like to emphasize a point Dr. Novitch made in his testimony. The elderly are not now ignored in drug testing. We are still developing a quantitative evaluation of the extent of such testing so we do not have definitive data on this matter. However, in a group of 11 recent NDA's selected at random, elderly patients were studied in all. We should not necessarily expect the number of elderly persons in clinical trials to be in proportion to their numbers in the population, as it is necessary in many studies of a new agent to examine it in uncomplicated patients (who are usually younger) so that its effects can be distinguished from effects of other drugs or other illnesses.

Your letter also asks several questions about FDA's pilot program for patient package inserts (PPI's), which the agency withdrew on September 7, 1982. The agency has no present plans to reintroduce the program on a trial, limited, or demonstrated basis. FDA did, in fact, as part of its deliberations concerning the revocation of the program, explore the possibility of restricting it to certain geographic areas. This idea was rejected because it was probably unlawful and, in any event, certainly impractical. Our conclusion that such a plan would not be lawful was based on the legal justification for the PPI regulation—that a drug was misbranded if it failed to bear the required patient brochure when dispensed. There was no way, in our view, to justify considering a drug misbranded in only some States if it failed to bear a required patient brochure. From the practical standpoint, it would have been difficult to single out pharmacists in a particular State or group of States to conduct such a test, due to the expense that would have been incurred by those pharmacists, but not by others not subject to the program.

The agency's position regarding the pilot PPI program has not changed since revocation of the program. Copies of the proposed and final revocation regulations are enclosed, as their preambles discuss in detail the agency's reasons for withdrawing

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the program.[1] To summarize them here, our decision to withdraw the program resulted from a variety of factors. While at no time did we question the need or desirability of providing patients with increased information about prescription drugs, including written information, the agency was not convinced that patient package inserts provided by pharmacists at this time of dispensing were the best method to achieve this goal. The agency concluded that the pilot program was too limited, in that it would have provided patient information only at the time of dispensing, that its costs were high and were disproportionately borne by pharmacists, and that the program was not consistent with the cost-benefit regulatory objectives of the administration. A further issue which the agency considered was that, while cooperation of pharmacists was essential for success of the program, pharmacists were apparently universally opposed to its implementation.

To date, voluntary efforts continue to be made. You are aware of several, particularly those of the AMA and the AARP. We are optimistic that they will prove to be at least as successful as the agency's PPI program might have been. We are, as ever, convinced of the need of patient education as a primary contributor to the public health and will utilize our resources in every way that we can contribute to non-Government programs, those currently underway and any new ones that are brought to our attention.

Concerning postmarketing surveillance procedures, there are in place, at present, data resources which can examine the risks of drugs in much of the population including some segments of the elderly population. The best resource, to our knowledge, is the medicaid data, but this is still under evaluation and does not cover certain portions of the elderly population, most notably those patients in nursing homes. Nonetheless, the data available should be able to provide some insight into relative risks of various drugs, new and old, in this population. We are not aware of data sources which will consistently allow clear-cut measurements of benefits of the various drugs. The other data base being used, and currently under evaluation for estimating risks to the elderly, is the spontaneous reporting system. Four volunteers from the American Association of Retired Pharmacists are evaluating all of the information in FDA's data base with the goal of defining those areas where adverse reactions uniquely occur in the elderly. This should provide another perspective on this issue.

We are currently encouraging reporting through the "FDA Drug Bulletin" and in the recently published 5th edition of "AMA Drug Evaluations." Our reporting form has been provided in one other book along with prompts in the text to encourage reporting.

The Joint Commission on Accreditation of Hospitals require adverse reaction reporting programs in all hospitals and the FDA is currently providing ad hoc assistance to institutions requiring assistance. We are also preparing a packet to provide advice to all hospitals, including those primarily caring for the elderly, on developing an adverse reaction reporting program.

Regarding the prescribing of medications, FDA's principal means of encouraging proper prescribing for the elderly is through drug labeling. We believe all information pertinent to prescribing in the elderly should be in the labeling, at an appropriate location (e.g., warnings section or dosage and administration section).

Additionally, the efforts described above will help us focus on those areas which appear to result in greater drug toxicity for elderly patients. These include polytherapy, especially redundant therapy with drugs with similar actions (e.g., multiple drugs with sedative effects).

Such information can be used as the basis for instructions in the label for prescribing drugs for the elderly and for writing specific articles or sections in the "FDA Drug Bulletin."

We hope that the above comments will be helpful to you.

Sincerely yours,

ARTHUR HULL HAYES, Jr.,
Commissioner of Food and Drugs.

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[1] Retained in committee files.

ITEM 2. LETTER FROM JEROME L. AVORN, M.D., ASSISTANT PROFESSOR OF SOCIAL MEDICINE AND HEALTH POLICY, DIVISION ON AGING, HARVARD MEDICAL SCHOOL, BOSTON, MASS., TO SENATOR JOHN HEINZ, CHAIRMAN, SENATE SPECIAL COMMITTEE ON AGING, DATED AUGUST 18, 1983

DEAR SENATOR HEINZ: On returning from vacation, I am responding somewhat belatedly to the additional questions you posed to me in your letter of July 8, concerning medication use in the elderly.

Your first question dealt with ways in which more elderly could be included in premarketing testing of drugs, without imposing risks on the group to be tested. The first step in accomplishing this would be to test new agents on elderly people known to be healthy. Collections of such "well elders" have been identified and studied over long periods of time by several gerontological research groups, such as the Baltimore Longitudinal Study of the National Institute on Aging, and the Normative Aging Study of the Veterans Administration in Boston, to name a few. I would hope that many more such groups of healthy elderly would be identified and invited to volunteer for such research as a major part of premarketing testing of new drugs. Such investigations would have the merit of disclosing the effect of the aging process itself on the metabolism and effectiveness of the drugs, which would be invaluable in considering how they would be used in less-healthy older patients.

A second question dealt with the need for the now-aborted program of the Food and Drug Administration that would have provided patient package insert information with several key medications. As I mentioned in my testimony, an intelligent approach to this question would look beyond all of the hand waving and lobbying and consider the actual research that has been done (and it is extensive) in this area. The lengthy report commissioned by FDA and performed by the Rand Corp. showed that many of the bugaboos that have been cited as potential problems in any PPI approach are simply not real (patients would not understand or remember them, they would stop taking their medications, they would experience a markedly increased number of "side effects," etc.). I basically agree with your contention that no harm could possibly come from a well-designed evaluation of such an approach in a few locations around the country. We in the medical profession would learn a great deal from such an experiment and would then be in a more intelligent position to decide upon the future fate of this rather benign program.

Let me take this opportunity again to thank you for your invitation to participate in the hearings which you conducted along with your colleagues in the House. I think a great number of important issues were brought to light, and hope that the session will serve as a springboard for additional action on this increasingly important topic. Please don't hesitate to call upon me if I can be of any further assistance.

Sincerely,

JERRY AVORN, M.D.

ITEM 3. LETTER FROM JONATHAN D. LIEFF, M.D., DIRECTOR OF PSYCHIATRY AND CHIEF OF GERIATRICS, LEMUEL SHATTUCK HOSPITAL, JAMAICA PLAINS, MASS., TO SENATOR JOHN HEINZ, CHAIRMAN, SENATE SPECIAL COMMITTEE ON AGING, DATED JULY 18, 1983

DEAR SENATOR HEINZ: Enclosed are reponses to your two questions in the letter addressed July 8, 1983. Concerning the question as to the possible requirement of premarket testing of prescription drugs on a population that is more representative of those who purchase and use drugs (i.e., more persons over 65 and more women), there are several considerations.

Most medications have increased side effects, often in unpredictable ways, and thus elderly persons receiving medications need more careful scrutiny than those who are younger. It is possible that the testing of medications on elderly persons should be done in carefully controlled in patient settings. While more expensive, this will cut down on the dangers of experimentation.

Side effects in the elderly may include idiosyncratic and unusual reactions. Therefore, the observation of reactions should include a standardized, broad-based rating of all possible symptoms, not just those symptoms that have become associated with the drug in the younger population.

Careful age analysis of the testing of all previously approved medications should be presented to the committee to determine which have been appropriately tested on the elderly. Perhaps new testing should be required where this has not been already accomplished.

The second question concerned the need for the Food and Drug Administration's once proposed pilot program for patient package inserts.

There is a great need for adequate information for the people who are using medications in language that they can comprehend, and in a manner that will not unnecessarily scare them.

Consumerism in medicine is a mixed blessing. While shopping for physicians and medications, the elderly can potentially create more problems for themselves by inadvertently combining inappropriate medications. On the other hand, my firm belief is that for both health and economic reasons, in the future we will need an educated public who will take some personal responsibility for their own health decisions. Only with this personal responsibility and education will people be protected against unnecessary medications, and will the Nation be able to curtail unnecessary costs. One way to begin to accomplish this is with clear inserts in all drug packages.

It is not clear to me what happened to the FDA insert program and why it was never instituted. It is an excellent concept. There have been already a number of good attempts to provide this simplified information for the consumer. This information could be gathered and coordinated by the agency quite easily.

It is a great honor and privilege to help your committee, whose goal is to help the elderly citizens of our Nation. My firm desire is to be of any service to this effort now or in the future.

Sincerely,

JONATHAN D. LIEFF, M.D.

ITEM 4. EXCERPT FROM FORTHCOMING BOOK, "YOUR PARENTS KEEPER—A HANDBOOK OF PSYCHIATRIC CARE FOR THE ELDERLY WITH CASE HISTORIES," SUBMITTED BY DR. JONATHAN D. LIEFF

CHAPTER TWO: OVERDOSING OF THE ELDERLY

Either prescribed by physicians or self-prescribed, the elderly use at least a quarter to a third of all medications but are only 11 percent of the population. The inability of the medical profession to keep track of the multiple interactions of the many medications that are used creates a very dangerous situation. Those who work routinely with the elderly, unlike the majority of health professionals, know that this is a serious problem.

"Social ostracism apart, the most common cause of sudden, unexplained mental illness in the old is medication—self-administered, doctor administered, or borrowed from neighbors. Accordingly, the first psychodiagnostic step is the withdrawal of all medication which is not life sustaining and the review of medication which is. The 'plastic bag test'—provision of a plastic bag in which all medication without exception is to be placed—many yield dozens or even scores of preparations."

The number of drugs used by the average elderly person are very surprising. Ill institutionalized elderly consume an average of 5 to 10 medications daily. The average elder takes four prescriptions or over-the-counter medications every day and uses 11 to 13 prescriptions per year. (See Salzman, Hosp & Comm Psych., February 1982). One study in New York City showed that 92 percent of all elderly people use over-the-counter medications regularly (cite). Other studies have shown that only 5 percent of the elderly use no drugs at all (cite). The real figures may even be higher. Of the medications mentioned, the most commonly prescribed drugs are the cardiac drugs, painkillers, tranquilizers, and diuretics; followed by aspirins, vitamins, and laxatives. One study showed varying proportions of these patients received cathartics (60 percent), analgesics (51percent), tranquilizers (47 percent), thioridazine—Mellaril (26 percent), chlordiazepoxide—Librium (23 percent), and diazepam—Valium (18 percent) Butler, AMH 355).

Psychiatric medications are one of the largest groups of potentially overused drugs; 180 million mood doses of altering psychiatric medicines are prescribed each year. Butler writes that two-thirds of all nursing home patients receive psychotropic drugs, yet only about 20 percent have psychiatric diagnoses" (page 355, Butler). Verwoart states that:

"A survey of 12 Veterans Administration hospitals revealed that 61 percent of the elderly patients studied were receiving psychoactive drugs. Psychoactive drugs were administered to 55 percent of the patients with organic brain syndrome, 70 percent of those with schizophrenia, and 66 percent of those with other mental illness. Antipsychotic drugs were prescribed most frequently (44 percent) followed by antidepressants (11 percent), antianxiety drugs (10 percent), and cerebral vasodilators and dihydroergotoxine (10 percent). Of the patients receiving antipsychotic drugs, 20

percent received antiparkinson drugs. In this survey, 16 percent received multiple drug combinations * * *" (Verwoart, page 156).

At the same time the elderly are more susceptible to the adverse effects of drug-drug and drug-food interactions, possibly because the receptors in the nervous system are more sensitive. Some have stated that a quarter of the hospital admissions for the elderly are for drug-related causes. Research has demonstrated that up to a quarter of the nursing home patients have drug-related ailments. Little is known about the effects of drug-drug interactions when more than two or three medications are used simultaneously. This presents serious difficulties that are currently insoluble. The Senate Subcommittee on Long-Term Care estimated that 30,000 nursing home deaths per year are caused by drug miscombinations and interactions (Butler, page 99). Since many medications have interactions with numerous other medicines and foods and the information changes weekly, it is literally impossible for the physician to keep up with all of them. It is necessary for doctors to have access to accurate, simple, usable information.

Side effects are common when drugs, such as barbiturates, are taken together with many of the over-the-counter medications. Commonly used bromides (e.g., sominex, Bromo Selzer) may have side effects when taken with other medications. Many drugs have a particular set of "anticholinergic"side effects. (The word "anticholinergic" refers to a medication inhibiting the nerves which secrete acetylcholine. This causes a series of symptoms which may include dry mouth, blurry vision, increased heart rate, constipation, and urinary retention.) Any drug with this set of adverse reactions compounds the side effects produced by any other. Drugs in this category include all cough and cold medicines, antihistamines, "nerve" and "sleep" pills, and almost all medications prescribed for psychiatric problems, including antiparkinsonian medications, antipsychotics medication, and antidepressants.

ALCOHOL

A substantial number of elderly, perhaps 2 to 15 percent abuse alcohol. One study showed 25 percent of elderly men admitted to inpatient wards were alcoholics (cite). Among the factors that have been found to increase alcoholism, we can include medical problems, living alone, and being widowed. There is a large group of new alcoholics among the elderly; one-third to one-half of all elderly alcoholics had no history of drinking before the age of 40. Fortunately, these elderly alcoholics do not exhibit the elements of a hard core pathology (e.g., personality disorder, legal difficulties, drug abuse, and antisocial behavior) that are found among younger alcoholics. This sort of alcoholism that begins late in life is often treatable and can be traced to the depression, isolation, social and occupational withdrawal, bereavement, and medical and social stress that occur with advancing age. The elderly alcoholic frequently suffers from concussions and broken bones that are the result of falls, as well as confusion, argumentativeness, organic brain disease, lowered judgment, intolerance, and impotence. Alcohol that is used with other drugs accounts for 20 percent of total accidents or suicidal deaths that are drug related (Butler, 345). Alcoholism complicates the effects of almost all other medications by exacerbating mental confusion and lack of compliance.

Occasionally doctors treat certain elderly patients with alcohol. This may particularly be the case for unsociable patients in nursing home settings. Others, including the author, feel that this merely rationalizes a bad habit, that substitutes for constructive therapy activity. Since the water compartment of the elderly body has decreased, susceptibility to alcohol toxicity, confusion, and so forth, is much higher. Most geriatricians believe these little drinks do not constitute positive treatment. Comfort explains:

"Alcohol has been lauded in geropsychiatry as a 'miracle drug' for palliating the distress of age (Stotsky, 1975), although the reasons behind this view are clearly argued, to those obliged to deal with its effect, this kind of assertion belongs to the realm of massive social denial which generally surrounds the subject * * * old people must be warned of the increased susceptibility to falls and to hangover effects, which even lifelong moderation cannot avoid. More than ever, the older person needs to have his head together * * * Alcohol, even in moderate amounts, can lead to amnestic syndrome." (Comfort, page 7.)

Regular alcohol use, in even moderate amounts, can precipitate a clinical picture resembling dementia. In the long run, of course, alcohol can also cause real dementia. For those with multiinfarct dementia, alcohol can greatly aggravate the confusion, as it can with any brain pathology. There is evidence that this is a direct toxic effect of alcohol on the brain, not a result of thiamine depletion (page 53, Comfort). In one study by Gaitz (1971, in Comfort), 44 percent of geropsychiatric patients suf-

fered from alcoholism. Alcoholism must be considered as the pathogen in all cases of psychopathology in the elderly.

CAUSES OF EXCESSIVE DRUG USAGE

Compliance issues.—One immediately obvious cause for this serious health problem can be traced to the fact that the elderly may have multiple chronic illnesses each requiring a separate medication. Studies on compliance show that less than half of patients take their medications as directed. This is not hard to imagine when one considers that so many drugs are prescribed simultaneously. Most elderly patients do not take all of their medication and this can lead to increased medical problems; 10 percent of all patients are taking excess medications which may cause adverse reactions, toxicity, and death. Childproof caps on bottles often present problems to elderly patients who can only occasionally open them. Decreased vision and hearing contribute to erroneous self-medication. It can also be caused by the confusion that stems from brain disease. Sometimes confusion itself is a side effect of the medicines, thus creating a vicious circle. Loneliness, isolation, or absense of support may allow the development of inappropriate drug-taking habits. All of this must be seen in light of the fact of the inherent physiological change in elderly persons that leads to increased susceptibility to side effects and toxicity.

Lack of medical coordination.—A second major contributing factor to the inappropriate medication of the elderly is the lack of coordination among the patient's different doctors. A patient may go to several different specialists each of whom may use a different pharmacist. Specialty care is desirable if it can be coordinated, but it may result in overdoses and unintended medication interaction side effects. Consumerism is a health concept for patients, especially when there are conflicting views and different treatments available. Many patients have learned to get a second opinion before undergoing significant surgery or the treatment. But, multiple caretakers for each patient can easily produce confusing and possibly contradictory medication regimens. Patients often collect and keep large pharmacopeias, trading pills, offering them amongst friends. This is particularly the case for the more expensive medications that cost as much as $40 a bottle. This unmonitored hoarding and trading of medication can be extremely dangerous. It has been estimated that 30,000 people die each year from drug miscombinations in institutions where the medications are supervised by professionals. This risk is much greater for the hoarding isolated elder.

Medical prescribing habits.—Doctors may contribute to the problem in other ways. Often they do not take sufficient time to explain complex regimens. It is very important that the doctor fully explain or write down all instructions. Kramer (page 238) notes some important factors to remember when physicians are prescribing medications:

(1) Patients are unable to recall more than one-third of what they are told.

(2) Senior physicians make stronger assumptions than junior physicians that patients will follow their instructions.

(3) Less than one-quarter of any group remember everything.

(4) With the increase in given information the less the patient is to remember everything.

(5) Patients remember their diagnosis first and treatment only second.

(6) They remember best what told first.

(7) There is no relation between intelligence and memory.

(8) Most people ignore orders to change personal habits, such as sleeping, smoking, eating, relaxing, etc.

(9) Patients will ignore regimens that are complex or annoying or which show no immediate effect (this is common with hypertension medications and antidepressants).

(10) Patients who are moderately anxious remember better than those with high or low levels of anxiety.

(11) Older patients without brain damage remember as much as younger ones.

(12) The more that patients understand the medical situation the more they will remember about the treatment (Kramer, 238).

A doctor may not be up to date on all drug interactions (in fact it is impossible to be totally up to date at present because of the information explosion of drug and medical information). Doctors may prescribe via telephone without proper evaluation of the situation. This is especially likely to happen with difficult, resistant patients, and persistent problems. A patient may demand a prescription and the doctor responds positively merely in order to show affection or concern for the patient. Some patients feel a visit is not worthwhile unless they leave with a prescrip-

tion. Due to inaccessibility of psychiatric evaluations in nursing homes, a single visit by a physician may result in a regimen of medication which continues for years without review.

In summary Alex Comfort writes that:

"The student must be aware that in view of the increased homeostatic instability of age, the prescription of any drug in old age is no light matter. For the old, there is no such thing as a minor tranquilizer" (page 73, Comfort).

Case: Rosa S., a 69-year-old woman suddenly developed hallucinations, ataxia, and extreme confusion. She was first treated for asthma with aminophylline and inhalant medication. She developed some side effects to these medications including a tachycardia and some dizziness. She was treated for the side effects with antianxiety agents and sleeping pills which caused increasing ataxia and weakness. She then argued with the medical doctor and went to see another doctor at a different hospital in a different section of the city. This second physician prescribed five new medicines to replace the previous six. Later, the second physician instructed Rosa to return to the first physician and refused to see her again.

At this point the patient and her granddaughter attempted to figure out which of the 11 medicines to take. Her anxiety increased and her asthma worsened. She was given steroids for the severe asthma and was admitted to the hospital. She was given medicine for vertigo because of the dizziness and antacids for stomachaches. She was given antibiotics for her lungs as well as oral brochodilators, and several inhalors. Because of some congestion in her lungs, she was given diuretics and potassium. The granddaughter felt that she was on too many medications and asked to take her from the hospital. The doctor refused. An argument ensued and the patient felt that the doctors were imprisoning her. The granddaughter and a friend carried the patient home against the advice of the doctor. At home, she now had 22 different medicines and once again tried to figure out which to take.

The patient became acutely psychotic and was referred to our psychiatric unit. Upon admission we were amazed to find the 22 bottles of pills. All her medication was discontinued and it was ascertained that all she really required was a bronchodilator on an as needed basis along with a mild antianxiety medication. She did very well after this and went home for several years, returning to the hospital for occasional brief treatment of asthma.

ITEM 5. PREMARKETING STUDIES, PREPARED BY PETER P. LAMY, PH. D., DIRECTOR, CENTER FOR THE STUDY OF PHARMACY AND THERAPEUTICS FOR THE ELDERLY, SCHOOL OF PHARMACY, UNIVERSITY OF MARYLAND, BALTIMORE, MD.

Approximately 1½ years ago, then Director of the National Institute on Aging, Dr. Robert Butler, approached FDA Commissioner Arthur Hull Hayes, Jr., M.D., about the need to introduce specifications for testing drugs in an elderly population. In the fall of 1982, the NIA surveyed several specialists in geriatric care about the need for such specifications and their possible content. The issue has not yet been resolved.

It is most important, of course, to see whether a new drug or drug product has been tested in a sufficient number of elderly. A newly released drug, for example, claims to have been tested in thousands of patients, but a closer inspection of the data reveals only one study involving 42 elderly patients.

Of great importance is the study population. Have enough females been included? In many instances, bioavailability studies involve only healthy males, while geriatric medicine is predominantly concerned with elderly females. In the community, elderly females outnumber males by a ratio of 2:1, a ratio that increases to 3:1 in nursing homes. As early as 1972, the Food and Drug Administration warned that the female over 50 years of age is most susceptible to adverse reactions. Many studies also tend to "clean up" the study population, looking for "healthy" elderly, while the prescriber is faced with an elderly patient with multiple pathology and several intercurrent diseases.

It must be ascertained whether or not the drug or drug product has been tested in healthy people or actually in people suffering from the disease or disorder to be treated. For example, the elimination half-life of furosemide in healthy subjects is about 0.79 hours, but in patients with kidney disease, it may increase to almost 25 hours (30). Intercurrent diseases, such as CHF, can change drug activity characteristics considerably (31), adding to the uncertainty of geriatric medicine.

How long was the drug tested? If it was for only 3 months, one should consider that the elderly patient may have to take the drug for 10 or 15 years, and it be-

comes important to decide whether or not 3 months data can be projected to 10 or 15 years with any degree of confidence.

Patient Population

Any study must take note that among the elderly, women outnumber men 2:1.
(a) Women are more sensitive to adverse drug reactions than men.
(b) Greater differences in body composition (lean body weight/lipid tissue) in women are possibly of profound clinical importance.

Therefore, studies should not only include elderly, but a good representation of elderly women.

But inclusion of "elderly" per se may not be at all helpful. What should be used is the Veterans Administration classification of the "three stages of life" in old—65 to 74, 75 to 84, and 85 and beyond. There should be representation from each of these age groups.

Protocols must insist on "comparability" of study subjects and patients. It is entirely possible, that too many studies on antidepressants, for example, are conducted in hospitalized patients and then the drug is used to a large degree on patients living in the community. These usually have a different type of depression and may well respond differently.

Selection of patients must be done with utmost care. It has been estimated that between 30 and 80 percent of elderly hospitalized patients and residents in nursing homes, even those who can feed themselves, suffer from protein-calorie malnutrition, which may influence drug effect profoundly.

Efforts should be directed to find methods other than blood sampling to establish pharmacokinetic parameters. While apparently fit elderly ambulatory persons often do not mind, in original studies an enormous number of blood samples is taken. When studies reach the final stage and one wishes to include patients with specific disease, who are probably debilitated, this often is a great hindrance.

Goals of Studies

In general, any clinical study has, as goal, the safety and effectiveness in "treatment and cure" of a disease. Most often, this is not the case in the management of disease in the elderly. One of the major implications, of course, is that drugs may be taken for a decade or longer, and studies must at least develop trends as to implications of drug action over time.

Side effects should be very clearly outlined, in much more detail than is usual. In complex clinical cases, demanding complex therapeutic regimens, it is often impossible, with current information, to separate drug effect from disease effect and to detect the effect of any possible drug interaction, detrimental or beneficial.

In deference to the heightened susceptibility of elderly, goals should be more rigorously established. It would seem that a host of studies is being reported which compare, for example, a new antidepressant against a placebo. The risk posed by the study would not warrant such a comparison, as the outcome, even if the antidepressant is better than the placebo, really does not mean much in terms of clinical practice.

In view of the multiple pathology that is so frequently encountered among elderly and the subsequent multiple drug use, it would not be unreasonable to test any drug which is thought to impact on the liver and/or kidneys, both presenting with decreased effectiveness in the elderly, in combination with a diuretic (very frequently used). Furthermore, study parameters should pay particular attention to any CNS effect, such confusion and other effects on the brain (such as effect on memory and concentration) may be easily ascribed to a patient's developing "senility."

Protocols should be flexible enough so that special considerations can be used on a case-by-case basis, increasing or even abridging the usual criteria for safety and efficacy.

Pharmacodynamic and Pharmacokinetic Considerations

The increased sensitivity of the brain of elderly to the action of some drugs must be carefully investigated.

Another pharmacodynamic factor that would seem to have generated much interest is the action of drugs in the presence of a compromised immune system.

Of prime importance will be the consideration of pharmacokinetic factors, in the presence of a possibly significant physiologic decrement, immobilization, dehydration, and other factors. Are these parameters changed in the presence of intercurrent diseases and concomitant therapy?

Half-life studies, per se, in the elderly are often inconclusive and do not yield the data needed. Total excretion, in presence or absence of hypoalbuminemia, kidney impairment, and others, is important.

Almost nothing is known about the possible effect of liver enzyme induction or inhibition in the elderly. What is known is that they quite often are given many drugs which may act on the liver enzymes.

Again, it is important to study the liver in detail and for a prolonged period of time. Recent reports from the FDA of fatal, massive, and unanticipated hepatic necrosis in elderly patients receiving ketoconazole would support such need.

Urinary excretion studies should take into account that, in many elderly due to changes in nutritional intake or use of drugs, such as antacids or diuretics, the urinary pH tends to be more alkaline, changing the excretion and/or reabsorption profile of drugs.

When absorption studies are undertaken, the general lessened intestinal mobility, general delay in gastric emptying, and often prevailing anacidity and hypochlorhydria must be considered. Changes in the gastrointestinal flora also occur more frequently in elderly than in younger people.

Finally, biavailability studies need to be enhanced when studying drugs for safety and efficacy in the elderly. The particular dosage form assumes much significance and can affect clinical outcome much more importantly in the elderly than in younger people.

ITEM 6. STATEMENT OF THOMAS W. PAUKEN, DIRECTOR, ACTION, WASHINGTON, D.C.

ACTION'S CONCERN ABOUT SUBSTANCE ABUSE AND THE OLDER ADULT

Any program that is involved with large numbers of older adults quickly becomes aware of the problems that older people face with alcohol, prescription drugs, and over-the-counter drugs. The older American volunteer programs (OAVP), funded by ACTION, have more than 385,000 older adult volunteers participating in the retired senior volunteer program (RSVP), the foster grandparent program (FGP), and the senior companion program (SCP). In 1980, ACTION established substance abuse as one of the areas that the agency would promote as a major programing initiative.

ACTION's interest in developing volunteer strategies which address the issues of substance abuse and the elderly is twofold. Like the older population, the volunteers in OAVP are subject to and sometimes experience the full range of problems related to use, misuse, and abuse of substances. However, when organized and trained, OAVP volunteers can provide supportive services which prevent problems related to substance abuse.

Substance abuse has long been thought of as a problem of the young. Yet, the problems that older adults are experiencing with drugs are generating increasing national concern. OAVP has incorporated a recognition of the many forms substance abuse can take with the elderly and the need for supportive services which address the problem, its symptoms, and many causes.

Many crises and losses accompany growing older: Death of a spouse or friends, lowered income, increasing health problems, loss of meaningful social roles. These events place older persons at risk for a variety of emotional problems. An estimated 15 percent of the elderly are in need of mental health and supportive services.

Substance abuse and mental health problems are closely intertwined. Depression, the most common mental health problem of all age groups, has its highest incidence among the elderly. Depression is commonly associated with increased alcohol consumption, abuse of tranquilizers and/or sedatives, or both. Studies have shown that much of what is diagnosed as chronic organic brain syndrome (OBS) is actually misdiagnosed depression, or more often acute—reversible—organic brain syndrome caused by alcoholism, illness, malnutrition, and unwanted drug effects. The rate of suicide peaks in the elderly (25 percent of all suicides are 65 or older); drugs are becoming an increasingly common suicidal agent.

The problems that the elderly face with substance abuse are extensive.

Approximately 7 to 9 percent of the older adult population have problems with alcohol. This includes those who begin to abuse alcohol late in life and usually in response to a major loss.

Older adults use many types and combinations of drugs both to treat disease and for pleasure. This increases their risk of experiencing drug-related problems. In a survey done by the State of Michigan in 1978 of 383 senior citizens, not one was found to be "drug free." Forty-seven percent used alcohol, 71 percent used perscrip-

tion medications, 54 percent used over-the-counter drugs, 79 percent used caffeine, and 24 percent used tobacco.

Nearly one out of every four older adults is taking four or more prescription drugs at once. There are many kinds of drug interactions that can intensify, negate, or alter the intended effect of one or both drugs. The probability of experiencing a drug interaction increases with the number of drugs taken simultaneously.

Many older adults save medications and use them again at a later time based on self-diagnosis and even though some drugs break down or alter with time.

Approximately one-third of the seniors take drugs prescribed by more than one doctor. Frequently, they do not discuss with one physician the medications prescribed by the other physician(s). This lack of coordination of prescriptions and treatment plans can contribute or result in medication problems.

Estimates of the evidence of side effects vary. Some studies show that 90 percent of the elderly have suffered drug side effects and that 20 percent have required hospitalization. Up to 144,000 people die per year as a result of severe drug reactions.

Most older adults are relatively uninformed about medications, even those that they are taking. This lack of knowledge and awareness contributes to the unwise use of medications among older people and many of the health problems they experience.

All OAVP projects to date have been encouraged to provide volunteer training in the area of substance abuse. Most projects are providing either personalized training for the volunteers or some form of volunteer service-specific training on substance abuse. Though all three programs serve substance abusers, only SCP and RSVP can specifically focus volunteer resources on elder drug abuse.

RSVP has more than 3,000 volunteers serving in the area of substance abuse. RSVP, which provides supportive services to both young and old substance abusers, plans to expand its volunteer strength in this area by nearly 700 volunteers in 1983. Currently, RSVP volunteers are involved in treatment, counseling, and rehabilitation programs for alcoholics. Other activities include preventive education and information dissemination on alcoholism and drug abuse.

Some RSVP efforts focused on elder substance abuse include:

Local surveys to determine the extent and degree of older adult drug addiction.

The development of education and health counseling programs for addicted adults.

Involvement in drug and alcohol abuse hotlines which offer counseling and information and referral services.

Recruitment of recovered alcoholics. One such RSVP volunteer received a mayoral citation for service excellence. The volunteer counseled other older alcoholics.

The senior companion program has had substance abusers as one of the special populations to be served by projects and components funded from 1979 to present. The projects have had success in providing companion services to substance abusers. To date, more than 350 senior companions are serving older adults who are addicted to alcohol or who have problems related to prescription and over-the-counter drugs. In some cases, exsubstance abusers have been recruited and are serving as volunteers also. The success of these efforts supports the continuation and expansion of senior companion services in substance abuse.

The roles and activities of SCP volunteers in the area of substance abuse include:

Being informed consumers of health care services and products.

Being aware of and watchful for possible overdose, side effects, or other adverse drug reactions with the elderly that they serve.

Promoting the use of medication passports or profiles by volunteers and the older adults whom they serve.

Helping recipients of service prepare for doctor visits by:

(1) Listing problems/symptoms the recipient is experiencing.

(2) Writing down questions that they want to ask.

(3) Listing medications they are currently taking with dosages.

(4) Listing any drug interactions or side effects that they have experienced.

Implementing the "vial of life" program.

Providing information and assistance in purchasing low-cost drugs, generic drug laws, AARP, drugstore discounts.

Encouraging clients to dispose of old and unneeded drugs that may have deteriorated or might be used for self-"medication."

Helping clients develop a "system" for taking drugs if they exhibit signs of being not able to accomplish this themselves.

Deterring drug abuse through regular contact and activity with clients.

Providing the opportunity for exercise to reduce the need for drugs.

Providing information and assistance in the area of nutrition in an effort to prevent the need for drugs.

Recognizing the "signs" that indicate that their "clients" are having alcohol-related problems.

Assisting the client in deciding a course for recovery with the support from the volunteer station, available family, and project staff (inpatient treatment, outpatient, AA).

Continue to provide the support and companionship that so many elderly alcoholics need.

Although ACTION has not undertaken formal evaluations related to voluntarism and elderly substance abuse, feedback from our more than 1,000 community-based projects and volunteers themselves indicate SCP and RSVP have been effective in expanding the scope of program involvement in substance abuse and the elderly.

ITEM 7. STATEMENT OF THE AMERICAN PHARMACEUTICAL ASSOCIATION, WASHINGTON, D.C.

The American Pharmaceutical Association (APHA) is the national professional society of pharmacists in the United States. Its members practice not only in community and hospital pharmacies but also include pharmaceutical scientists, health care administrators and educators. About 12,000 pharmacy students—the pharmacists of the future—are also members of the association.

APHA appreciates this opportunity to address a matter of great concern to the association and pharmacists generally—the drug therapy needs of the elderly. It is distressing that the elderly, whose need for and use of medications far exceed that of the younger population, receive so little assistance in meeting the costs associated with their therapeutic requirements. Also, APHA has been committed for years to assisting pharmacists to hone their skills in dealing with the elderly patient to best assure that the drug therapy prescribed for that patient is effective in practice as well as in theory. There are submitted with this statement several examples of the materials APHA has provided for the profession to achieve the goal.[1]

Three years ago, on June 25, 1980, Dr. Richard P. Penna. APHA director of professional affairs, testified before the House Select Committee on Aging during its hearings on drug "misuse" by the elderly. There is little that can be said to improve upon what Dr. Penna said on the subject at that time. Some of those comments will be referred to herein. But, first, APHA would like to address the matter of the inability of many elderly to meet the cost of their drug therapy needs.

One of the greatest failures of the medicare program is attributable to the coverage gap created by the failure to provide a benefit for "out-of-hospital" drugs for medicare beneficiaries. In all of the years that APHA has promoted the enactment of such a benefit—virtually from the inception of the program in 1965, almost 20 years ago—the association has never heard a single objection to the concept. Certainly, many Members of Congress in both the Senate and the House have recognized the fact that it is illogical to pay for medical diagnosis and treatment up to a point and then to say to the patient, "We have taken you as far as we will go. You are on your own if you want to get well and stay well and stay out of the hospital."

APHA worked closely with Senators Montoya and Long in their to date unsuccessful efforts to enact a Senate bill as the first step in making medicare "whole" by addition of an out-of-hospital drug benefit. This legislation has been stymied by only one factor, and that is the anticipated cost of the benefit. The failure to add the benefit for that reason is a blatant exercise in false economy.

It is sometimes apparently easy to forget the underlying purpose of the medicare program. It is to improve and maintain the health of its beneficiaries, primarily the elderly, who have contributed so much to the strength of our country during their younger years and who now require the assistance of some of that strength now that they have reached "senior" status. It simply makes no sense—especially in economic terms—to provide a substantial but incomplete program of health care for these citizens. It is like developing, preparing, and fielding the fastest race car for the Indianapolis 500 and then buying only enough fuel to go 499 miles. Everything spent is wasted because the desired goal cannot be reached.

In the case of medicare, this "failure to achieve the final goal" kind of waste is endemic in the program. Moreover, it has led to the use of increasingly costly alternatives with many medicare patients in an effort to satisfy their medication needs. Although APHA is unable to quantify the extent of the practice. Anecdotal informa-

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[1] Retained in committee files.

tion indicates that medicare patients are being hospitalized and retained in post-hospital nursing facilities in order to obtain the benefits of drug therapy for which medicare does pay in such facilities.

Recently there was publicized the case of a young child whose illness was treatable within the home environment and who, by everyone's—medical and insurance carrier's—admission, would have benefited from being at home rather than in a hospital. Nonetheless, the child had to be hospitalized, because its parents' insurance coverage paid only for services provided in a hospital. A representative of the insurance carrier involved stated that, while the situation might seem ludicrous, no exception could be made without threatening the integrity of its program. APHA submits that the situation did not just seem ludicrous, it was ludicrous, but no less so than the medicare situation. Medicare has become two programs of health care, one that is complete with the addition of their private resources by the elderly affluent, and one that is seriously flawed because of a lack of private resources among the elderly who are financially less fortunate.

APHA is aware that the subcommittees are concerned about the use and possible misuse by the elderly of nonprescription medication—popularly referred to as "over-the-counter" or OTC drugs—because of their ready availability and relatively low cost. There are several comments to offer on this subject. First, largely because of the manner in which such drugs are promoted, there seems to exist a fair amount of skepticism about their usefulness. However, by and large, and particularly as a result of the review of such drugs currently being conducted by the Food and Drug Administration, OTC drugs are both safe and effective. One must remember, however, what they are safe and effective for and under what conditions.

OTC drugs, as a class, are not a substitute for prescription medication. Generally, with a few notable exceptions, such as the use of iron for the treatment of anemia, OTC drugs provide largely symptomatic relief. They are not intended to and they do not attack the underlying disease state. Thus, an OTC analgesic, such as aspirin or acetaminophen, may relieve a headache caused by hypertension, but it will not serve to treat the "high blood pressure" itself. There exists very effective prescription hypertension medication, but as noted, medicare will not make that available to nonhospitalized elderly patients.

APHA, with the financial support of Lederle Laboratories, has developed and is distributing a program called the self-medication awareness test. This is an audiovisual program for pharmacists to present to consumer audiences on the subject of nonprescription medication. Experience with two other similar programs (the national medication awareness test, and the health check test) indicate that the elderly constitute a large portion of the audiences.

The major problem relating to elderly misuse of OTC drugs relates not to the inherent qualities of these drugs themselves, but to their use as seemingly necessary substitutes for indicated prescription medication. Also, the use of some OTC drugs would be contraindicated where some prescription drugs are being used. This subject is one for direct counseling of patients by physicians and pharmacists. In his 1980 testimony, Dr. Penna listed several factors that "contribute to drug misuse and the potential for increased drug problems in the elderly population." This list is repeated here, because the information remains timely and important:

The more drugs a patient takes, the more prone he or she is to experiencing an adverse drug reaction or interaction.

The aging process affects the way the body handles drugs. As a result older people are more sensitive to the adverse effects of many drugs.

Acute and chronic disease states may affect a patient's response to drugs. A patient with several chronic conditions—not uncommon in the elderly population—may be especially vulnerable.

Many elderly people have poor eyesight. Hence they cannot read prescription labels easily and often take their medication at the wrong time or not at all.

Many elderly have difficulty in opening prescription containers, particularly those that have child-resistant caps. Many elderly simply stop taking their medication or leave containers opened to be exposed to oxygen, heat, and moisture, which may hasten drug decomposition.

Many elderly become confused regarding the array of medicines they must take. This is perhaps the most frequent problem encountered by pharmacists. For example, digoxin, a potent cardiac drug, is confused with quinidine, another potent cardiac drug. Digoxin is usually taken once daily, while quinidine is usually taken three times daily.

Many elderly patients see more than one physician and other prescribers such as dentists and podiatrists. As a result there is a very real potential that prescribers may place a patient on similar or interacting medication.

Self-medication is a way of life. People usually try to treat a disease first with nonprescription drugs before consulting a physician. This practice can be hazardous among the elderly if they are taking prescribed medication or have a disease which is contraindicated with nonprescription medication. Advertising, especially for arthritis remedies, laxatives, and vitamins are directed toward the elderly population "market."

Because drugs can be expensive, there is a tendency among the elderly to save their medication in the event the symptoms recur. This can be a dangerous practice. It encourages self-medication with potent drugs.

It has become common practice to compare symptoms and exchange drug products. The result is that medication prescribed for patient A is taken by patient B who may be allergic to it or be on other medication that is contraindicated.

Since a main focus of APHA activity is on the use of rational drug therapy to keep the elderly as well-functioning members of society. The association would like to paraphrase earlier testimony regarding pharmacist involvement with elderly patients who are living independently.

Independent Living

The vast majority of elderly people do not live in institutions. This group, which represents approximately 10 percent of the total U.S. population, spends about 25 percent of the total annual U.S. drugs expenditures. The average annual per capita expenditure for drugs by the elderly is almost 2½ times the amount for the population as a whole. Drug therapy represents an important aspect in the lives of many elderly who live independently and also poses the greatest challenge for control and appropriate utilization.

A survey of 447 elderly Washington, D.C., residents revealed that 62 percent used prescription drugs. More than one-third used two to four prescription drugs and 5 percent used five to nine prescriptions. Approximately 12 percent reported having experienced overdoses or side effects. Over two-thirds of this group used nonprescription drugs. A Minnesota study of 50 elderly people found an average of 3.4 prescription drugs and 2.9 nonprescription drugs taken per patient. Sixty-six percent of the drugs were taken with inadequate instructions and 25 percent were not being taken as labeled. A Michigan study of 338 senior citizens found that almost 25 percent of those interviewed were using four or more prescriptions at one time. This study also surveyed health providers who reported problems with noncompliance, sharing medications with others, and difficulty in following medication regimens.

These three studies are representative of findings of many studies that indicate a need for close monitoring of drug use in elderly patients and for patient education and use of other techniques to simplify drug regimens and increase compliance. Included with this statement is a copy of the May 1980 issue of "American Pharmacy" (attachment A) which focuses on information on drug use by the elderly and the role of the pharmacist.[1]

The American Pharmaceutical Association has been encouraging pharmacists to take a more active professional interest in their elderly patients. For example, in 1978 former APHA president Jacob Miller suggested that pharmacists make house calls for those elderly patients who are in need of that type of service. Pharmacist Miller made that recommendation with the knowledge that some drug-related problems could be detected and resolved only when the pharmacist visited the patient in his or her home. Many pharmacists accepted this suggestion and now offer home visits as one element of their service packages. How widely this practice spreads depends on whether government, third-party payers, and patients recognize the potential value of this service and are willing to pay for pharmacist house calls.

Pharmacists' activities for elderly outpatients can be categorized as follows:

Drug therapy recordkeeping and monitoring.

Patient counseling and education.

Providing compliance aids, such as medication calendars and special packaging.

Community health education programs.

The association has developed a series of practice aids to assist the pharmacist in caring for elderly patients. Included in this series is a pharmacy health questionnaire, a diabetic monitoring checklist, a personal drug information checklist, and a home drug administration record (attachment B).[1] These aids are made available to pharmacists for their use in serving their elderly patients.

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[1] Retained in committee files.

APHA is also aware that pharmacists require periodic refresher courses in order that they might continue to serve their patients competently. The association pioneered in the development of drug monitoring continuing education workshops for pharmacists serving long-term care facilities. These same programs are pertinent for pharmacists' service to ambulatory patients as well and are currently being used for that purpose. APHA devoted a significant element of its 1981 annual meeting program to the various issues involved with serving the elderly population.

The association has conducted educational programs at each of its last three annual meetings on the subject of drug use by elderly patients. The section on long-term care of the association's academy of pharmacy practice is committed to keeping pharmacists up to date with the latest knowledge in the use of therapeutic agents in the older population. Ultimately, services that improve drug utilization decrease other health care costs because of decreases in adverse drug reaction consequences.

APHA believes that pharmacists and government agencies can affect public health and promote proper drug use by encouraging more aggressive actions by pharmacists to:

Monitor drug therapy for all patients and followup actions when problems are detected.

Communicate with and educate other health professionals about drug-related problems and effects to improve drug prescribing practices.

Counsel and educate patients on a one-to-one basis.

Provide compliance aids for patients.

Provide community health education on appropriate drug use.

These actions will decrease unnecessary drug use, decrease the problems that occur from inappropriate drug use and thereby decrease the need for other and more costly health services. They will improve the quality of life of older people and increase independence of those using self-care by simplifying their treatment. All of these effects represent a savings to society.

APHA is encouraging development and continuation of these activities through its educational services and practice aids. Another private sector program designed to reach a specific segment of the population is the Parke-Davis "Eldercare" program which focuses on making the elderly patient aware of the physician and the pharmacist as personal health care advisers and the means by which the elderly patient can best assist these health care professionals to assist them.

The government can and should also encourage those activities through education campaigns to the health professionals, and by providing funds to facilitate these activities. One of the best methods of accomplishing these goals is to provide a structure within the health financing system that gives financial incentives for health promotion activities.

The health care problems of the elderly can be severe. But, many of them are amenable to treatment and the caring attention of health care professionals interacting with such patients. The profession of pharmacy is doing a great deal to enhance and encourage the establishment of a close personal relationship between the patient and the pharmacist. This kind of relationship and the communications that can arise from it offer the best opportunity for reducing and even eliminating many of the problems discussed in this statement.

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