FRAUDS AGAINST THE ELDERLY: HEALTH QUACKERY

HEARING

BEFORE THE

SELECT COMMITTEE ON AGING
HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

OCTOBER 1, 1980

Printed for the use of the Select Committee on Aging

Comm. Pub. No. 96-251

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON: 1980

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FRAUDS AGAINST THE ELDERLY: HEALTH QUACKERY

WEDNESDAY, OCTOBER 1, 1980

U.S. HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON AGING,
Washington, D.C.

The committee met, pursuant to notice, at 10 a.m, in room 2322, Rayburn House Office Building, Hon. Claude Pepper (chairman of the committee) presiding.

Members present: Representatives Pepper of Florida, Roybal of California, Bonker of Washington, Hughes of New Jersey, Drinan of Massachusetts, Evans of Indiana, Oakar of Ohio, Ferraro of New York, Grassley of Iowa, and Shumway of California.

Staff present: Charles H. Edwards III, chief of staff; Val Halamandaris, senior counsel; David Holton, chief investigator; Kathleen Gardner, professional staff; Nancy Smythe, investigative researcher, of the Select Committee on Aging; and Pete Conroy, minority staff director, Subcommittee on Human Services.

OPENING STATEMENT OF CHAIRMAN CLAUDE PEPPER

The CHAIRMAN. The committee will come to order, please.

Our hearing today has for its subject a very interesting, sometimes amusing, and altogether very tragic subject. It concerns fraud against the elderly, particularly in the area which means so much to the elderly—their health and their life.

It is a pleasure to welcome you to the hearing this morning at which the committee will examine the subject of frauds against the elderly, with particular emphasis on medical frauds.

Every year thousands of older Americans spend millions of dollars in search of miracles that never happen. Driven by pain and despair, many older Americans fall victim to con men who tout elixirs, remedies, and fraudulent treatments. Some of these remedies are ridiculous but cause no harm. Others are downright dangerous and may result in injury or death.

The list of phony cures, devices, and remedies is endless. There is holy water from Lourdes which sells for $2.98. It really comes from a pond in southern California and it has no special curative powers. There are promoters who will sell you cocaine or some form of novocaine as a guaranteed cure for arthritis.

Some promoters sell special diets of watermelon rind juice or yucca as a cure-all. Other promoters counsel victims to refrain from eating altogether for long periods of time, or that patients should refrain from eating certain foods like potatoes and tomatoes.

There are some people who charge for putting live bees and ants on the arthritic knees of the elderly and inducing the insects to bite. Still other people peddle vitamin cures or copper bracelets or health slippers purportedly containing uranium ore.

The range of worthless devices also includes something called a plasmatic therapy instrument which is nothing more than a large plastic body bag that the patient crawls into. Then there is a version of the health slippers which comes equipped with an electric cord so that they can be plugged into a wall socket.

The Oxydoner, as it is called, is a stainless steel tube which is touted to reverse the death process. The Spectrochrome is a device which was very much in vogue over the last 15 years. It is in essence a light bulb and different colored filters fitted into a stainless steel box. The patient uses this device only when facing north, when the Moon is full. And the patient is advised that he must be naked. The yellow filter is supposed to cure cancer, the red is claimed to cure arthritis.

The FDA is doing its best to keep these devices off the market.

Our research indicates that the incidence of health quackery is dramatically on the increase. The U.S. Postal Service has been doing a great job of trying to protect the public interest against such phony cures and devices that are sold through the mails, but I am convinced the department doesn't have adequate resources or authority to deal adequately with the overall problem.

It is hard for me to imagine a more flagrant example of man's inhumanity to man than these medical frauds. Obviously, there is more to the problem than the theft of the hard-earned dollars of the elderly.

Quite often, the victims of health quackery ignore seeking legitimate medical help, often until it is too late. And then, too, the purveyors of health quackery often inflict real damage with their alleged cures.

So we look forward to the interesting testimony we will have today. We want to see what can be done to stop the epidemic of medical quackery which has infected our land and victimized so many of our senior citizens.

Now I would like to call upon our distinguished colleague, Mr. Grassley.

STATEMENT OF REPRESENTATIVE CHARLES E. GRASSLEY

Mr. GRASSLEY. Thank you very much.

Mr. Chairman, among the cruelest of all hoaxes is the confidence game that bleeds the elderly of their assets by defrauding them with phony remedies for their infirmities.

The vulnerability of the elderly to illness and pain is evident in the fact that persons over 65 spend 44 percent more per capita for medical services than do those below the age of 65. The elderly are especially susceptible to the pain and disability of arthritis and the ravages of cancer.

Today there is no cure for arthritis and cancer continues to exact a high toll of those who contract it. In light of such gloomy facts, it is no small wonder that many persons, and especially the elderly, are willing to experiment with various nostrums which purport to offer them hope when none is available elsewhere.

Such people are fair game to quacks, the charlatans and the fly-by-night con artists who prey on the misery, the fears, and the trust of the elderly.

In this hearing we shall look forward to gaining a better understanding of the nature and the extent of this vicious practice. Of greater importance, however, we hope to obtain guidance and recommendations that will help us to develop corrective measures.

I appreciate the qualifications of our witnesses and look forward to their testimony.

The CHAIRMAN. Thank you, Mr. Grassley.

Mr. Bonker?

STATEMENT OF REPRESENTATIVE DON BONKER

Mr. BONKER. I want to thank you once again for sponsoring these hearings. In fact, during this past Congress we have seen through a series of hearings how the elderly are not only the true victims, but to compound the problem they are the victims of fraud and abuse on a monumental scale. Only through these hearings and allowing witnesses to testify can we expose the problems and abuse.

Hopefully, we can deal with it legislatively, but it seems incredible that on the one hand we have a difficult job convincing FDA that it should legalize DMSO, which is a proven medication for these ailments. On the other hand, these other bizarre examples of medication being perpetrated on senior citizens seems to go undetected.

So I am hoping this hearing will be a first step in dealing with this problem.

As I flip through the briefing materials prepared by the staff—incidentally, Mr. Chairman, I want to commend the staff for the excellent job it is doing in bringing this information to our attention—I am not only amazed but disgusted at the examples of fraud aimed at our citizens.

Some of the cures for cancer seem so outrageous it is unbelievable anyone could believe in them. But without reciting further, and of course we will hear from our witnesses, I would like to say I think we have a responsibility to those Americans who have labored so hard to make this a great and free country to give them more protection from the abuses placed upon them by people in the private sector and also by the Government by not providing the protection they need.

Thank you, Mr. Chairman, for this opportunity. Incidentally, I have to Chair another committee meeting this morning. Regrettably I have to leave early.

The CHAIRMAN. Thank you.

Mr. Evans?

STATEMENT OF REPRESENTATIVE DAVID W. EVANS

Mr. EVANS. I just want to say you are to be commended for holding this hearing. This is an important issue, one which I have come in contact with through constituents of my own. I think the ability of this committee to publicize what is going on currently and also to seek remedies to prevent this occurrence in the future is important.

Thank you, Mr. Chairman.
The CHAIRMAN. Thank you.
Father Drinan?
Mr. DRINAN. Mr. Chairman, I agree with everything that has been said and they said it better than I could.
Thank you very much.
The CHAIRMAN. Thank you.
Ms. Oakar?

STATEMENT OF REPRESENTATIVE MARY ROSE OAKAR

Ms. OAKAR. Thank you, Senator Pepper. This is the sixth anniversary to the date of the Select Committee on Aging. Under your leadership we have seen some very positive accomplishments, but we have a long way to go.

As I look at this table and see the real obvious and bizarre gimmicks that are used to prey upon the elderly, let us not forget some rather typical types of things which confront people in false advertisements. Let's not forget that we see advertised in many areas the so-called hormone treatment which can cause cancer. Let's not forget the extensive overuse of vitamins which can cause vision and liver problems. Let's not forget we very often see older people following food fads which we know sometimes cause anemia which affects up to 25 percent of our older Americans.

Let's not forget other kinds of more subtle things that happen in the area of fraud, for example, I know in my own district, the operator of a nursing home attempted to inflict grave hardship on one of the patients by telling the patient in order to stay at the nursing home she had to turn over her savings account to him. As a result, her entire account of more than $900 was nowhere to be found. We were pleased that he went to jail after some investigation.

Last, I want to mention that as a member of the Post Office and Civil Service Committee, I am very pleased with the work that the post office has been trying to do. I think we have to give them more opportunities to do that.

I think there are some legislative solutions that this committee is already on record with that would attempt to waylay some of these problems. Some of us have introduced a drug abuse bill which would make it mandatory for people to report elements of fraud that they see in terms of the victimization of the elderly.

One reason older people turn to all these insane, bizarre medical remedies is because we have not provided adequate comprehensive health care for older people. We know medicare only covers a third of their needs right now and as a result they sometimes look to the short-term type of cure.

I believe very strongly if our Nation provided a comprehensive health policy for older people and all Americans, we would see a lot of these kinds of problems removed from our society.

I look forward to your leadership, Senator, for many, many years to come and I consider it personally a privilege to serve with you and other members on this committee.

[The prepared statement of Representative Mary Rose Oakar follows:]

PREPARED STATEMENT OF REPRESENTATIVE MARY ROSE OAKAR

Senator Pepper, I want to commend you for holding this hearing on the important issue of health quackery. The con man is a familiar and sometimes comic figure in our society, but many believe that fake medical cures and the practice of medical quackery are things of the distant past. Sadly, this is not true. It is indeed shocking to learn that in 1980 health fraud and abuse is so prevalent and that the elderly so often are the victims. I hope that today's hearing will result in strong and positive action to correct this abuse.

There are a number of issues that we need to investigate. We need to be concerned about the improper use of hormones which can cause cancer, and the overuse of vitamins which can cause vision and liver problems. We need to be concerned about older people who follow food fads. I am sure that these fads contribute to the anemia resulting from poor nutrition which affects up to 25 percent of our older Americans. We also need to be concerned about financial rip-off schemes and fraudulent practices of nursing home operators. In my own district last year our office was instrumental in having a nursing home operator investigated for fraudulent practices. This investigation resulted in the conviction and imprisonment of the operator for taking $900 from the savings account of a seventy-five old nursing home patient.

Why are the elderly so vulnerable to fake cures and unproven remedies? Why are they so viciously preyed upon by unscrupulous promoters and medical charlatans? What can be done about the problem?

The existence of such a problem may be symptomatic of our society's neglect toward the aged. Isolated in their homes or institutions, removed from family and friends, suffering from diseases and ailments which medical personnel label as incurable, some elderly turn in desperation to supposed cures promising "health and happiness" in their old age. Others are unable to afford the high cost of medical care and are caught between the gaps of Medicare coverage, or are victimized by the attitude of doctors that little can or should be done to cure the elderly of inevitable diseases. For them, one-shot "affordable" treatments, no matter how ridiculous or dangerous, may be the only offer of hope.

No less serious are gaps in our medical knowledge. Many of the elderly turn to fake cures because sometimes it seems preferable to receiving no treatment at all. We must extend the boundaries of medical research in order to better understand the cause and prevention of age-related diseases, and we must also assure that funding of research is adequate. This Committee heard testimony last Friday that we are only now beginning to investigate the interrelationship between cancer and the aging process. There is still no cure for arthritis and the pain of arthritis cannot always be alleviated. Holding down health costs, strengthening Medicare, funding and encouraging medical research into the problems of the elderly may not eradicate health fraud, but it may eliminate some of the causes.

Lastly, legislative solutions to this problem must be developed and enacted. As a member of the Post Office and Civil Service Committee, I am very pleased that our Post Office is vigorously prosecuting fraud and abuse perpetuated through our postal system. However, their enforcement capabilities are limited. I am supportive of legislation that would establish penalties against persons who violate a mail stop order issued by the Postal Service. I also support legislation that would authorize the Postal Service to purchase any article or service offered for sale by mail and to have access to records pertaining to any advertising claim for such product or service.

Although the Post Office Department can prosecute quackery and abuse through the mails, their scope is limited. Many older Americans are victimized by persons who claim to be their "caretakers." At the Elder Abuse hearing held by the Aging Committee in June of this year, I introduced the Adult Abuse Prevention and Treatment bill to provide protection to abused and exploited adults who presently lack full legal protection. This bill will provide federal funds for States that have enacted adult abuse laws which mandate reporting of suspected cases of adult abuse, neglect, or exploitation, and additionally provide for immunity from prosecution for those who do report suspected cases. This bill will provide the legal protection needed by an estimated one to two million older Americans who are victims of abuse, neglect and exploitation.

The CHAIRMAN. Thank you, Ms. Oakar.
Ms. Ferraro?

STATEMENT OF REPRESENTATIVE GERALDINE A. FERRARO

Ms. FERRARO. I want to commend you for holding this hearing. We were all affronted by this type of fraud, but as a member also of the Post Office and Civil Service Committee, I am anxious to hear the testimony of the Postal Service and if there is any kind of legislation we can start working on in our committee, I will be more than happy to work with them and this committee as well. I am anxious to hear the testimony.

Thank you, Mr. Chairman.

The CHAIRMAN. I have been given the prepared statements of several members and, in the interest of hearing our witnesses, will submit them all for the record at this point. Hearing no objections, the prepared statements of Representatives Edward R. Roybal, Mario Biaggi, William Wampler, James Abdnor, and Norman Shumway will appear at this point in the record.

[The prepared statements follow:]

PREPARED STATEMENT OF REPRESENTATIVE EDWARD R. ROYBAL

I want to commend the Chairman for holding this hearing and highlighting the growing problem of fraud and quackery committed against older persons in this country.

Hearings which my Subcommittee on Housing and Consumer Interests has held show that crimes such as robbery and assault have a greater economic impact on the elderly than the rest of the population. But, as serious as these crimes are, none are as despicable as health fraud which takes advantage of fears and hopes the elderly have. This type of crime, not only removes much needed cash from them, but also jeopardizes and impairs their health.

I am sure that many of you have read in magazine advertisements for cures and equipment for medical ailments which sound very professional and effective but, in reality, have no medical base and are worthless. Prominent among these are cures for cancer and arthritis. Many older persons, because of lack of information fall prey to unscrupulous salespersons and "quacks" who promise them miracle cures for a price. The National Cancer Institute estimates that millions of dollars paid for cancer cures and remedies with little or no proven effectiveness. The Arthritis Foundation cites a figure of $500 million a year also for gimmicks and worthless cures. Older persons must be educated and warned about these unethical practices and law enforcement agencies must take a more active role in protecting these individuals.

I hope that this hearing will provide us with additional information on how extensive the problem of health quackery is, and also provide us with some recommendations on how we can bring this serious problem under control.

PREPARED STATEMENT OF REPRESENTATIVE MARIO BIAGGI

From Ponce de Leon's search for the Fountain of Youth to the medicine men of the Old West to the miracle drugs of the twentieth century, history is replete with tales of quackery.

Today, the House Select Committee on Aging conducts a hearing more akin to an exposé in order to show the extent to which elderly citizens are more susceptible to crimes of fraud.

This is not the first time our committee has discussed the issue of consumer fraud against the elderly. Our November 1978 investigation and hearing into phony medical insurance policies resulted in the passage of legislation which will more closely monitor the sale of the so-called medigap policies.

For too long quacks have been afforded the mantle of respectability when in fact they are the perpetrators of pure chicanery. I recall an opera I attended called "The Elixir of Love" where an entire town is duped into buying what they think is a magic potion by a seemingly respectable professor.

Mr. Chairman, I hope that this hearing today will both educate and sensitize our elderly citizens to be more discerning consumers in all areas.

PREPARED STATEMENT OF REPRESENTATIVE WILLIAM C. WAMPLER

Mr. Chairman, I commend you for conducting today's hearing on "Health Quackery: Fraud Against the Elderly." For the past several years the Committee has conducted an ongoing study of fraud and abuse in the health care field, including: "Cancer Insurance: Exploiting Fear for Profit," "Abuses in the Sale of Health Insurance to the Elderly," and "Fraud and Racketeering in Medicare and Medicaid." I find it unconscionable that the exploitation of the tragedies of cancer and arthritis victims exists and feel confident that today's hearing will help combat these abuses.

I am especially interested in learning more about public education programs designed to inform seniors about medical quackery. Perhaps this is a legitimate role for area agencies on aging and senior centers. I also wish to discuss the adequacy of the authority presently given to the U.S. Postal Service in curtailing the flow of unproven medical alternatives. Also what role should be delegated to the Federal and State government?

I look forward to reviewing the testimony of the United States Postal Service, the Food and Drug Administration, the National Cancer Institute, and the Arthritis Foundation. I also welcome the testimony of our panel of senior citizens whose individual situations shed light on these abuses. It is my hope that today's witnesses will define and characterize what is meant by medical quackery.

During these high inflationary times it is critical that older persons are made aware of schemes promoting the sale of worthless remedies, treatments, devices, and gimmicks. We must protect the rights of elderly consumers who suffer most severely from fraud in the health field.

PREPARED STATEMENT OF REPRESENTATIVE JAMES ABDNOR

Mr. Chairman, I am pleased to join in this hearing on fraudulent health remedies, especially those which affect the elderly.

As we all know, health care is of vital importance to senior citizens. The elderly spend a higher proportion of their incomes on health related items and use a higher percentage of health resources than their younger counterparts. Health is, as many studies have pointed out, one of the strongest influences on an older person's sense of optimism and worth, and it is essential that the elderly be allowed the best health care possible.

Those who promote fake remedies to serious ailments like cancer and arthritis are certainly taking cruel advantage of the elderly. Taking money from a person on a fixed income with a never-fulfilled promise of health is thievery. One glance at most newspapers and magazines will find an incredible number of ads claiming to do just about anything—help you lose weight instantly, look younger, or feel relief from a vast array of medical problems for which science has not yet found a cure.

While I join you, Mr. Chairman, in condemning the so-called "quack" health remedies with which we are all familiar, I would like to make a plea for consistency in our approach to one aspect of this problem, the Food and Drug Administration's role in approving new drugs. I am sure that most of the problems relating to fraud that the Postal Service will tell us about today are in fact true frauds against consumers. Aside from obvious fakes, however, the area of new drug approvals within FDA is a far more complex issue.

What we need to do is look more closely at the drug approval process itself. As the GAO reported in May, the FDA's drug approval process often delays new drug accessibility needlessly. Certainly we have to insure that new drugs will be safe before we allow them to be marketed. But there is no reason we have to prove that the drug will be 100 percent effective before we allow people to use it. By requiring such strict standards of effectiveness, we are depriving many people of new medications which can relieve suffering and, in many cases, save lives. As one of my constituents pointed out in a briefing in July, the FDA's procedures make it extremely difficult for small producers to get new products approved for market use. Certainly that is not the intent of the efficacy requirement.

What is the connection between the FDA's drug approval regulations and health gimmickry? An important one: we don't, in our attempt to prevent health fraud, want to slow down the approval process still more for important, necessary drugs, or drugs sponsored by small producers. The FDA's efficacy requirement, for example, has helped control the proliferation of useless drugs in the marketplace. We must remember, however, that this same efficacy requirement has kept important drugs like DMSO from being studied as fully as possible. Let's control fraud against the elderly, but let's do it in as meaningful a way as possible by re-examining the procedures which regulate the health and drug industries as a whole.

Again, I would like to thank you, Mr. Chairman, for putting together such a timely hearing.

PREPARED STATEMENT OF REPRESENTATIVE NORMAN D. SHUMWAY

Mr. Chairman, thank you for providing us the opportunity to hear testimony today on frauds aginst the elderly; in particular, postal crimes aimed at the elderly. While the percentage of false mail order promotions may be small compared to the entire mail order industry, the dollar losses involved, and the impact of these fraudulent schemes on the elderly, demand the immediate attention of the Aging Committee, Congress, and citizens alike.

There are several types of fraudulent practices, including work-at-home schemes, investment and job opportunity ventures, land and merchandise frauds, and medical promotions. Because the elderly in America are, as a group, less mobile, restricted by physical impairments, and limited by fixed incomes, they become the unfortunate victims of these unscrupulous mail practices. Lured by promises of improved health and financial success, our senior citizens invest their time, money—their futures—in fraudulent remedies.

While certain preventive and punitive measures have been taken by the U.S. Postal Service, the incidence of fraud is on the rise. I look forward to hearing today's testimony, and am confident that the recommendations presented will assist us in future legislative efforts.

The CHAIRMAN. I want to thank all of you for your excellent statements. Now I would like to introduce the director of our staff, Charles Edwards.

Mr. EDWARDS. Our staff has been collecting various examples of consumer products peddled to desperate people, many of them elderly, in an attempt to solve their problems. Mr. Val Halamandaris will explain some of those devices.

Mr. HALAMANDARIS. I would like to have the staff assist me, Kathy Gardner, David Holton, and Nancy Smythe.

The first item is the Oxydonor. This is purported to reverse the death process. It is still in use. It is a stainless steel tube which one puts in ice water, attaches to the ankle, and places the iced tube wherever there is pain.

The cost is around $30.

Then we have the Inducto-Scope. This device claimed to cure arthritis through magnetic induction. Basically, you place the rings on the affected part of your body, plug it in the wall socket and there is a switch which you use for control. It's only achievement is to expose the sufferer to the further hazard of electric shock. These are useless devices.

The Virilium Tube or Miracle Spike. Arthritis and cancer sufferers paid something like $300 for this tube and it contains about a penny's worth of barium chloride. You can wear it around your neck, put it under your pillow, or chew on it. It was also falsely claimed to cure diabetes. This claim tragically misled a 27-year-old man who had been a diabetic since he was 6. He bought a Virilium Tube and stopped using insulin. He died.

The Theronoid Belt was promoted as a cure-all which worked by magnetizing the iron of the blood. The two-speed switch was for effecting a slow or a gradual cure. Perhaps we can have one of the members demonstrate that. Father Drinan.

Mr. DRINAN. No.

Mr. HALAMANDARIS. Father Drinan performs miracles on his own. He doesn't need this.

If we can have the Rado Pad brought forward. This is supposed to contain radioactive ore and the radium from the uranium is

supposed to cure your arthritis. This pad is full of nothing more than pea gravel, which obviously doesn't have much in the way of curative powers. The price is about $30. It was very much in vogue for a while.

Mr. GRASSLEY. Have these sales been made within the past 10 years?

Mr. HALAMANDARIS. There are still sales being made for the Rado Pad.

We would like to demonstrate the vibrator device. Obviously, they can have some usefulness in relaxing muscles, but when promoted as an arthritis and cancer cure, we and the FDA take exception.

We have a vibrator here sold for health purposes. Obviously, it doesn't fulfill those purposes. This was promoted to prevent baldness and cure your dandruff and also the literature said it was helpful in treating women's ailments.

We have now the classic copper bracelet. A lot of people swear by copper bracelets. The FDA states there is absolutely no curative power in copper bracelets. What you are supposed to do is wear two of them; wear one on your left wrist and the other on your right ankle. It is supposed to set up an electromagnetic current. The bracelets cost about $1 but the purchasers are charged $100 for two.

The Kongo kit. The Kongo kit was promoted as relieving the pain of arthritis by rubbing the mittens or belt over the affected part of the body. It is made of hemp and literally peels the skin off. It causes so much pain you forget your arthritis pain.

Ms. OAKAR. How much are they?

Mr. HALAMANDARIS. They cost $5.

We have seawater back there. That is touted as a cure. The seawater, again, is a product which is not more than just that, salt brine. The cost here was $3, containing 10 times more than normal concentration of minerals.

Then there was another little item I forgot to mention, the Vivicosmic Disc. You are supposed to put that in your glass of water and it makes bubbles. Then you drink the water. If you don't like that, you can chew on it. The advertisement says pregnant women can chew on this. It is made up of minerals, yeasts like pumice stone, and cereals, and it is supposed to cure whatever ails you, including nervous conditions, toothaches, and skin problems. According to its promoter:

> I promise nothing as a result of use of this Vivicosmic Disc. I will promptly refund your money if the disc does not fulfill your most optimistic expectations. I do know that it will be useless to zombies, thieves, cheats, atheists, professional liars, and exploiters.

There are other things that are on the table. We want to demonstrate the classic of all devices, the Spectro-chrome. As you will see, it is nothing but a large box containing nothing more than a large light bulb and different colored filters, depending on your ailment. It will cure your cancer, arthritis, constipation, or whatever.

Set it for arthritis.

The CHAIRMAN. Is this the color for cancer or arthritis?

Mr. HALAMANDARIS. We can change to cancer if you like.

He is supposed to stand in front of it, and as you remember, you are supposed to use this when the Moon is full and you have to be nude and facing north. I don't think you want to strip down for these folks, but it is still in use today. We found some cases right here in the District of Columbia of this device being used by doctors of naturopathy. This sold for $250 and is in use by doctors of naturopathy.

The FDA has been successful in removing most of them from the market. There are some, however, which continue to be in use.

The CHAIRMAN. Thank you.

Our first witness this morning is from the U.S. Postal Service, Mr. Fletcher F. Acord. He is accompanied by Michael Gump and Mr. Wayne Kidd.

Mr. Acord, our practice is if anyone has a written statement that he would like to put in the record, we will be glad to receive it and you can summarize. But if you prefer to read the statement, we would be pleased.

STATEMENT OF FLETCHER F. ACORD, ASSISTANT CHIEF POSTAL INSPECTOR, CRIMINAL INVESTIGATIONS, ACCOMPANIED BY MICHAEL A. GUMP, POSTAL INSPECTOR IN CHARGE, SPECIAL INVESTIGATIONS DIVISION; AND WAYNE KIDD, MANAGER, FRAUD BRANCH, OFFICE OF CRIMINAL INVESTIGATIONS

Mr. ACORD. Mr. Chairman, I am Fletcher F. Acord, Assistant Chief Postal Inspector for Criminal Investigations. I am accompanied today by Mr. Michael A. Gump, Postal Inspector in Charge, Special Investigations Division. I welcome the opportunity to appear before this committee to discuss our efforts to prevent and combat crimes against the elderly.

As you know, the Postal Inspection Service is the investigative and audit arm of the U.S. Postal Service. We have investigative jurisdiction and enforcement responsibility over all violations of Federal laws relating to the Postal Service. These violations fall into two broad categories.

First, actions which involve a criminal attack upon the mails, postal facilities, or postal employees, such as armed robberies, burglaries, theft of mail, and assaults on postal employees. And, second, those which involve criminal misuse of the postal system itself, such as the mailing of bombs or pornography and, of course, mail fraud.

The magnitude of these responsibilities is in direct proportion to the size of the Postal Service itself which last year handled just about 100 billion pieces of mail, has some 650,000 employees, over 40,000 facilities, and cash receipts of about $18.5 billion.

To meet these responsibilities, the Inspection Service has a nationwide complement of 2,000 postal inspectors, a uniform postal security force of approximately 2,500 in the larger cities throughout the country, and a variety of other support and administrative personnel, including six forensic science laboratories strategically located throughout the United States.

The CHAIRMAN. I presume, without being vain, ours is the largest Postal Service in the world.

Mr. ACORD. Indeed it is. We handle half of the world's mail.

With that brief summary, let me move to the purpose of my appearance here today, which is to discuss our common interest in protecting the elderly against crime.

Senior citizens are heavy users of the mail. It is convenient for them. It provides an ideal way by which they can obtain services or goods at a minimum of cost and effort. In fact, the Postal Service has been promoting shop-by-mail since the country first experienced the energy shortage. As a group, the integrity of senior citizens is superb. They pay their bills on time.

Unfortunately, these very factors make the elderly prime targets for the unscrupulous mail order swindler. Let me here insert a cautionary note about what I am saying: The vast majority of mail order firms or offerings are legitimate. I am focusing on the relatively few who have distorted and used the system for their own illegal gains.

Recognizing this, we have designated the area of postal crimes against the elderly as one of our highest priority programs. A little later in my testimony I will be discussing actual case files which are representative of schemes where the primary victims were senior citizens. While we feel successful criminal prosecution in these types of cases serves as a deterrent to others, the fact remains that the victims of these schemes will generally lose. The ideal solution is, of course, to prevent individuals from being victimized in the first place.

We, therefore, consider the prevention of crime as our best tool in our criminal investigative effort. We will always investigate criminal cases because even the best preventive efforts will not deter all crime. However, we do believe a substantial reduction in crime can be accomplished through a combination of public awareness and a lessening of opportunity for the criminal. We think the efforts of this committee in holding these hearings is very helpful.

To this end, last year the Postmaster General initiated a consumer protection program—a program of prevention through education and awareness. This is a united effort of the Postal Service. It brings to bear the resources of several departments of the Postal Service—the Public and Employee Communications Department, the Customer Services Department, the Law Department, and the Inspection Service.

We selected and trained inspectors across the country as consumer protection specialists. Their mission is to educate and inform—working with such groups as the American Association of Retired Persons.

We are jointly preparing information programs to be taken to all 6,000 chapters of that organization. We are also cooperating with other similar regional and local groups. As a part of that effort, we are preparing or have prepared pamphlets and handouts, some of which I have here, which address specific problem areas or schemes.

We are also cooperating with the media and have appeared in hundreds of talk shows and interview programs, all in an effort to heighten public awareness.

In our investigative efforts we use a two-pronged attack. First, we consider the possibility of criminal prosecution under title 18 U.S.C. section 1341, which is the mail fraud statute. It is one of this

Nation's oldest consumer protection laws. The law is quite simple but very broad. Essentially, whoever uses or causes the mails to be used in an effort to defraud is guilty of mail fraud.

Second, and perhaps more important to the consumer, we take action under title 39, United States Code, section 3005. This section permits the Postal Service, upon proper showing before an administrative law judge, to withhold and return to the sender mail addressed to anyone who solicits moneys through false representations. Oftentimes this is the only effective remedy, particularly with work-at-home and medical schemes, where victims are very reluctant to publicly display their gullibility in any criminal proceeding.

There are several types of fraudulent promotions which, by their nature, tend to focus on our senior citizens. They include work-at-home schemes, investment and job opportunity ventures, land and merchandise frauds, and spurious medical promotions which probably affect senior citizens more than any other. Through cleverly conceived advertising, promoters tout all manner of miracle cures.

Due to rising costs of medical attention and perhaps previous unsuccessful attempts to alleviate their suffering, the elderly are often tempted to try these purported cure-alls for a long list of problems, including arthritis, cancer, obesity, impotency, and baldness. Our years of dealing with the problem of medical fraud has led us to believe that a great part of this type fraud is controlled by a rather small group of operators.

The callous nature of these promoters and the grave danger involved in their product is perhaps best illustrated by a California case. The promoter sent thousands of direct mail advertisements to people throughout the United States and Canada purporting to have a wonderful new medical discovery to cure cancer and, "any complaint that may be treated via the bloodstream."

The home treatment cure was priced at a staggering $700, but in spite of the price, the promoter was receiving up to 10 inquiries per day concerning the product. No medical examination was required and each purchaser was furnished instructions with the purchase.

The product which we show you here was composed of injectibles represented as 100 percent pure organic extractions from kelp and seaweed, and oral medicine to be taken by the patient. We purchased the product and received bottles of B–12 vitamins, bottles of fluids containing a kelp compound, and a needle to inject the fluid.

These fluids were so contaminated by poisonous bacteria that serious illness or death could result. The promoter was arrested and when confronted with the evidence, pleaded guilty to mail fraud. Part of his sentence was to notify as many people as possible of the danger of the product and to urge them not to use it.

[The following was received for the record:]

Various
Advertisements

National Institute of Justice
United States Department of Justice
Washington, D.C. 20531

Mr. ACORD. Then there was a promoter who, with these half-page newspaper advertisements, touted a cure for nearsightedness, farsightedness, astigmatism, and middle-age sight problems, with only an eye exercise program. The exercise method directed users to ignore standard medical advice, telling them instead to do such visually destructive things as to gaze directly into the sun and to ignore their medication for such disorders as glaucoma. The program cost $9.95 plus $1 shipping. Medical experts who reviewed the program said it could actually lead to blindness. Approximately 66,000 people responded to the ads with an estimated loss of $726,000.

Dr. John Gamel, assistant professor of ophthalmology, University of Louisville, also read this advertisement. I would like to quote to you some of the unsolicited comments he wrote to us about this eye exercise program, known as the Bates method:

I can only describe it as nothing more than the rantings and ravings of a clearly insane person.

Dr. Bates has been dead for many years now, and I cannot explain to you how the insane writings of this most unfortunate fellow came to be published.

Although I feel the lesson learned by investing $10 in a mail-order fraud might very well be worth the minimal monetary cost, I think that blindness is a most unreasonable price for someone to pay for simple mindlessness or gullibility.

I will unequivocally support your department with all my professional expertise and will stake my professional titles upon the dangerousness of Dr. Bates' method.

Millions of senior citizens suffer the crippling effects of arthritis. All too frequently arthritis sufferers grasp at anything to relieve their pain and suffering and therefore are open targets for the con artist. Medical fraud promotions alleging cures for arthritis are common occurrences. All kinds of concocted potions and tablets have been touted as cures for arthritis. Whether it be as promoted in the late 1960's and early 1970's, a powder as shown consisting of wheat cereal, protein, and small amounts of vitamins, or as in 1979 a mixture of cod liver oil and orange juice, it has been guaranteed as the new-found cure for arthritis.

[The following was submitted for the record:]

Mr. ACORD. Nor do the fraudulent claims for arthritis cures stop with orally taken potents. In 1974, and again in 1978, a copper bracelet as we show you here and as was previously demonstrated was advertised as a "space age discovery" and guaranteed to cure arthritis, rheumatism and bursitis.

[The following was received for the record:]

[illegible]

postage & handling.) That is our guarantee!! Santa Monica, Calif. 90403

Mr. ACORD. About 36,000 people responded to this advertisement which promoted a product that would enable a person to "make love with anyone you desire." The advertisement claimed this product was the "miracle that can revitalize your sex life in just days even if you are 100 years old." For $10, a person received a bottle of vitamin/mineral capsules similar to those purchased across the counter of any drugstore, and this so-called advice manual resembling an advice to the lovelorn column.

[The following was received for the record:]

Mr. ACORD. Robert Butler, M.D., Director, National Institute on Aging, provided the expert opinion which refuted these advertising claims. Approximately $360,000 was lost to this phony promotion before the concern was put out of business.

A nationwide direct mail and national publication campaign which advertised a formula to get rid of prostate pain and distress drew an estimated 42,000 victims who lost about $420,000 from Krueger-Ross Laboratories.

[The following was submitted for the record:]

Mr. ACORD. Purchasers received a 90-day supply of tablets which medical experts described as an irrational concoction of zinc, pumpkin seed, and bee pollen. The experts also stated that this promotion was pure quackery, adding, dependence on this product as therapy could lead to death since it may delay getting proper medical treatment.

We are frequently asked to place a dollar value on this type of fraud. However, any effort to do so would be strictly a guess. Let me assure you, however, the losses are substantial. One medical fraud promotion recently stopped by us resulted in over $400,000 worth of orders being returned to the senders, and this represented only 30 days of business. A diet-type fraud stopped this summer was receiving 5,000 pieces of mail a day and the average order was for $22.45. For those of you who do not have a calculator, that promotion was grossing over $112,000 a day. This year alone, we have taken action against 132 medical fraud promotions.

A very prevalent fraud aimed at the elderly is the so-called work-at-home scheme. The most common offerings are for envelope stuffing or the making of a product, perhaps baby booties or aprons. It is usually alleged there is a market for such products when there is none, or that the promoter will buy the products where, in fact, the promoter will not. I think you are all familiar with the kind of advertisements I am talking about. "Earn $400 or more per month in your own home, no investment necessary, choose your own hours," and that kind of come-on. We know of no such work-at-home scheme that ever produces income as alleged.

In an effort to identify these operations, we have developed a brochure which has had far more response than we anticipated. This brochure describes the typical work-at-home schemes with cautions for the consumer. It also asks the consumer to notify us of suspicious advertising and has a tear-off portion for their use in notifying us.

Since we put this out in June of this year, we have been receiving over 150 reply cards a week identifying numerous promotions, some of which we were totally unaware of. In the last 6 months, we have put out of business through false representation orders or consent agreements hundreds of these phony work-at-home promotions.

As of this morning, Mr. Chairman, we have jacketed over 200 investigations as a direct result of consumers notifying us of what appears to be fraudulent advertising. They are sensing it through this campaign of ours.

I brought with me some of the reply cards we are receiving and I will take a moment to read to you some of the comments. As you can tell, these persons are elderly and are interested in obtaining legitimate ways they can augment their incomes.

Mrs. Mabel V. Statts, 58, of Denver, Colo., whose husband is 64 and on disability retirement states, "I have been a victim—almost! Thanks to you, my check was returned. I am very grateful and I think your program and the people carrying it out should receive some good publicity. Perhaps it might help to stop such schemes."

Mrs. Irene N. Rae of St. Petersburg, Fla., states she "answered an ad in the St. Pete Times for addressing and stuffing envelopes. After sending the required deposit of $15, I learned I would have to

do similar advertising in all leading magazines and papers at my expense. This ad is very misleading and deceiving. Since I am on a small social security income, I was looking forward to making some extra money. Any help you may give that others, too, might not be taken in like this would be appreciated."

Mrs. Margaret G. Whitney, age 70, of Albuquerque, N. Mex., states, "I have been a victim, almost. Thanks to you for sending my check back. I thought I had lost it. Thank you again and hope you can help me if I can do something at home."

A typical scheme was a promoter who offered work-at-home employment making foundations for wreaths. These foundations were to form the backing for decorated Christmas and funeral wreaths. The operator, Harry Morrison, formed a company called W.C. Wreath Co., and guaranteed to purchase these foundations for $1.50 each. Morrison also guaranteed the investors they would be earning more than $1,200 per month.

No wreaths were ever purchased by Morrison and before we were able to arrest and convict this man for fraud, 300 of Florida's senior citizens invested $47,000 in this promotion. This wreath is one of 500 made by Mr. Frank J. Gruber from Titusville, Fla., a 68-year-old retired machine designer who wanted to continue his life as a productive citizen. Mr. Gruber personally went to Morrison with some wreath foundations and was assured they were quality and would be bought by W.C. Wreath Co. That is all he got, a lot of promises.

[The following was received for the record:]

[redacted]

[redacted]

Mr. ACORD. Another example involves four San Antonio, Tex., promoters who, through nationwide, direct mail and newspaper advertising campaigns that reached beyond our borders into

Canada, offered work-at-home employment stuffing envelopes. For a $15 application fee, respondents were guaranteed a weekly income of more than $350.

Actually, those who sent the application fee were instructed to place a newspaper advertisement exactly like the one that enticed them to send $15 and to send the responses directly to the San Antonio promoters. These respondents were then given the same instructions.

At the peak of these promotions, the firms were receiving up to 5,000 pieces of mail daily. When we stopped this scheme through a false representation order, we returned to senders over 25,000 pieces of mail containing approximately $375,000 in additional orders. This letter of instruction and an innocuous booklet on business opportunities were all the people received for their application fee.

[The following was received for the record:]

[redacted]

Mr. ACORD. Some schemes even go beyond all bounds of decency. Last spring a woman in San Francisco sent billing notices to recently deceased persons' families, the names of which she obtained from newspapers ranging from San Francisco to Seattle. The notices were printed on stationery bearing the name of a phony gift service, billed in the names of the deceased and stated that a payment of over $100 was due on a gift they had purchased. She even made statements in the billings which led the intended victim to believe that the gifts were purchased by the recently deceased as a surprise gift for the spouse.

This is an old scheme and in the past has claimed numerous victims before we were alerted. However, in this case we were lucky. A woman who received one of the invoices knew at once it

was a phony and contacted us. As a result, Marguerite Moore was arrested just 2 weeks after she mailed her first invoice. She later pleaded guilty and was sentenced to 3 years in jail.

Another growing problem area which affects the elderly is in the broad spectrum of investment swindles. This involves a variety of schemes, including franchise/distributorship, investments in coins, gems, stocks, land sales, and a host of others.

We feel that the increase in investment-related schemes has a direct relationship to the economic situation of today. During times of inflation, people are looking to invest their savings in ways that will keep up with that inflation. Those on fixed or low incomes are seeking ways to supplement that income.

We frequently find that the victims are elderly people who have been persuaded to invest their nest eggs. As I indicated earlier, there are many legitimate investment opportunities available in all of the areas I have mentioned and a preponderance of these opportunities are legitimate. However, this only serves to give the mail fraud operator a better climate in which to conduct his fraudulent promotion.

A typical investment swindle was carried out by the Progressive Farmers Association (PFA), an investment corporation formed in the State of Missouri by Russell Phillips. Phillips allegedly organized the corporation to raise working capital for a new type of cooperative which would bring farmers and consumers together, eliminating the middleman, and would raise crop and livestock prices while cutting food prices.

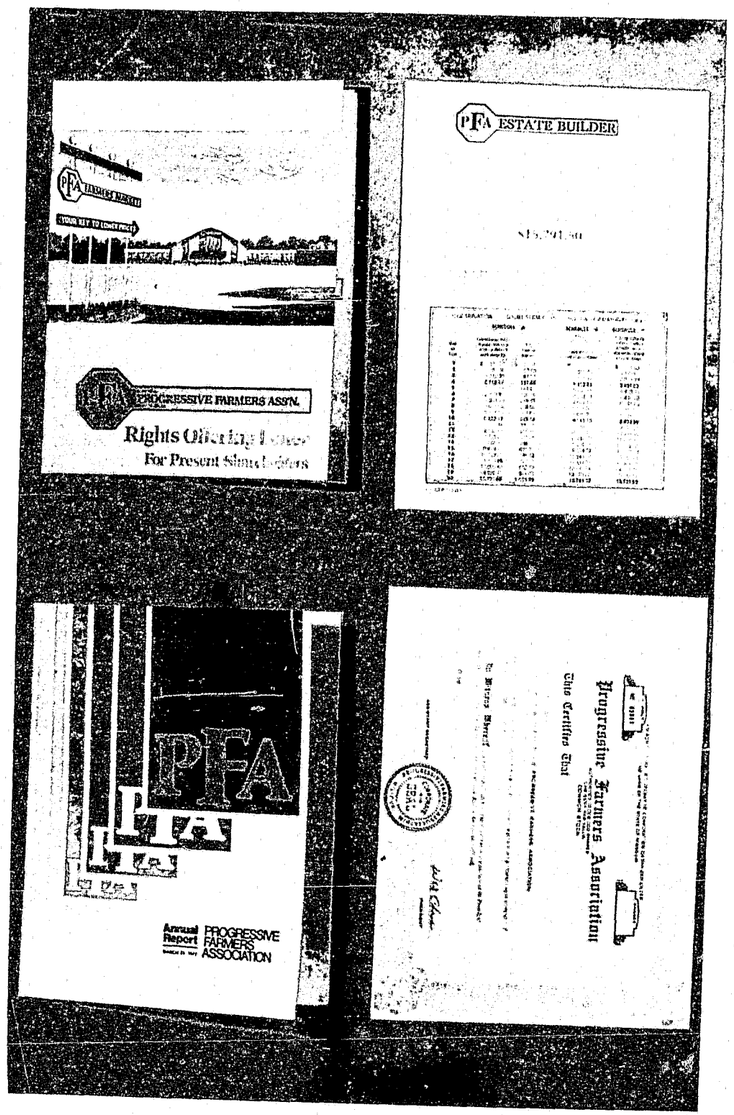
To raise capital, Phillips sold securities known as estate builders to individuals, the majority of whom were retired or semiretired farmers. In fact, they comprised 60 percent of all the victims.

PFA salesmen conned people into investing their savings with promises of doubling their money. These investments were to be used to establish farmer's cooperative markets throughout Missouri.

However, none of the promised markets were opened. Instead, the operators of PFA used the money to pay themselves exorbitant salaries and for investments in other personal enterprises. In May 1977, PFA filed bankruptcy, but not before they had convinced 6,000 people to invest $12 million in this venture.

One 72-year-old man invested over $70,000. Another elderly farmer, who invested approximately $50,000, committed suicide as a result of his lost investment. A Federal grand jury indicted 22 individuals on 175 counts for mail fraud and Rico Statute violations. Through plea negotiations, 12 pled guilty and as of August 25, 1980, after a 10-month trial, Phillips and the remaining defendants were found guilty. They are scheduled for sentencing next week.

[The following was received for the record:]



Mr. ACORD. I know insurance fraud directed against the elderly has been a major concern of this committee and one which through your efforts has received considerable attention by both legislative bodies and prosecutors throughout this country.

We recently concluded a trial in Massachusetts which is indicative of the type of criminal action being taken against those who set out to cheat the elderly through insurance policy scams. The owner and associates of the Charles T. Marquis Insurance Agency were convicted of defrauding over 100 elderly women residents of Massachusetts and Connecticut.

This scheme was carried out through overcharging for insurance premiums, falsifying health histories, selling life insurance under the pretext it was health insurance, duplicating insurance coverage, and even selling maternity insurance to one 93-year-old woman. Some of the victims were paying $6,000 to $9,000 a year in insurance premiums. The youngest victim was 64 and the oldest to testify at the trial was 95.

I believe U.S. district court Judge Frank H. Freedman best described this case at the time of sentencing, and I quote from his statement:

> This is one of the worst cases of mail fraud I have ever seen. This is like vultures circling over the heads of people dying of thirst in the desert. You are like those vultures. You picked your victims and took their life savings. These were people in their eighties and nineties who depended on you and trusted you. You violated that trust and hurt your own profession. You eked out their life savings. Whenever you needed money, you went and got it from the elderly.

As you can see, the variety of fraudulent schemes is seemingly endless. I pointed out earlier in my testimony the Postal Service is encouraging the use of the mails to shop, and we therefore feel very strongly about our obligation to keep the mails as free from misuse and abuse as possible.

I state again the percentage of phony mail order promotions is small when compared to the vastness of the total mail order industry. But the dollar losses are substantial and any percentage, no matter how small, will be addressed by us.

Mr. Chairman, it has been my pleasure to report to you the efforts of the Postal Service to combat crimes against the elderly. I will be happy to answer any questions you may have.

The CHAIRMAN. Thank you very much, Mr. Acord, before we ask any questions, suppose we also have the statement of Mr. Gump.

Mr. ACORD. He will not be making a separate statement.

The CHAIRMAN. Our distinguished member, Mr. Roybal is with us. I want to commend him especially as chairman of the Subcommittee on Housing and Consumer Interests for the work he has done which has covered very ably the area we are working in today. He has an acute interest in that subject and is doing a splendid job in trying to acquaint the country with the problems we face in that area.

Mr. Roybal, do you wish to make a statement?

Mr. ROYBAL. I ask unanimous consent that my opening statement be included in the record.

The CHAIRMAN. That has already been done.

Mr. ROYBAL. Thank you. The question I have concerns investment swindles. I have had several people complain to me about articles in newspapers and magazines that advertise how a person

can became very wealthy by using a certain technique. For $13 or more dollars, they offer to sell a book which describes this technique. The book the consumer receives is not printed, but mimeographed.

Mr. ACORD. Yes we have, Mr. Roybal, it is difficult for me to respond directly to your question without a specific occasion. So let me handle it in generalities and say this: Where we have printed matter such as that, we have an obligation to recognize there are other safeguards we must recognize, such as first amendment safeguards. As a consequence, sometimes those printed books almost defy prosecution under the mail fraud statute, because of the safeguards invoked as a result of the first amendment. There have been successful prosecutions of some kind of offerings. If you have a specific example in mind, I would be glad to talk to you after these hearings or at your convenience and we can work together on it.

Mr. ROYBAL. I do have specific examples and I appreciate the fact we can discuss this.

Mr. ACORD. Suppose I have my staff get in touch with you.

Mr. ROYBAL. Fine. However, I am particularly interested in those individuals who do not receive a printed book as such, but receive instead, something that is mimeographed. My question is, is there a difference between those who sell books and those who sell mimeographed information?

Mr. ACORD. Yes, generally there is. The person who sells the printed book, generally is offering the article advertised, whether the information in that book is valid, is another issue. The person who advertises the book and sends a mimeographed book is not sending the article advertised and hence you have a potential violation of the mail fraud statute.

Mr. ROYBAL. Suppose the information that is advertised, is not contained in the written material that he sends? In other words the advertisement says—if you use my system, I guarantee you that within 6 months you will be ahead $1,000. If that kind of promise is made and I get that book or both of us get that book and we follow a system exactly the way it is described and we find out that it does not work which most of the time it does not, is that man in violation.

Mr. ACORD. Yes, he is.

Mr. ROYBAL. Have you had any experience with that?

Mr. ACORD. Yes, we have.

Mr. ROYBAL. Will you talk to me about that also.

Mr. ACORD. I do not have specific information with me today, but we have had three successful prosecutions in matters of that kind. The difficulty there is the perpetuation of the scheme as the person who gains the book or pamphlet tries to put it in order, then the variations which arise out of an attempt to put it in order so we can in a court of law, say to the court, this scheme was tried exactly as was prepared and did not work when in fact, that is almost impossible. So we have a great deal of difficulty in prosecuting those kinds of cases but we have had some success.

Mr. ROYBAL. What powers does the Postal Service have in prosecuting these frauds and second, do you need any additional legislation to make your powers more extensive?

Mr. ACORD. As Mr. Pepper indicated at the beginning of this hearing, we subscribe to the thought that we lack some of the legislative tools with which to deal with that vast problem completely. Senator Glenn, and within the House, Chairman Hanley, have introduced in House Bill 6307, some proposals which we put forth to that committee, which we think will give us the kind of tools by which we can do a more effective job.

Mr. ROYBAL. Thank you, Mr. Acord.

The CHAIRMAN. Thank you very much, Mr. Roybal. Ms. Oakar.

Ms. OAKAR. Thank you Mr. Chairman. I do not know what page this is on, but you mentioned you have taken action against 132 medical fraud promotions. It is on page 8. How many of these resulted in stop action or prosecution?

Mr. ACORD. Let me defer to Mr. Gump.

Mr. GUMP. Of the 132, some of those are still continuing. The actions are pending at this time. However, this year we have taken action against 28 stop orders, we have had 22 consent agreements and we have had 12 temporary restraining orders in support of the false representation orders this past year.

Ms. OAKAR. Do you see these people operating in other States?

Mr. GUMP. This is one of the things we encounter in investigating these frauds the way the false representation statute is worded, we have to identify a specific company name, trade style, and address. It is very easy for the operators of these firms to simply change their address and start marketing from a new address so we are required to go back and start the action all over again.

Ms. OAKAR. What do you recommend we change in the law?

Mr. ACORD. In working with Mr. Hanley's committee, we have proposed several changes, one of which addresses the issue which you ask about. We presently do not have civil penalties of any sort when an order by an administrative law judge is violated. We are proposing civilian penalties be applied with proper judicial restraints where it is shown the operator has avoided, deliberately, the intent of the order. That word "intent" we believe will cover the individual who moves to a new locale, sets up a new address or operates under a new assumed name but in essence is offering the same product.

Ms. OAKAR. 6307?

Mr. ACORD. Yes.

Ms. OAKAR. The diet fads that you mentioned, I am not sure they relate only to the elderly, but can you tell me what percentage of people are bilked?

Mr. ACORD. In diets only?

Ms. OAKAR. If you can break it down, fine.

Mr. ACORD. Approximately 60 percent of all the frauds are aimed at the elderly or the elderly are the primary victims.

Ms. OAKAR. What about insurance?

Mr. ACORD. I do not have that data at my fingertips.

Ms. OAKAR. I guess one of the points I am trying to make is that this issue, while geared so much toward the elderly, all Americans should be aware of this type of mail fraud. Am I correct about that?

Mr. ACORD. Indeed, we wish they were.

The CHAIRMAN. Ms. Ferraro.

Ms. FERRARO. Thank you, Mr. Chairman. You said there are no civil penalties? Is there injunctive relief that is granted or what?

Mr. ACORD. There is in the preliminary processing of the mail fraud stop order. In this sense, as we move to stop an operation, the first thing we can do is go to a U.S. district judge and there seek a temporary restraining order which stops the operation immediately. In order for us to do that we have to satisfy the same purpose that must be satisfied in any TRO hearing.

Following that hearing the process moves to an administrative law judge. In that hearing, of course, the evidence we have to follow is the same as in the case of any civil hearing, that is we must present a preponderance of evidence to show there has been a fraudulent operation or aspect to an operation. If the administrative law judge finds in the Postal Services' favor, he issues a permanent order which stops the mail permanently from going to that operation.

Beyond that point, however, we have no additional remedies.

Ms. FERRARO. So there is no criminal prosecution by your office?

Mr. ACORD. Except for criminal prosecution which may be months, sometimes years following the immediate move we make to put them out of business, obviously the thing we want to do where there is a fraudulent offering is to put them out of business as quickly as we can and follow that with the criminal action if in fact the evidence we can gather will support and sustain that kind of action.

Ms. FERRARO. So actually what happens with the criminal prosecution you have a greater burden?

Mr. ACORD. A much greater burden on the proof.

Ms. FERRARO. On page 9, you mention brochures. Do you have a copy and can you submit it for us?

Most of our congressional offices have the ability to disseminate most of this information to our senior citizens and I wonder if it is available to the congressional offices.

Mr. ACORD. Indeed it is and we will make them available.

Ms. FERRARO. I agree with you, it is great to stop the person, but once you have a victim who does not get his money back and certainly elderly people suffer much more traumatically than a younger person, it is a tremendous traumatic reaction.

Mr. ACORD. Let me respond to that by adding we have found over the years in dealing with this subject, that most people will not complain if the loss is less than $20. Hence, we know there is a vast group of people out there who have been swindled who simply will not take the time or are not willing to talk about it and acknowledge their gullibility for something less than $20, so there is a vast undercurrent which continues to influence and work against the American public.

Ms. FERRARO. There is also the fact that sometimes people are embarrassed at having been taken.

Mr. ACORD. Indeed I would be.

Ms. OAKAR. I want to ask what the responsibilities are of the papers and magazines which advertise these so-called products? Can you prosecute them for permitting that kind of advertising?

Mr. ACORD. No, we have no prosecutive authority in a case like that.

I think perhaps the best article to review the very question you are talking about, comes in a January 1979 issue of Consumer Reports, entitled "Delusions of Vigor, Better Health by Mail."

We in the mail service, think it is a helpful article which discusses the issue you have raised.

Ms. OAKAR. It seems to me, Mr. Chairman, we ought to have some kind of a governmental ombudsman program where we would recommend to the media, the communication network in this country to accept a certain degree of responsibility in terms of the apparent false advertising that is done. I know how expensive these investigations are and what it means to the advertising. But on the other hand, the same consumers reading the newspaper, ought to be up in arms that they permit this kind of falsehood to be served to the American people. Are you permitted to respectfully suggest this is false advertising or not?

Mr. ACORD. We in our preventive effort have worked closely with many of the major publications and with the news media, particularly radio and TV. I do not think the advertisements you see on television and radio are nearly in quantity or in deed, that which you are talking about. So I am limiting my comments just to the printed word. We have worked with some of those people and in some instances they do have some good sorting processes by which they refuse advertisements. But obviously with all the advertisements which appear, there are many who do not screen any of the advertisements at all. It speaks for itself. The publications, be they magazines, newspapers, or whatever, are loaded with them.

Ms. OAKAR. It is something we might like the committee to look into.

The CHAIRMAN. That is an excellent thought because obviously people reading a reputable newspaper think the ads are probative. When the staff makes recommendations as to our action, that should be considered.

The CHAIRMAN. Mr. Shumway.

Mr. SHUMWAY. Thank you, Mr. Chairman. Mr. Acord, I was not here for the presentation of your statement but I have looked through it and I think I have captured the substance of what you have mentioned this morning. I am glad you placed emphasis on education. I am curious as to whether you have adopted a particular program for education and particularly, if you have made any plans or see any way that such a program could be used through area agencies on aging or programs through senior citizen centers and if so to what extent should we be involved and are you suggesting that this morning?

Mr. ACORD. The simple answer to all facets of that question is yes.

Let me enlarge a little on my testimony so you will have some appreciation on what we have tried to do.

We are presently making contacts with all the known agencies representing special interest groups. We feel these groups probably are a better way to carry our message than it is to generally shotgun a message to people who may or may not be listening. So as a consequence, we have made a great deal of effort in identifying special interest groups and then going to them, such as the American Association of Retired Persons. I comment on them,

because they represent a tremendous number of people. I think they count around 13 million in their numbers. As we have worked with that organization, as you are probably aware, they have a cartoon strip advising people on various facets of life, how to purchase a car, and so on. They now have a postal agent in the scenario and he comes forward and warns them about certain schemes they should be aware of.

We have done the same thing with State and local legislative bodies where we think they can be more useful in making the public more aware as to what they can do in preventing themselves from being victimized. We would be delighted to work with this committee in our joint efforts to inform and educate the American public. That is the real key to stopping so much of this victimization.

The CHAIRMAN. Excuse me. I want to express my appreciation for the media covering this hearing today. I hope the warning will go out all over the country and many people will profit from what is being said here today.

Go ahead.

Mr. SHUMWAY. Have you worked with the Administration on Aging?

Mr. ACORD. Yes, we have. As you may well guess, this is a new area for us. In law enforcement in general, particularly on the Federal level, we have not been responsive to our responsibilities in the preventive aspects of our work. So as we get into it and plow what is to us, virgin ground, we are making contact with all the agencies, hoping we can gain from their experience and hoping we can be of benefit to them.

The CHAIRMAN. Mr. Hughes.

Mr. HUGHES. Thank you, Mr. Chairman. I want to thank you Mr. Acord and your colleagues for your testimony. I have read it. Many of the questions I have, have been anticipated or already asked. But the one area you did not touch on, when you talk about the interface with other agencies, special interest groups interface with consumer agencies in other States which I would think would be important.

Mr. ACORD. We think we have a complete list of all those individuals and we routinely supply them now with information which we feel would be either of benefit by way of warning or information which tells them of actions we have taken.

Mr. HUGHES. One of the things I have noticed, and I served about 10 years as a prosecutor in my own area, is whenever we begin to focus in on one aspect of a consumer fraud, the people who think they are clever, always to go another forum. I have noticed a shift from mail to telephone. What are we doing to address that particular problem? Obviously we cannot treat it on a fragmented basis. We can accomplish the same thing—a swindler can accomplish the same thing by using the telephone because older people like to talk on the telephone. Do we have some interface with agencies trying to address that aspect of the problem?

Mr. ACORD. As you know, Mr. Hughes, that aspect is handled by the wire fraud statute, section 1343 of title 18.

We unfortunately do not have investigative jurisdiction assumed or assigned under that section except as it may be peripheral to

69-629 O - 81 - 3

one of our investigations. We are worried about that and are entering into negotiations with the Justice Department. We have noticed particularly in the last 60 days, that some of the major medical fraud operators in the country, as we have applied the pressure, have swung to the 800 number routine in order to avoid charges by us.

Mr. HUGHES. I am happy to hear that because in the short time I have been around here, I find agencies do not communicate with each other and as a result we do not address a problem. It seems to me the telephone does offer an alternative. If we are not sharing the information you have developed, identifying the people who are trying to pull these fast buck routines, then we would not address the problem correctly.

Mr. ACORD. The Department of Justice has just recently issued prosecutive guidelines and priorities that will be of great help in providing the coordination you are talking about.

Mr. HUGHES. The only directions through a consumer protection agency such as we have in New Jersey which can pull it all together, which works with investigative agencies such as yours which tries to promote and point out to the unsuspecting some of these frauds as they are being developed, anticipating problems before people are taken, not after the fact. Frankly, I think there is a tremendous need for that type of service. Our own consumer agencies in New Jersey do a pretty good job in trying to alert the public as to the promotions we are talking about. Agencies such as yours are important because they enable us to focus in on the schemes after the fact.

Mr. ACORD. I was the inspector in charge of the Newark division before I was appointed to my present position and it is a fine effort in consumer protection.

The CHAIRMAN. Thank you, Mr. Hughes.

What percentage of the total volume of the kind of fraud you have described, do you think, through your operation and others of the Government, are we able to curtail or able to stop or able to punish the perpetrator?

Mr. ACORD. Mr. Chairman, I hesitate to put any kind of figure on that because the basis is the unknown, what is out there, and we simply do not know what is out there.

The CHAIRMAN. In other words, it is possible that what we know is only the tip of the iceberg?

Mr. ACORD. Indeed it is.

Mr. ROYBAL. May I ask one quick question?

The CHAIRMAN. Yes.

Mr. ROYBAL. Is there some place people can call for advice before making the investment?

Mr. ACORD. We suggest they do several things: That they check with their Better Business Bureau; that they check with their consumer advocacy offices available to them; that they do business with firms they know or can check on. The Postal Service does not offer advice such as you are suggesting, nor does any other Federal agency that I am aware of. We tend to look at ourselves as perhaps playing too much of the attorney role when we do that kind of thing. I do believe that to be fact, that we are replacing or substituting an attorney in this particular instance because we do offer

information on many subject matters. The Federal Government is involved in that and it seems to me, we should have some agency, some office somewhere where people can call for that purpose. I think it is something this committee can look into and make the recommendation when it finally comes.

The CHAIRMAN. Mr. Roybal, as to the suggestion you have, would it be within the law and would it be desirable in the public interest, for the Postal Service to run some kind of ads in the papers of the country, let it come under your auspices, that we are engaged in trying to protect the people of this country from fraud of one sort or another. Our experience suggests that much of this kind of fraud is perpetrated upon the people and we would recommend before people spend their money on things presented to them as being very desirable in any area, that they make an appropriate investigation into the matter?

Mr. ACORD. You must be reading our minds because that is what we are planning to do now. In addition to that, many of the major newspapers and indeed the electronic media have offered us free space, at their expense, and have prepared public service announcements.

The CHAIRMAN. I am delighted to hear about that. It can do a lot of good and forewarn people. I wish we could take more time but we are running short of time.

We thank you Mr. Acord, Mr. Gump, and Mr. Kidd.

We always get too interested in our first witnesses.

The next panel are people who have had experience in quackery and fraud. Our first witness will be Mrs. Lena Rosenberg of Philadelphia, accompanied by Steven Kaplan, assistant district attorney of Philadelphia. The next is Mr. Don Harbour of Oklahoma City; and Mr. Robert White of Panama City, Fla.

Will you proceed, Mrs. Rosenberg. If you have a written statement, we would appreciate it if you let us put your statement in the record and you give us a 5-minute summary of what you want to tell us. We would welcome it, if you could make an oral summation of your testimony. If you do not feel you can make the summary and would prefer to read the statement, you may.

Mr. Kaplan, you may present Mrs. Rosenberg.

STATEMENT OF LENA ROSENBERG, PHILADELPHIA, PA., ACCOMPANIED BY STEVEN KAPLAN, ASSISTANT DISTRICT ATTORNEY, PHILADELPHIA, PA.

Mr. KAPLAN. Chairman Pepper, members of the committee. Good morning. My name is Steven Kaplan. I am an assistant district attorney on the staff of Edward G. Rendell, the district attorney of Philadelphia, Pa. I am also a member of the D.A.'s economic crime unit, lead by Chief Laurence H. Brown. That unit bears the primary responsibility for handling the investigation of white collar crimes of every description, from frauds against banks, insurance companies, and the agencies of our State and local government, to frauds committed against ordinary individuals in our city of nearly 2 million people. People like Mrs. Rosenberg, who is here with me today.

Of all of the thousands of people who come into contact with my colleagues and me each year because they have been victimized by

fraud, theft, and deceit, perhaps no class is more often represented or more compelling in its plight than the class of senior citizens.

Senior citizens are victimized because of a variety of factors that seem to occur more often among them as a group than among others:

First, they are, as a class, less mobile than other groups, thus less able to go from merchant to merchant comparing qualities and prices. As a result they often end up with inferior goods at wildly inflated prices.

Second, many senior citizens find that their age brings with it impairment of their sight or hearing. Though such problems may exist for anyone—senior citizens are often too proud, or too embarrassed, to ask a salesman to repeat himself or to have someone help them with a contract's small print. Thus, they are often easy victims for an unscrupulous home improvement contractor or door-to-door salesman.

Third, the elderly, too, seem to be attractive victims for individuals who have become familiar enough with the criminal justice system to know that if a prosecution witness is too infirm to make it to court, or if they cannot remember the facts or identify the defendant, no conviction can be obtained.

Fourth, finally, the ailments and afflictions that go with age often leave this class groping for the miracle, magical cure that will restore lost vigor or extend threatened lives. Charlatans and healers of every description thus often find willing prey among our elderly.

At the committee's request, I have brought Mrs. Lena Rosenberg with me today to tell you of her experiences. I believe that she typifies a group of senior citizens who when confronted by the grim realities of a loved one's medical condition turn to anyone who offers hope. When a man in Philadelphia told her that her husband's condition would take as much as 2 years to help, she wanted so much to believe that he would be alive for that treatment that she accepted his entire regimen.

Thank you. I will introduce Mrs. Rosenberg.

The CHAIRMAN. Thank you, Mr. Kaplan. Mrs. Rosenberg we are pleased to have you.

Mr. HUGHES. Good morning.

Mrs. ROSENBERG. Good morning. My name is Lena Rosenberg. I am 61 years old and have worked for the last 10 years as a court clerk.

Before 1979, my husband, Benjamin, had never been sick of any serious nature and we had no family doctor. So when he became sick with very bad pain that January 1979, my daughter took him to the Kennedy Hospital, near where we live. My husband stayed in that hospital for 2 months. He had two operations while he was there, one resulted in a colostomy and another was on his prostate. After the operations, his surgeon told me that he had cancer in his colon. He said that it could not be removed.

While my husband was in the hospital, my daughter met someone in a health food store who told her about a couple in West Philadelphia who helped people by giving advice on their diet. My daughter and I went to see about this and met Steven and Ellen

Haasz. They both call themselves reverend and they say they have Ph. D.'s. They call their place "Temple Beautiful."

Steven Haasz told me that everything that was bad with the body came from the foods that people eat and that people should eat as little as possible. When they did eat, he said people should only eat raw fruits or vegetables or the juice from them. He particularly thought that wheat grass juice and watermelon rind juice were good to eat. When I told Haasz about my husband, he said that he had cured himself of cancer in four places by proper dieting and that I should get my husband out of the hospital because doctors are murderers and hospital food is poison.

When my husband got out of the hospital in March 1979, he was supposed to make appointments to go back to see the doctors there. We went to Steven Haasz instead and my husband went back to the doctor only twice. I happen to know her Ph. D. is in English and his in engineering. They called the place Temple Beautiful. Through my own interpretation, the temple is supposed to be the body. First of all, he said, he cured himself of cancer in four places. Since then, "I have become an expert on the illness." At that time I believed everything he said. You get cancer from food and he could treat my husband a certain way and that it should go into remission, within 2 months.

Haasz put my husband on a diet of wheat grass juice, watermelon rind juice, and juice of green vegetables. He was supposed to eat that for 2 months. He sold us a juicer for the wheat grass for $180 and told us where we could get one for watermelon rinds, used, from his friend for $50. We even bought trays to grow our own wheat grass. We paid Haasz $20 an hour for consulting.

I was so convinced that this method of treatment was my husband's salvation that I became obsessed with the idea of visiting the place founded by Ann Wigmore, a woman who wrote a book on this. So my husband and my daugher and I went to a place in Boston called the Hippocratic Institute. It was somehow connected to Haasz' place in Philadelphia. We stayed there for 2 weeks and ate raw fruit and vegetables. The director of the place told us that they had had a person with the same condition as my husband come there and after getting on their diet, the cancer dropped right out of him. This director also told me the cured man ultimately died of cancer because he went off the diet. This was the same message told me by Dr. Haasz when he said that unless I stayed on the diet, I would develop cancer of the pancreas, since I'm diabetic. They charged $385 for each of us to stay in Boston for 2 weeks.

After returning to Philadelphia, Haasz suggested that my husband's body was out of harmony because of the colostomy that he had. He suggested that we have a second surgery performed to reverse that which had already been done.

We consulted a doctor Haasz had recommended about reversing it and he said my husband was too weak to be operated on. He went down to about 90 pounds. Perhaps he was 80 pounds at the time of his death, because he was a walking skeleton. I could count every bone in his body. He said he needed protein and should have one egg a day and toast. I actually went out and bought a dozen eggs and bread but when I told Haasz about it, he said, "You know he should not eat them." So I gave them away. My husband was

excited about the prospect of having an egg to eat but regretfully, at the recommendation of Dr. Haasz, I repeatedly denied them to him.

In May, my husband started to have pain and I panicked and told Haasz I was going to call a doctor. Haasz said, "Never mention doctors or hospitals to me again—or do not ever talk to me."

I know now that I was foolish to listen to Haasz and to spend about $2,000, including the trip to Boston, on the raw food things. But my husband and I were married for 37 years and when he got sick, I was looking for magic. Their false promise of hope may have actually shortened my husband's few numbered days on this Earth. My husband died on May 17, 1979, at age 67, at home. I have my husband's death certificate and other documents to submit for the record.

[See appendix p. 59 for material submitted by Mrs. Rosenberg.]

The CHAIRMAN. Thank you very much, Mrs. Rosenberg, for giving us those sad facts.

Mr. Don Harbour?

STATEMENT OF DON HARBOUR, OKLAHOMA CITY, OKLA.

Mr. HARBOUR. Mr. Chairman, I am Don Harbour. I am a retired real estate broker and I currently reside in Oklahoma City, Okla.

Today I would like to discuss my personal experience with mail order health quackery.

I was suffering from prostatitis and had not been to see a physician. The reason I had not sought medical treatment was because I had had heart surgery and my physician said my heart could not stand further surgery.

So I began to explore other avenues of relief.

Consequently, an advertisement in the National Enquirer for a prostatitis treatment was quite attractive since it made quite elaborate claims of relief from pain and related symptoms.

There was also a money-back guarantee based on returning the unused portion. I ordered the product, used it for approximately 16 days according to their instructions, with no signs of improvement.

I therefore returned the product and asked for a refund in accordance with the terms of their guarantee.

After not hearing from them for several weeks, I wrote another letter and received the same silent treatment. Although it was only for $9.95, it was the principle I cared about, not the money.

I contacted the Postal Inspector in Washington, D.C. and they, in turn, contacted the Krueger-Ross Laboratories. You have heard the U.S. Postal Service talk about this case here this morning. They had the Food and Drug Administration analyze the so-called prostate medication. It turned out to be made of pumpkin seeds, bee pollen, and zinc. The medical experts of the Food and Drug Administration said the product had no medicinal value. Even though the Postal Service had told the company that it could no longer sell the product through the mails, it took me several additional weeks to take advantage of the company's money-back guarantee.

Interestingly enough, the company informed the Better Business Bureau, to whom I had previously complained, that payment had already been made to me.

I finally received a check weeks later which included a rather crude note that said if I received the other check mentioned above, to please return it to them.

My personal feeling is that the note was an attempt to cover their failure to remit payment upon my first request in accordance with their guarantee. I feel that had I not been persistent in demanding a refund, that it would never have been forthcoming.

Mr. Chairman, for the record I would like to submit copies of pertinent correspondence.

The CHAIRMAN. It will be received without objection.

[See appendix p. 62 for material submitted by Mr. Harbour.]

Mr. HARBOUR. I would like to state that I feel that unscrupulous advertising of worthless products should be curbed, at a minimum, and, if possible, stopped.

Mr. Chairman, I would like to thank you and members of your committee for the opportunity to make a contribution to your efforts. Protecting and improving the lives of our senior citizens is a noble endeavor and I know I speak for all the elderly people of America when I say that we appreciate what you are doing very much.

The CHAIRMAN. Thank you very much, Mr. Harbour, for your excellent statement.

The CHAIRMAN. Mr. Robert White. Glad to have you, Mr. White.

STATEMENT OF ROBERT WHITE, PANAMA CITY, FLA.

Mr. WHITE. Good morning, members of the committee, ladies and gentlemen.

My name is Robert White and I reside in Panama City, Fla.

I appreciate having the opportunity to share with you my experience at a Mexican clinic.

Several years ago I began suffering from rheumatoid arthritis which affected every joint in my body except my back. After seeing five or six physicians and specialists, the only relief from pain I had received was from taking steroids. When I would deplete my steroid prescription, I needed more to relieve the pain.

My son is a pharmacist and is familiar with the adverse reactions one can experience from too many steroids.

Now, I consider myself to have a high tolerance for pain, but when the pain became so severe that I could no longer run my business, that it completely limited my mobility and I was becoming a vegetable, then I became vulnerable to any ray of hope for relief from the tormenting pain.

Several acquaintances had mentioned a clinic in Mexico that offered treatment to arthritics. It was always spoken of positively and promoted as successful. My son was able to make an appointment for me in November 1978. By that time I was in such severe pain I could not even open a car door, so my son-in-law drove me to Piedras Negras, just across the border from Eagle Pass, Tex.

I arrived at the clinic at 8 a.m., having abstained from food and liquids for 8 hours. I registered and went to the room they had reserved for me. I was visited by a person who asked if I had brought my insurance forms with me. I was surprised because I had assumed my insurance would not pay for treatment outside of the country.

A woman in a white uniform who could not speak English came to the room and took a vial of blood. Later the doctor came by, listened to my heart, took my blood pressure and pulse and looked at the medicine I had been taking.

He said it was all right for me to have the treatment.

Around 10 a.m., I started my first intravenous treatment. The treatment lasted for over an hour. I asked what the treatment consisted of and they never answered. In fact, I asked three times that day and a few times the second and third days and never received an answer.

After 3 days of treatment, I felt no improvement whatsoever. After the last treatment was completed, I was handed a slip and told to go by the office and pay the bill, still feeling no relief from the severe pain.

The 3-day treatment cost $808.66.

After paying the bill in traveler's checks, I was handed another slip and told to go to the clinic pharmacy to receive a year's supply of medication.

I was handed three plastic bags, each filled with a different colored pill. You might be interested to know this treatment is administered to approximately 70 people a week, most of them elderly Americans.

A few days after returning home I noticed that the pain was just slightly less severe. This lasted for about 2 weeks. Then my pain returned and might even have been more severe than before I had gone to the clinic.

For months after my visit to Mexico, I was in a bad way. My health seemed to go from bad to worse. Finally I was referred to Dr. Graybeil of Pensacola. He put me in the hospital where I stayed for more than a week. I had extensive tests and finally began to regain my health.

Dr. Graybeil apparently treats a large number of arthritics who have had unfortunate experiences with the Mexican clinics. One of Dr. Graybeil's patients suffered internal hemorrhaging and another has permanently deformed hands as a result of the treatment.

Dr. Graybeil says that there are vans which take people to the clinics from Florida. These same vans bring medication, some of which is not available in the United States, across the border to resupply patients who have been to the clinics.

Upon returning home, I contacted my insurance agent. I showed him the bill and he said he thought the treatment would be covered, much to my surprise. He sent the bill to the main office in Tampa. They called me and asked a few questions which seemed to me to be irrelevant.

The main office sent insurance forms to be filled out by the Mexican clinic. Six months later, I was shocked to receive a check for $1,303.25, or almost $500 more than I was charged at the clinic. To my knowledge, this reimbursement was only for my stay at the clinic.

I would like to say that although my first experience with physicians was quite frustrating, one must seek out a specialist and, although hard to find, once you have found one, relief can be obtained.

I have first-hand experience and know that these Mexican clinics do not provide the relief from pain that they advertise and are so well known for. For me, it was a complete waste of time and money.

I am also concerned that American insurance and medicare may be being defrauded for the highly questionable treatment being offered to patients who search for hope at the Mexican clinics. Something must be done to regulate the solicitations of these ambulance chasers and purveyors of quackery who presume to operate on this side of the American border.

The CHAIRMAN. Thank you very much, Mr. White.

Mr. Roybal?

Mr. ROYBAL. Mr. White, you testified that several acquaintances mentioned the clinic in Mexico and that they had spoken of that clinic positively and said it was successful.

Your son made the appointment for you in November of 1978. Did your son investigate the clinic before——

Mr. WHITE. Yes, sir. He talked to three different people that had been down there recently. Their cases were not nearly as severe as mine and it had relieved their pain.

Mr. ROYBAL. When he investigated, he was—he talked to ex-patients who had had some success with—at the clinic?

Mr. WHITE. Right. Their arthritis was not very severe.

Mr. ROYBAL. But there had been some success?

Mr. WHITE. Right.

Mr. ROYBAL. Do you know whether or not they were also reimbursed for their stay at the clinic?

Mr. WHITE. No, sir. I have no idea. When the lady at the clinic came by and asked for the insurance forms, she said that my insurance company would pay for it, which surprised me.

Mr. ROYBAL. About 6 months later you received a check for $1,303.25, which means the insurance did pay for it?

Mr. WHITE. Right. They did pay for it.

Mr. ROYBAL. What I would like to establish is this one fact and that is, whether or not it is a common practice for insurance to pay for services at this clinic?

Mr. WHITE. Apparently it is because they come around before they do anything to you and ask for your insurance forms and all to fill out.

Mr. ROYBAL. Do you know what happens if you don't have insurance? Do you have to pay on the spot?

Mr. WHITE. Yes, sir. You pay right then.

Mr. ROYBAL. Like any other hospital, I guess?

Mr. WHITE. Yes, sir.

Mr. ROYBAL. The next question I would like to ask is, Mr. Harbour, with regard to the advertisement in the National Enquirer, was the fact that the advertisement was in this magazine something that influenced you to seek their help?

If you had seen that same advertisement in a throwaway sheet, would it have been the same?

Mr. HARBOUR. It would have been the same. It would have made no difference.

Mr. ROYBAL. The fact it was in the National Enquirer didn't make any difference?

Mr. HARBOUR. No.

Mr. ROYBAL. A lot of times you find something in a magazine that is well known, you say well, this is legitimate, which you would not feel if it was in a throwaway sheet.

Mrs. Rosenberg, you stated that you went to a place called Temple Beautiful?

Mrs. ROSENBERG. Yes.

Mr. ROYBAL. Was anything beautiful about that temple?

Mrs. ROSENBERG. With all due respect to the Smithsonian Institute, it looked like—he has all kinds of—it looks like a museum. It looks like you were admitted to a museum.

Mr. ROYBAL. You said that was in west Philadelphia?

Mrs. ROSENBERG. Yes.

Mr. ROYBAL. Can you supply for the committee the address of Temple Beautiful so we can take a look at it?

Mrs. ROSENBERG. What is it, 800——

Mr. ROYBAL. If you don't have it now, you can provide it later.

Mrs. ROSENBERG. Yes.

Mr. ROYBAL. That is all, Mr. Chairman.

The CHAIRMAN. Do you have the address, Mr. Kaplan?

Mr. KAPLAN. Yes, I do. It is part of the materials Mrs. Rosenberg has submitted to the committee staff.

The CHAIRMAN. Has any action been taken in this case by your office?

Mr. KAPLAN. Your Honor—Your Honor, I am used to talking to judges. I am a criminal prosecutor. Excuse me, Mr. Chairman.

Our office has investigated Mrs. Rosenberg's claim. Our determination at this point is that the crimes code of Pennsylvania has not been violated by this man's actions.

That is one of the reasons why we are down here today, to urge the legislative branch of the Federal Government, as well as we will be urging our State legislative branch in Harrisburg, to look into this matter for the purpose of new legislation.

The CHAIRMAN. You don't think there was any medical basis for the treatment that they gave to Mrs. Rosenberg's husband?

Mr. KAPLAN. I personally do not believe so, no, sir.

The CHAIRMAN. Well, thank you very much. We appreciate very much all of you being here.

Your testimony will be helpful to us and will be helpful to a lot of other people.

Thank you, Mrs. Rosenberg, Mr. Harbour, and Mr. White.

The CHAIRMAN. Our next panel will be the Food and Drug Administration. Mr. Joseph P. Hile, Associate Commissioner for Regulatory Affairs and Head, Standing Committee on Quackery, accompanied by Ms. Diana W. McNair, Acting Chief, Consumer and Regulatory Affairs; and Jeffrey B. Springer, Deputy Chief Counsel of the FDA.

STATEMENT OF JOSEPH P. HILE, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS AND HEAD, STANDING COMMITTEE ON QUACKERY, ACCOMPANIED BY DIANA W. McNAIR, ACTING CHIEF, CONSUMER AND REGULATORY AFFAIRS; AND JEFFREY B. SPRINGER, DEPUTY CHIEF COUNSEL, FDA

Mr. HILE. Thank you.

The CHAIRMAN. May I ask you, ladies and gentlemen, if you will submit your written statement for the record and summarize your statement, please, orally, for us?

It would be a great favor to the committee. We would appreciate it.

Mr. HILE. Thank you, Mr. Chairman. We would be pleased to summarize our statement because we would like to include in our presentation today some discussion of some quack devices that the agency has taken action against over the last number of months as examples of our current regulatory efforts and also discuss with you some of our own consumer education activities.

The CHAIRMAN. Excuse me just a minute.

Unfortunately a bill that very critically affects my district and State is coming up on the floor at 12:15. I will ask my distinguished colleague, Mr. Roybal, if he can preside for a while and then I will get back just as soon as I can.

Mr. Edwards, our director of the staff, will proceed to take the testimony of the remaining witnesses until I can return.

Mr. ROYBAL. Off the record.

[Discussion off the record.]

The CHAIRMAN. Go ahead, Mr. Hile.

Mr. HILE. As the committee knows, the Food and Drug Administration regulates human foods, almost all human foods, human drugs, cosmetics, and medical devices, and as a consequence the statute extends to products that are labeled or purported to be foods, drugs, or medical devices.

It is in that area for the most part that the agency finds itself involved in quackery and the promotion of quack products.

As a consequence, quackery for FDA can take a number of different forms. These include false claims for drugs and cosmetics that may otherwise be legitimate products, irrational food fads, unnecessary food supplements, and fake medical devices.

Generally speaking, quackery is the purposeful misinformation about health care and health care products.

The most unfortunate aspect of the problem, as the committee well understands, is that it frequently preys on the elderly who are on fixed incomes and cannot afford to spend any of their limited budget on unproven products and on the seriously ill who are susceptible to the false hopes held out by the quacks and their products.

Unfortunately, they also prey on man's vanity. The promoters of such products are primarily interested in financial gain and generally have little knowledge or interest in legitimate health care activities.

With your permission, Mr. Chairman, I would like to interject here an example of a device that we recently took extensive regulatory activity against. It is a substitute for a wig or for a legitimate hair transplant, and it is an artificial hair product, plastic hair that is implanted into the scalp.

I would like to bring an example of it to you and show you some pictures of scalps that have undergone the treatment.

These are plastic fibers, the kind that are used in some wigs, in dolls' hair, in larger diameters are used in rugs and other fiber materials.

Here, Mr. Chairman, are pictures of the device that is used to implant them and then two pictures of a person's scalp showing first the abscesses where the product was implanted into the scalp, and later it shows how it has sloughed off, leaving the knotted portion of the product in the scalp.

Specifically in regard to that product, it is a synthetic hair implant. It is unlike the natural hair transplants, and they trigger the body's natural defense mechanisms usually causing the rejection of the synthetic fibers. Most of these synthetic fibers are, as I mentioned, synthetic materials used in other similar kinds of—or the familiar kinds of fiber products that we see in our home every day, carpets and so forth, polyacrylic or polyester fibers.

Not only is the process for implanting synthetic hair lengthy, taking as long as 7 days to complete, and extremely painful, since clusters of fibers have to be literally sewn into the scalp and anchored by knots under local anesthesia, but also quite expensive, costing anywhere from $1,500 to more than $5,000.

The CHAIRMAN. I am sorry. They have changed the signals again. We are going to have to go to the floor right now.

Mr. Edwards will please go ahead and receive your statement. You go right ahead.

Mr. HILE. Fine.

Infection occurs in almost all cases, resulting in rejection and scarring. In some cases the clusters have to be surgically removed, which is a costly, painful, and time-consuming process.

Some victims actually required plastic surgery and skin grafts and a few reported that their scalps had to be surgically removed and repaired because the infections had become widespread and possibly life-threatening.

Certainly this is an example of a direct health hazard quack product.

I am pleased to report to the committee that our compliance actions, both at the Federal, State, and local level, appear to have this particular device under control.

The committee this morning demonstrated that there is considerable quackery activity in the area of devices. Certainly there is no machine which can diagnose or treat different diseases by simply turning a knob or by flashing lights.

Excess body weight cannot be eliminated with special clothing or by vibration. Certainly no glove or bracelet can cure or prevent arthritis.

We have some devices with us this morning that we have taken action against in recent months that reflect that.

Diana.

Ms. MCNAIR. The first one, the most recent one we have taken action against is the Acu-Dot. It is advertised as a magnetic analgesic patch. What it really is is a small magnet with an adhesive backing that is attached to the aching joint or diseased part of the body that you want to relieve pain for.

They recommend that these be placed at the acupressure joints on the body. Earlier this year it was the subject of a litigation in Cleveland, Ohio.

The Federal court there judged that the labeling was misleading and that the product should not be allowed on the market.

In fact, in this summary they said that a kiss from mother on the affected area would serve just as well to relieve pain if mothers' kisses were marketed as effectively as the Acu-Dot device.

In addition to that—I will be glad to pass these around if you would like to see them—I have brought with me various kinds of magnetic and copper jewelry that is advertised much the same way, except that you wear the jewelry, it creates a biomagnetic current in the body and thus relieves your pains, your aches in the joints.

The traditional copper bracelet which you have already seen today. In addition, what they call an electrogalvanic bracelet that operates much the same way, has some metal in the back, copper, zinc, I assume. It produces the same current in the affected area.

I also have the Infralux pain reliever. Here is a device that claims to provide deep heat therapy for safe, fast, and effective pain relief of arthritis, bursitis, sprains, aches, and pains. Yet when you plug it in what you really have is a cute little red light. The end of this thing just lights up and could in no way produce the infrared rays that they say are going to promote the healing deep within the body beneath the skin. So I have this.

We also have two different kinds of mitts that have been promoted for arthritis healing or treatment; the electric mitts do emit heat and would provide some kind of temporary relief, I assume, from the heat on the arthritic hand. However, when the mitt is removed or it is unplugged and the heat vanishes, the pain comes back.

That is not a cure or a long-term treatment for arthritis.

This mitt operates much on the same principle as your Rado Pad. It can be filled with uranium ore—in most cases, which turns out to be gravel—or tiny magnets. Once again, the electromagnetic kind of theory to draw the pain from the body.

I might point out that these are examples of indirect health hazards. These devices, if you wear them or use them as directed, would not cause direct harm to the body, but obviously they are not going to produce any lasting results or cure your ailments.

Mr. Hile?

Mr. HILE. During the period of the mid-1940's through the late 1960's, FDA placed much emphasis on combating quackery and our regulatory mandate was regularly reinforced by court decisions that brought injunctions against manufacturers of Dya-Pulse, Relaxizer and Micro-Dynometer devices, devices not dissimilar from those you have been shown this morning, and many other quack products, forcing their removal from the market.

These cases were successfully prosecuted and it included prosecution against quacks such as food lecturers who preyed upon the unknowing with a large array of cooking utensils and the other products for which extravagant health claims were made.

Not unlike the Post Office Department in their testimony earlier this morning, the Food and Drug Administration has concluded we must fight quackery on two fronts: Certainly we will continue to bring regulatory action against quack products, but we also need a well-educated public that can make important decisions on their own to turn away from these quack devices and quack products.

Most recently in our efforts to improve our educational program, we have published a booklet called "The Big Quack Attack."

This booklet is directed at the present time toward medical devices or fraudulent devices, but it is our intention to look to see whether or not we might expand the use of this approach to include other quack products over which we have jurisdiction.

The interesting aspect of this particular booklet is that in addition to giving advice and counsel to consumers on how to recognize quack devices and how to make decisions in regards to whether or not a device is a quack device and giving instructions on where to go for help, it also includes in the back portion of the booklet a list of the devices over which we have taken regulatory action in the last year or so, and it is our intention to update this booklet at least on an annual basis and more frequently if we possibly can.

So the consumer will not only have the general instructions that are in the front portion of the booklet, but also can look at actual devices, the names of firms, and see the actions that we took against the kinds of claims that were made for those products. I think this will be a most useful piece of information for consumers.

Coupled with that, we have a slide program that follows along the lines of the booklet. Our 50 or more consumer affairs officers in our 50 district offices are carrying out a program of using this particular slide presentation, particularly with groups of elderly consumers at the local level.

We believe this will be a most successful campaign in advising consumers about quackery generally and about quackery devices specifically.

We also provided to the committee a number of the other kinds of educational materials that we use in our local consumer information and education programs.

Many of them are reprints from our monthly magazine, FDA Consumer.

We have regular articles in that magazine about quackery warning consumers about frauds in foods, drugs, cosmetics, and therapeutic devices.

[The prepared statement of Mr. Hile follows:]

PREPARED STATEMENT OF JOSEPH P. HILE, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, I welcome the opportunity to speak before this Committee on the Food and Drug Administration's (FDA) role in dealing with the problem of quackery.

Quackery can take a number of different forms. These include false claims for drugs and cosmetics, irrational food fads, unnecessary food supplements, and fake medical devices.

Quackery involves both people and products. It includes the charlatan with a miracle cure, but with little or no medical training. The drug or food supplement promoted with false health claims which becomes a quack product. The machine with only knobs and dials and no proven therapeutic value is a quack device.

Generally speaking, quackery is purposeful misinformation about health care and products. The most unfortunate aspect of the problem is that it frequently preys on the elderly who are on fixed incomes and cannot afford to spend their limited budgets on unproven products and the seriously ill who are susceptible to the false hopes held out by the quacks and their products. The promoters of such products are primarily interested in financial gain and generally have little knowledge about health.

Quack drugs include cures for baldness, for which there is no cure; chemical "face-peels" which promise new youth but which may bring only permanent disfigurement; laxatives for colitis which can in fact seriously worsen the condition; and creams and lotions to "melt away" fat, or enlarge or reduce parts of the body. Perhaps the most cruel and dangerous of all quack drugs are unproven treatments for cancer, and other serious diseases which rob the patient of the element that might save a life—valuable time in which effective treatment could still be administered.

In the food area, many so called "nutrition experts" who sell food supplements argue that the American food supply is produced from "depleted" soil and that chemical fertilizers and modern food processing have deprived our food supply of its high nutritive quality. They also claim that there is widespread disease in the United States caused by dietary deficiencies. Such statements are simply not true. The need for vitamins, minerals, or other food supplements for people who actually have deficiencies, can only be established after careful and complete medical examination.

In the area of device quackery, there is no machine which can diagnose or treat different diseases by simply turning a knob or by flashing lights. Excess body weight cannot be eliminated with special clothing or by vibration, and no glove or bracelet can cure or prevent arthritis.

FDA's ability to regulate quackery has come a long way since the limited scope of public protection provided by the Food and Drugs Act of 1906. In 1911, the Supreme Court ruled that the drug labeling provisions prohibited only false statements about the identity of the drug product but not false therapeutic claims. A dissenting opinion said this would open the way for the sale of false cures for all manner of diseases.

President Taft immediately called on Congress to eliminate the deficiency in the 1906 Act. Congress responded by passing the "Sherley Amendment" which prohibited false and fraudulent curative or therapeutic claims on a label. But this action created a new weakness in the law. It required proof that therapeutic claims were fraudulent as well as false, a matter extremely difficult to prove since fraud involves proving an intent to deceive.

The Federal Food, Drug, and Cosmetic Act of 1938, corrected this problem by eliminating the requirement to prove fraud. The Amendment also brought under FDA control, devices intended: (1) for use in diagnoses, cure, mitigation, treatment, or prevention of disease in man or other animals, and (2) to affect the structure or any function of the body of man or animals. The 1938 Act prohibited traffic in new drugs unless they had been adequately tested to show that they were safe for use under the conditions of use prescribed on their labels.

The drug amendments of 1962 provided, among other things, that the producer of a new drug had to establish that his product would be effective, as well as safe for its intended uses. Although the Government still bears the burden of proof, focus is on false and misleading—not fraudulent—acts.

The period from the 1940's through the late 1960's was one in which the FDA placed must emphasis on combatting quackery. FDA's regulatory mandate was reinforced by court decisions that brought injunctions against manufacturers of the Diapulse, Relaxicizor, and Microdynameter devices and other quack products, forcing their removal from the market. Cases were successfully prosecuted against quacks such as food lecturers, who preyed upon the unknowing with a large array of devices and other products for which extravagant health claims were made.

The 1976 Medical Device Amendments contained a provision (section 304(g) of the Act) allowing for administrative detention of a violative deceptive device for up to 30 days, during which time the manufacturer could voluntarily correct the problem or the Agency could take other administrative or legal action against the manufacturer or his device. This is a useful tool for controlling quack devices.

Even before FDA's regulatory mandate was reinforced by these recent changes in the law, it was apparent that sanctions alone could not control the burgeoning and more sophisticated activity in quackery. We have long recognized that a concerted effort to educate the public is also needed to stem the tide of quack products.

Over the years FDA's campaign against quackery entails a combination of regulatory actions and educational programs for consumers. The philosophical basis for developing this consumer education program is the concept that health care should be a joint effort among medical practitioners, agencies mandated to assure safe and effective health care products and the consumer/patients themselves.

More recently, in September 1978, the Commissioner established the FDA Standing Committee on Quackery, thereby placing renewed emphasis on dealing with quackery. The functions of the Committee are to determine the scope of the quackery problem, to identify, evaluate, and advise the Commissioner, our field people and the bureaus about the activities regarding quackery; to develop Agency strat-

egy; and to work with the FDA staff in coordinating Agency quackery activities with other Federal agencies.

I would like to distribute to you some brochures and leaflets on quackery as an example of our consumer education program. My associate Diana McNair will describe a few of the "quackery" products that we have taken legal action against.

Thank you very much and I will be glad to respond to any questions you may have.

Mr. EDWARDS. Does that conclude your testimony?

Mr. HILE. Yes.

Mr. EDWARDS. Thank you very much for your statement.

We are wondering if we can keep some of the devices you brought with you here this morning for a couple of days so we can examine them? They will contribute to our study of this problem.

Mr. HILE. Yes, you certainly can.

Mr. EDWARDS. I have a couple of questions for you this morning though.

Is it your impression that the people who are engaged in promoting these sorts of frauds move on from item to item and jurisdiction to jurisdiction, or are there new people constantly coming into the promotion of these sorts of materials?

Mr. HILE. It is my impression the answer would have to be both because we know of individuals who are regularly involved in promoting one fraud; once some Government agency takes action against those individuals, we see them again promoting another.

Sometimes it is a completely different kind of product. At least from our standpoint, at one moment in time a device, at the next moment a food, and that sort of thing. They move from product to product; but new persons come into the business regularly as well. It is a very attractive business.

Mr. EDWARDS. Is Federal law currently adequate in your opinion to help you fight these problems? Are there any sorts of amendments that Congress should consider that would give you a stronger hand?

Mr. HILE. Generally speaking, we have a strong law. We have seizure authority; we have injunctive and prosecution authorities under the Food, Drug and Cosmetic Act; however, I draw the attention of the committee to H.R. 7035, which is the administration's amendments to the Food, Drug and Cosmetic Act for 1980.

Those amendments are directed toward all of the products we regulate. However, incorporated in those for the consideration of the Congress would be additional authority such as subpena authority, which would assist us in getting to records that might be necessary for us to make decisions in regard to possible legal action.

It has—it contains detention authority over all products. We currently have detention authority over only medical devices or fraudulent devices.

It would expand our inspection authority, allowing us to review records that we currently have no authority to review, and it could increase the criminal fines as a result of guilty verdicts under our law. Currently for each count it is $1,000 for the first offense; $10,000 for the second offense. It would increase those substantially for individuals to $25,000 and $50,000 and $50,000 and $100,000 for firms.

Those are important amendments and we draw your attention to them.

Mr. EDWARDS. Do you feel those levels of fines are high enough or would these sorts of promoters merely regard them as business expenses?

Mr. HILE. Clearly there are levels higher and more punitive than the levels we currently have. Since they are for each count, and under our law each count could be each individual shipment of a violative product in interstate commerce, conceivably the court might have an opportunity to extend the fines beyond the apparent limit of $50,000 or $100,000 against an individual firm.

Mr. EDWARDS. Do you have any thoughts on the question that came up here this morning about the advertisements for these sorts of fraudulent products which appear in publications?

I think we have all seen them in newspapers and magazines which have very wide distribution, as well as some publications which carry a certain credibility to them.

What are your thoughts on that situation? Is there anything the Congress or the States could do to address that?

Mr. HILE. We are discussing very briefly the fact that it has been our experience that we run very quickly into first amendment rights, and we don't know to what extent it would be reasonable or possible for the Congress to treat that particular problem.

We do work very closely with the Post Office Department and with the Federal Trade Commission, the Federal Trade Commission having authority over advertising in newspapers and magazines for these kinds of products, and where it is appropriate we provide scientific support and testimony in support of their actions.

So certainly it is not an area that is devoid of Federal regulation but that, of course, again is not directed toward the magazine, but rather, toward the promoter of the product.

Mr. EDWARDS. Would you say at this point that the efforts of various Federal agencies are beginning to bring the problem under control, or is the problem growing more severe?

Mr. HILE. I would be terribly hesitant to conclude in any way that we are bringing the problem under control. I do believe our joint efforts are keeping it within the bounds that we have found it over the last number of years, but certainly to bring it under control would take a much greater commitment of resources than are currently available for this activity.

Mr. EDWARDS. Thank you very much.

Our next panel will consist of Dr. Jane Henney, Special Assistant for Cancer Treatment, National Cancer Institute, and Dr. Wilbur J. Blechman, representing the Arthritis Foundation. Dr. Blechman is from Miami I am told.

STATEMENT OF DR. JANE HENNEY, SPECIAL ASSISTANT FOR CANCER TREATMENT, NATIONAL CANCER INSTITUTE, ROCKVILLE, MD.

Dr. HENNEY. Thank you.

Mr. EDWARDS. Dr. Henney, if we can have your statement first? I would like to ask both of you to speak as loud as you can. The microphones have ceased functioning in this room. If you can pro-

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vide a brief summary of your statement, we will have the complete statement printed in the record.

Dr. HENNEY. Thank you.

On behalf of the National Cancer Institute, I would like to thank you for this opportunity to testify before the House Select Committee on Aging. Each year more than 1 million Americans are diagnosed to have cancer. If treated optimally, according to today's methods, at least 40 percent of all cancer patients who are diagnosed annually can be expected to be alive and well 5 years after diagnosis.

Many of these individuals, along with many other Americans who fear that they may have cancer, will explore alternatives to scientifically proven methods of diagnosis and treatment.

This exploration will prove to be costly in the time and dollars expended. By forsaking those means of diagnosis and treatment that have been subjected to scientific scrutiny, a patient may jeopardize his or her opportunity to alleviate the underlying disease.

One may ask, what is the psychological climate that makes it appealing for a patient to pursue alternatives to scientifically established methods. Many factors contribute, but probably fear is the strongest influence. A Gallup poll conducted in 1976 revealed that cancer is one of the chief concerns of the American public. This fear has many facets: fear of the disease itself; fear that if treatments can be offered the side effects may be worse than the disease; fear that even if treatment is effective it will only be temporary and that cure cannot be guaranteed; and finally, fear that if the cancer fails to respond to treatment, a lingering, painful course resulting in death will occur.

Two major features distinguish the types of treatments and diagnostic techniques the committee will consider today from those generally considered to be conventional therapy. The first is that the conventional drugs and devices have undergone the strictest of preclinical and clinical scientific scrutiny. The National Cancer Institute, in its role as a Federal Research Agency, seeks to explore and develop those drugs, devices, diets, or techniques which hold the most promise for benefiting the cancer patient.

For promising drugs, the NCI willingly tests materials in animal tumor systems to determine if there is any scientific evidence to justify pursuing the agent. The only qualification here is that the NCI must be informed of the nature of the material or how it is made. After reviewing the pertinent data, the Institute staff then must make selections and set priorities for which drugs or diagnostic tools will undergo scientific testing in patients, using Institute resources.

The approach taken by the Cancer Institute in its drug development program reflects its orderly approach in development of promising investigational treatments. The criteria used by the program to select compounds which merit further development include: evidence of antitumor activity in cell culture and animal tumor screening systems, unique mechanisms of action, or evidence of clinical activity.

It is possible that our screening techniques are at times too rigid, and from time to time we do readjust our priorities. This readjustment occurred most recently with the controversial drug, laetrile.

The scientific evidence for how or why laetrile should work had not changed, but the knowledge that thousands of Americans were leaving potentially curative conventional therapy in pursuit of a highly promoted but scientifically unevaluated drug was sufficient cause to reevaluate and change our priorities. Clinical trials are now being conducted at four comprehensive cancer centers. Investigators at these institutions are using the same systematic approach that has been used to evaluate and document the efficacy of all currently available anticancer drugs. The information developed from the clinical tests that result from this decision will provide the physician, patients, and the general public with a base upon which they can compare laetrile to other drugs which have undergone similar scientific scrutiny.

The second major difference between scientifically proven methods and those methods that have not been subjected to the scientific method is the manner in which they are promoted. Those who promote the latter frequently claim that there is a conspiracy which exists at some level of the State or Federal Government or organized medicine to keep the potential cures from the American public. Rarely does one see the advertising for such products or methods using the forum of a scientific meeting or a refereed scientific journal to present data from a well-controlled clinical trial. Rather, promotion is likely to take place at public meetings where patient testimonials are supplemented with pamphlets, books and other audiovisual techniques.

An even more disturbing method of promotion has become more frequent recently. In this individuals promoting such therapies enter the clinic and wards of reputable institutions to distribute literature, and to solicit recently diagnosed cancer patients to abandon the scientifically well ground management plan proposed for them in favor of an alternative method. This same information is supplied to friends and family members. Those well-meaning individuals often exert subtle but very real pressure on the patient to seek the alternative. Patients are made to feel that they would be letting their friends or relatives down if they did not participate in the alternative therapy, and that such a decision might result in abandonment.

For the already psychologically traumatized patient, this fear of isolation is intolerable.

I have provided in my written statement for the committee several approaches of examples to cancer diagnosis and treatment that have been promoted in this country over the past 50 years.

I will also submit for the committee's review a more complete listing, although it still is a partial listing, of scientifically unproven methods that have been promoted in this country during the same time period.

We became aware of these techniques or drugs or devices through mainly our National Cancer Institute's Information Service where we receive inquiries from cancer patients and family members regarding many of the alternatives mentioned.

In addition to providing information about the method in question, we also encourage the caller to notify his local health department, consumer protection office, or medical society and emphasize

to the caller the need to remain in the care of qualified health professionals.

The National Cancer Institute also alerts the appropriate regulatory agency and national organizations such as the American Medical Association, American Society of Clinical Oncology, and American Cancer Society of the method described.

Each of the examples I have cited in my written testimony serve to remind us that the fears of diagnosis, disease process, treatment, and death are very real and provide a prime opportunity for those at the margins of science who would fraudulently promote diagnostic methods or treatments that have not been subjected to careful testing.

Promoters of nostrums that have enjoyed a vogue have generally attempted to borrow on the validity of other similar methods that were concurrently under scientific testing.

Unfortunately, when patients who have sought alternative therapy fail to respond, they are disregarded by the promoter who claims the patients have had insufficient faith or failed to follow directions, have sought the cure too late or have a constitutional resistance.

Thus the promoter attributes all failures to the patient rather than the product.

In summary, I would like to assure the committee that the National Cancer Institute feels a major responsibility and commitment to be receptive to innovative approaches to the diagnosis and treatment of cancer, but we must insist and expect each method to meet stringent scientific tests of efficacy, not simply hope without evidence.

We must be able to assure those in greatest need of care and compassion that they will not be preyed upon by those offering only false promises and hollow results.

Thank you very much.

[The prepared statement of Dr. Henney follows:]

PREPARED STATEMENT OF JANE E. HENNEY, M.D., SPECIAL ASSISTANT FOR CLINICAL AFFARIS, DIVISION OF CANCER TREATMENT, NATIONAL CANCER INSTITUTE, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Committee, on behalf of the National Cancer Institute, I would like to thank you for this opportunity to testify before the House Select Committee on Aging. Each year more than one million Americans are diagnosed to have cancer. If treated optimally according to today's methods, at least 40 percent of all cancer patients who are diagnosed annually, can be expected to be alive and well five years after diagnosis. Many of these individuals, along with many other Americans who fear that they may have cancer, will explore alternatives to scientifically proven methods of diagnosis and treatment. This exploration will prove to be costly in the time and dollars expended. By forsaking those means of diagnoses and treatment that have been subjected to scientific scrutiny, a patient may jeopardize his or her opportunity to alleviate the underlying disease.

One may ask, what is the psychological climate that makes it appealing for a patient to pursue alternatives to scientifically established methods. Many factors contribute, but probably fear is the strongest influence. A Gallup poll conducted in 1976 revealed that cancer is one of the chief concerns of the American public. This fear has many facets: fear of the disease itself; fear that if treatments can be offered, the side effects may be worse than the disease; fear that even if treatment is effective it will only be temporary and that cure cannot be guaranteed; and finally, fear that if the cancer fails to respond to treatment, a lingering, painful course resulting in death will occur.

Two major features distinguish the types of treatments and diagnostic techniques the committee will consider today from those generally considered to be conventional therapy. The first is that the "conventional" drugs and devices have undergone the strictest of preclinical and clinical scientific scrutiny. The National Cancer Institute, in its role as a Federal Research Agency, seeks to explore and develop those drugs, devices, diets or techniques which hold the most promise for benefitting the cancer patient. For promising drugs, the NCI willingly tests materials in animal tumor systems to determine if there is any scientific evidence to justify pursuing the agent. The only qualification here is that the NCI must be informed of the nature of the material or how it is made. After reviewing the pertinent data, the Institute staff then must make selections and set priorities for which drugs or diagnostic tools will undergo scientific testing in patients, using Institute resources.

The approach taken by the Cancer Institute in its Drug Development Program reflects its orderly approach in development of promising investigational treatments. The criteria used by the program to select compounds which merit further development include: evidence of antitumor activity in cell culture and animal tumor screening systems, unique mechanisms of action, or evidence of clinical activity.

It is possible that our screening techniques are at times too rigid, and from time to time we do readjust our priorities. This readjustment occurred most recently with the controversial drug, laetrile. The scientific evidence for how or why laetrile should work had not changed, but the knowledge that thousands of Americans were leaving potentially curative conventional therapy in pursuit of a highly promoted but scientifically unevaluated drug was sufficient cause to reevaluate and change our priorities. Clinical trials are now being conducted at four Comprehensive Cancer Centers. Investigators at these institutions are using the same systematic approach that has been used to evaluate and document the efficacy of all currently available anticancer drugs. The information developed from the clinical tests that result from this decision will provide the physician, patients, and the general public with a base upon which they can compare laetrile to other drugs which have undergone similar scientific scrutiny.

The second major difference between scientifically proven methods and those methods that have not been subjected to the scientific method is the manner in which they are promoted. Those who promote the latter frequently claim that there is a conspiracy which exists at some level of the State or Federal government or organized medicine to keep the potential "cures" from the American public. Rarely does one see the advertising for such products or methods using the forum of a scientific meeting or a refereed scientific journal to present data from a well-controlled clinical trial. Rather, promotion is likely to take place at public meetings where patient testimonials are supplemented with pamphlets, books, and other audiovisual techniques.

An even more disturbing method of promotion has become more frequent recently. In this, individuals promoting such therapies enter the clinic and wards of reputable institutions to distribute literature, and to solicit recently diagnosed cancer patients to abandon the scientifically well-grounded management plan proposed for them in favor of an alternative method. This same information is supplied to friends and family members. These well-meaning individuals often exert subtle but very real pressure on the patient to seek the alternative. Patients are made to feel that they would be "letting their friends or relatives down" if they did not participate in the alternative therapy, and that such a decision might result in abandonment. For the already psychologically traumatized patient, this fear of isolation is intolerable.

I would like to cite for the committee some examples of alternative approaches to cancer diagnosis and treatment that have been promoted in this country in the past fifty years. I will also submit for the committee's review a more complete listing of scientifically unproven methods that have been promoted in this country during the same time period.

The National Cancer Institute's Cancer Information Service receives inquiries from cancer patients and family members regarding many of the alternatives I will mention. In addition to providing information about the method in question, we also encourage the caller to notify his local health department, consumer protection office or medical society, and emphasize to the caller the need to remain in the care of qualified health professionals. The National Cancer Institute also alerts the appropriate regulatory agency and national organizations such as the American Medical Association, American Society of Clinical Oncology and American Cancer Society of the method described.

DEVICES

Two devices that were alleged to be useful in the diagnosis and treatment of cancer were the Oscilloclast, developed by Dr. Albert Abrams of San Francisco, and a successor device known as the Drown Radio Therapeutic Instrument, developed by

Dr. Ruth Drown. The Oscilloclast was based on the theory that electrons are the basic biologic unit and disease is a disharmony of electronic oscillations. To adjust these oscillations, physicians from throughout the country were encouraged to submit samples of dried blood on a piece of paper to Dr. Abrams. This paper was then fed into a fairly simple box-like device that contained a series of lights and dials. Two metal plates connected to the box were held by a technician who served as a detector for any radiation emanating from the dried blood sample. The operator would then place a wand over the technician's body, and if the wand focused on a particular location, this was said to be the site of the "disease." Many treatment devices were then offered for sale to correct this "disease." These devices were still being distributed as recently as 1958.

The Drown Radio Therapeutic Instrument was a collection of dials, terminal posts and an ammeter or voltmeter. Dr. Drown claimed that crystals were formed, after she placed one drop of the patient's blood on a blotter. These crystals were said to be used in a similar fashion to those crystals in the early radio receiving sets, for if the device was activated to the proper wave length, a diagnosis could be made and then "healing waves" could be sent to the patient, regardless of his or her geographic location, and thus effect a cure.

DIETS

Diets have also been of interest, not only to the medical community but also to those who would promote scientifically unproven methods of treatment for cancer victims. In the late 1920's, Johnna Brandt published a book, The Grape Cure. This diet, limited almost exclusively to grapes, was said to be an effective treatment not only for cancer but for practically all other human diseases. As recently as 1969, this diet was promoted as a successful treatment for cancer.

Dr. Max Gerson, a German-born physician, also widely promoted a diet said to be useful in the treatment of cancer. In addition to the spartan-like diet which allowed for only minimal intake of protein, the patients were to take a variety of medications including niacin, brewer's yeast, defatted bile in capsules, liver and iron capsules, dicalcium phosphate and viosterol, intramuscular injections of crude liver extract, Lugol's solution, thyroid extract and coffee enemas. Despite many patients' rigorous attention to this diet, and persistent promotion by Gerson and his followers, reviews of small series of cases failed to provide evidence that the method could reduce tumor burden.

Dietary supplements such as vitamins C and A have also been proposed by some to be efficacious in the treatment of cancer. The Cancer Institute has supported two clinical trials in an attempt to define the clinical antitumor activity of Vitamin C. The first trial was conducted in previously treated patients similar to clinical testing of other anticancer drugs. This patient population failed to reveal any evidence that Vitamin C could effect tumor shrinkage. A second study in patients who have received no prior chemotherapy is now ongoing. The use of Vitamin A as a cancer treatment has not been tested by the Cancer Institute for the doses that are commonly advocated by promoters of such methods are 10 to 100 times above the levels associated with Vitamin A toxicity.

Another supplement that has recently been advertised to be a vitamin useful in the treatment and prevention of cancer, but is neither, is "Vitamin B–15." There is no scientific evidence to date that would support the contention that this substance is a vitamin, for it fails to meet the criteria for a vitamin. Further, analysis of the product currently being marketed in many health food stores indicates that it is primarily lactose (milk sugar), plus varying amounts of dimethylglycine hydrochloride, DMG. Recently, scientists have reported that when DMG is mixed with a substance similar to saliva, sodium nitrate, and then incubated, the resulting product is positive in a standard test for mutagens, which is one possible measure of carcinogenicity. A hazardous situation is thus created, since persons who consume the substance, are led to believe the drug is a cancer preventative but are not informed of its potential to cause cancer.

DRUGS

By far, the most common of the scientifically unproven methods is a drug or "medicine." In the 1940's, William Koch of Detroit, promoted a cancer cure, glyoxyline, that was said to be so strong it had to be diluted with 1 trillion parts of water. No firm evidence exists that it had any antitumor effect and laboratory analysis indicate it was only distilled water.

In the 1950's, many citizens went to the Hoxsey Clinic and obtained a physical examination and blood and urine tests. These exams routinely revealed the potential patient had cancer, and a lifetime supply of two medicines that were comprised of a variety of plant substances were offered for purchase. In the late 1959's,

inspectors from the Food and Drug Administration reviewed the records of 400 patients who claimed to be cured of cancer after receiving the Hoxsey method. In 1960, after the records failed to substantiate this claim, a Federal Court injunction was issued to prohibit the sale of this product in 1960.

Krebiozen was the scientifically unproven drug promoted for the treatment of cancer in the 1960's. Andrew Ivy, M.D., Ph.D., was one of its earliest and most prominent sponsors. Dr. Ivy claimed that Krebiozen was responsible for antitumor responses in many patients he had treated. Attempts were made at many prominent institutions to confirm these reports but to no avail. When confronted with these data and the data from laboratory analyses by both the NCI and the FDA that the substance was creatine monohydrate in mineral oil, supporters claimed that a conspiracy existed to keep this cure from the American Public. The public outcry led to hearings conducted by the United States Congress, but the ruling of the Food and Drug Administration that banned the interstate distribution of Krebiozen was upheld.

Each of the examples cited serve to remind us that fears of the diagnosis, disease process, treatment and death are very real and provide a prime opportunity for those at the margins of science who would fraudulently promote diagnostic methods or treatments that have not been subjected to careful testing. Promoters of nostrum that have enjoyed a vogue have generally attempted to borrow on the validity of other similar methods that were concurrently under scientific testing. Unfortunately, when patients who have sought alternative therapy fail to respond, they are disregarded by the promoter who claims the patients have had insufficient faith, have failed to follow directions, have sought the cure too late or have a constitutional resistance. Thus, the promoter attributes all failures to the patient rather than the product.

In summary, I would like to assure the committee that the National Cancer Institute feels a major responsibility and commitment to be receptive to innovative approaches to the diagnosis and treatment of cancer, but we must insist and expect each method to meet stringent scientific tests of efficacy, not simply hope without evidence. We must be able to assure those in greatest need of care and compassion that they will not be preyed upon by those who offer only false promises and hollow results.

Scientifically Unproven Methods Promoted for the Diagnosis or Treatment of Cancer:

Alkylizing Punch.
Almonds.
Aloe Vera Plant.
Anticancergen Z50-Zuccalalytic test.
Antineol.
Asparagus Oil.
Bacteria Enema.
Bamfolin (S.N.K.).
Bio Medical Detoxification Therapy.
Bonifacio anticancer goat serum.
Cancer lipid concentrate and the malignancy index.
Carcalon.
Carcin.
Carrot/celery juice.
Carzodelan.
Cedar Cones.
CH–23.
Chamonils.
Chaparral Tea.
Chase Dietary method.
Coffee Enemas.
Coley's mixed toxins.
Collodanrum and bichloracetic acid—Kahlenberg.
Compound X.
Contreras Method.
Crofton Immunization.
Diamond carbon compound.
DMSO (Haematoxylin dissolved in Dimethyl sulfoxide).
Esterlit.
Ferguson Plant Products.
Fresh Cell Therapy.
Fresh Defatted Bile Capsules.
Frost Method.

Gerson Method.
Glover Serum.
Goat's Milk.
Grape Diet.
H-11.
Hadley vaccine and blood and skin tests.
Hemacytology index (HCL).
Hendricks Natural Immunity Therapy.
Hoxley Method.
Hubber E Meter and Hubbard Electrometer.
Iscador-Mistletoe.
Issels Combination Therapy.
Kanfer neuromuscular handwriting test.
KC555.
Kelly Malignancy Index (Ecology Therapy).
Kellzyne.
Koch Treatment.
Krebiozen.
Laetrile: Vitamin B17; Amygdalin; Nitriloside; B17; Aprikern.
Lewis Methods.
Livingston Vaccine.
Makar: intradermal cancer tests (ICT).
M-P virus.
Marijuana.
Millet Bread.
Millvue.
Mucorhicin.
Multiple Enzyme Therapy.
Naessens.
Olive Oil.
Oncon Juice.
Orgone Energy Devices.
Polonine.
Rand Vaccine.
Revici Cancer Control.
Samuels Causal Therapy/Endogenous Endocrinotherapy/Daussets Method.
Sanders Treatment.
Snake Meat.
Snake Oil Capsules.
Staphylococcus phage lysate.
Sunflower Seeds.
Ultraviolet Blood Irradiation—Intravenous Treatment.
Unpolished Brown Rice.
Unsulfured Raisins.
Vitamin B-15, Pangamic Acid.
Zen Macrobiotic Diet.

Mr. EDWARDS. I have some questions I would like to ask you now. This committee recently sponsored a world symposium on cancer and aging in connection with Bankers Life and Casualty Co. and the National Cancer Institute and the National Institute on Aging.

One of the principal conclusions of that conference was that there was a drastic need for more research money, particularly into aging and cancer and cures for cancer.

Can you give us some idea of your opinion of what the impact would be if the hundreds of millions or perhaps even billions of dollars a year that are wasted on phony cancer cures were somehow to be channeled into cancer research?

Dr. HENNEY. I think redirecting those funds certainly would benefit the American public because we have seen great things come from the funds that we have been provided at the Cancer Institute.

I believe that we testified last June—I believe that is the correct date—to this committee also documenting many of the advances that have been made as a result of the Cancer Institute's work.

Mr. EDWARDS. With respect to laetrile, and I believe what you said probably would apply to some of those other sorts of remedies sold through the mail, you said NCI was responding by scientific testing to evaluate the efficacy of those sorts of products and substances.

It seems as though that the public has been resistant to believing what the Government has had to say to date about those sorts of things.

Do you have any other thoughts on what could be done by NCI or other arms of the Government to put out the word to the public that they shouldn't waste their money on those ineffective cures and that they may be damaging themselves as well as wasting their money?

Dr. HENNEY. I think the real credibility thing that came into question with laetrile was the fact that when patients or their families would go to physicians and ask for clinical information, how good is this drug really when compared to the management program that you are proposing for me, and what we had provided for the physicians was the results from our animal tumor screening system which does screen all anticancer agents.

Those tests were negative. There clearly was a credibility gap there because, in spite of knowing that the animal tumor studies were negative, patients were still leaving conventional therapy in pursuit of this promoted drug.

We hope that by providing the American public with information from a clinical test, be it positive or negative, that they will realize this has undergone the same kind of testing that the other drugs proposed for them by their physicians have and this will give them a better idea, indeed much better information, as to laetrile's real clinical activity.

Mr. EDWARDS. How about with respect to things other than laetrile? Is there anything you can see that NCI or any other government agency could do to help educate the public in general about not wasting their time, their money, and their health, by pursuing these phony cures?

Dr. HENNEY. I think we tried to do it at several levels. We tried to do that, as I mentioned, through our cancer information service for those people who seek us in terms of their information.

Mr. EDWARDS. How many inquiries do you get a year there?

Dr. HENNEY. Quite frankly, we don't get very many. We find that this is mainly—many of these techniques are confined to local areas of the country. They are usually not a nationwide promotional effort; so we get isolated pockets of calls on it—on any one particular drug or device. So we find by cross-fertilizing our information with the American Cancer Society, which deals much more on the local level, that we can work well in regard to providing information through using not only our own resources, but those of other organizations.

Mr. EDWARDS. Thank you very much. Dr. Blechman, could you summarize your statement for us?

STATEMENT OF DR. WILBUR J. BLECHMAN, DIPLOMATE, AMERICAN BOARD OF INTERNAL MEDICINE AND RHEUMATOLOGY, REPRESENTING THE ARTHRITIS FOUNDATION, ATLANTA, GA.

Dr. BLECHMAN. I am representing the Arthritis Foundation, through its unproven remedies committee.

The word "quack" is not a new word. Quack actually is an abbreviation of the 17th century word from "quack salver," which means "a medical charlatan who boasts or quacks about the superlative virtue of his product even while knowing nothing about medicine."

Voltaire was quoted as saying the quack was made "when the first knave met the first fool" many, many years ago.

Quackery really has a much broader connotation, because much quackery, which I define as unproved methods of treatment whether or not there is intent to actually get money for them, is thrown at a very gullible public and it is thrown with some very excellent advertising. In fact, perhaps the one scientific thing that the quack now has in his favor is the advertising modality that he uses.

Why should this be a gullible public? Over the past several decades, we have actually seen medical research show just how complex the human body is, how complex the various systems are that are required to work perfectly well for us to live and function. Yet during this period of time, even though our population has become better educated than ever, we have yet seen quackery flourish. One of the problems, in fact, may be our media communications because the media only has a limited time in which to put this information in front of the public, or it has a certain level of education to aim at and so much of what comes down to the general public is in just a few minutes of presentation or words that actually make a very complex system sound quite simplistic.

Perhaps it is no wonder then, that people should feel that it is easy to treat disease and wonder why organized medicine or the mainstream of medicine does not really come up with all the answers. Then too, we add the media headlines which are actually set up to direct the sale of the paper that they may be in. Or the hard sell that goes into some of these advertisements which have been mentioned here today. Whether or not the individual promoting it is scrupulous does not make too much difference to the sufferers who look at it, hoping they have something for them. Then as I mentioned, advertising which actually goes on scientific principles, how to affect a person's emotions and get them to buy something.

Then we have another unfortunate aspect of the media, we have at least in the Miami area, and elsewhere as well, talk shows where people can get 2 or 3 hours in a row of free advertising for their own feelings. Whether or not these feelings have ever be enbuttressed by medical testimony may make no difference at all.

I think this is another aspect which many people do not understand. Over the past several decades, perhaps the last 110 or 120 years, medicine or science, really, has learned what it takes to be able to prove something scientifically. It was just mentioned by a previous speaker: A scientific way of doing things. Scientific method, actually is a lot more difficult to attain than most people

understand, including many physicians who have not had to go through the rigors of scientific investigation.

Therefore, people can say the word "cure" or "I think it works" or take 100 people and give them medicine and they think they have shown something, when really they have not shown much of anything or nothing at all.

I admit much of this would be of no importance at all, if we did not have people who still hurt and if we did not have people who were afraid, in the case of arthritis, that they were going to be crippled. However, there are some people still mystically looking for that magic bullet and much of what we see here today is because these people have fear and this pain and are looking for a miracle and they look toward the physicians of today to attain these miracles.

We have seen some of the gadgets over there which utilize the electronic principle as a means of sale. We have seen others working on atom power.

There used to be a fellow named Jerry Walsh, who said, when man reaches the Moon, we will start seeing Moon dust as a cure. And he was right. We have a lot of problems in the field of quackery to try to solve. Even though we are a country which is well educated, we are still not well sophisticated in the area of science. Perhaps this is one of the ways to try to better educate our people.

I was delighted to hear that some of the governmental agencies are trying to educate people as to what quackery is; what medicine really is, not what somebody says it is; how to take from a headline and an article what is real and not real. These are not going to be easy, yet they are the things to do, because quackery uses science in a fictional way to try to make it sound more appropriate.

We assume everyone of our 33 million arthritics will be affected at least once by the arthritis quackery field. For some it will be many, many times. The foundation estimates that some $500 million is wasted on quackery yearly. I would have to say that is probably a conservative estimate, $500 million may be only the bottom of the bucket when we are looking in the field of arthritis.

When we look at arthritis expenditures for research in arthritis from NIH and the Arthritis Foundation, which only amounts to some $45 million we are way beyond the eight ball. Some of the things we are fighting are the same Mexican clinics you heard about today. Mexican clinics where if anybody is told anything, it is usually a lie where people are told they do not receive steroids, yet they do. Where people are given drugs, like Dipytone which can kill and has in the past. We are seeing aspects of nutritional quackery overwhelming us. There are books and pamphlets, and the interesting thing is, if you take the time to look at these books, you find they contradict one another, because really what they are is one person's opinion, not a scientific answer at all. But they are allowed and I assume they will always be allowed under the first amendment. Still something has to be done to control the promotion of these.

Vinegar and honey are harmless, I suppose. If somebody can stand the taste, they are healthy already. People are spending money all because they are hoping for something that medical

science does not always have an answer for. We do not know how to prolong life forever, we do not know how to cure arthritis and maybe people better learn this is a fact also. We have yucca, aloe vera, and all kinds of claims are made but these are just that, claims.

I have been in practice long enough to see them come and go and come back again and they will come and go and come back again, because people are afraid. So they reach for various types of drugs, snake oil, cocaine, all things which do not work.

Speaking for the Arthritis Foundation, I can tell you the foundation does suggest that as much help as possible be given to those Government agencies which can go after the fraud, help in the form of better law, help in the form of more appropriate funding, and as we mentioned better education of the American public in general—education so that people can learn to be a lot more critical than they now know how to be, to depend more on their own physicians and know which agencies that they can contact, whether private or Government.

I was very pleased to hear that there would be increased communication between the various health agencies and the fraud combating agencies. One further thought of my own is that we place strong restraints on our drug houses. Under the Kefauver amendments they have to prove efficacy and safety before being allowed to bring a drug out on a market place. Perhaps there is something that can be done when people want to bring a device out, that they will have to prove in an honest and scientific way that it is safe before they can promote it.

I appreciate the opportunity to be here.

Mr. EDWARDS. Thank you.

You made reference to other advertising contributing to the economic success of quackery. Have the efforts of Government and private organizations to educate the public about the false hope of these cures been of the same quality in terms of communications?

Dr. BLECHMAN. I do not know that the Government effort necessarily gets to the people who are going to the quack. This is a difficult thing to say because I doubt there is any real statistical base to go on. But many people who go for quackery do not like the general mainstream of medical care to begin with. Many of these people, because of cost factors, just think that it is going to be less expensive for them to go to a nonmedical source, than a medical source, they may never have checked it out.

I believe people who get a chance to see the literature that has been provided, the material shown by the FDA, DAR, will have some benefit. I believe this will be of some help to those who get a chance to see that. Perhaps our job, the Government's job, however, will be to see that more people get hold of this material.

Mr. EDWARDS. I have one final question. What is the psychology behind someone investing $10 or $20 or perhaps more in some sort of phony remedy? Would you both say that most of the people who do that, believe there is a darn good chance that this cure is going to work? Or do they view it as probably something that will not work but maybe it will and it could be a relatively minor economic investment for them?

Dr. BLECHMAN. I think you are right on both counts. There are some who will believe, they will believe anything put in front of them. There are others because the cost if not excessive, will believe anything because they are hurting and because they are afraid.

Dr. HENNEY. I would concur with that.

Mr. HALAMANDARIS. Dr. Blechman and Dr. Henney, it is a privilege to have you before the committee. I know the respect with which you are held by your profession. I would like to go through a list of unproven remedies so we can get them on the record.

We talked about cocaine as a remedy for arthritis. Does it cure arthritis to your knowledge?

Dr. BLECHMAN. It has no record of curing arthritis and it is my understanding the so-called investigation done in California had no scientific basis to it anyway, so I think we are safe in saying cocaine should not be considered a treatment.

Mr. HALAMANDARIS. Novocaine is used when I go to a dentist and he drills on my teeth. Is novocaine a cure for arthritis?

Dr. BLECHMAN. No, it does not help arthritis.

Mr. HALAMANDARIS. How about hormone therapy? If I were injected with the female hormone or hopefully male hormone, or both?

Dr. BLECHMAN. They are not helpful when given alone, and sometimes cortisone is added to it. When that is done, there is a definite chance the person will feel better. The question is, will they feel better 5 years from now or have the severe side effects of taking cortisone?

Cortisone even in lower doses, can predispose people to infection, diabetes, and tends to lead over a period of time to what we could call softening of the bones. It causes skin changes, problems with weight, also causes a tendency to blood spots on the skin. These are probably the more common ones other than cataracts.

In the higher doses, all these things happen, but they happen more quickly and with greater severity. Some people are making claims that by adding all types of hormones together, this will not happen. But they have never presented any proof. In fact, when the Arthritis Foundation requested proof or to be allowed to examine the records of some of these groups which use these combinations, they were given in return a list of counter demands. My answer is no; I do not think this will work.

Mr. HALAMANDARIS. Food fads, is there any evidence that if you ate something it will cure arthritis, or if you do not, it will cure arthritis?

Dr. BLECHMAN. Unfortunately, none. With the possible exception of gout.

Mr. HALAMANDARIS. What about water, whether it is from Lourdes or a stream in California as a cure?

Dr. BLECHMAN. None whatsoever.

Mr. HALAMANDARIS. Radiation cures?

Dr. BLECHMAN. None whatsoever.

Mr. HALAMANDARIS. Vitamins in combination with these megadoses, is that an arthritic cure?

Dr. BLECHMAN. Unfortunately no.

Mr. HALAMANDARIS. You have talked about copper cure, what about Vivacosmic Discs?

Dr. BLECHMAN. Vivacosmic Discs have been discarded, some use them. They have not been seen to be effective.

Mr. HALAMANDARIS. Therapeutic devices, we have had a good discussion on that.

I want to thank you for your eloquent testimony. It is of great help to us. Thank you also, Dr. Henney, for your statement.

Mr. EDWARDS. Thank you very much. The hearing is adjourned.

[Whereupon the hearing was adjourned at 1:10 p.m.]

APPENDIX

JOHN F. KENNEDY MEMORIAL HOSPITAL
PHILADELPHIA, PA. 19124

-7432

AUTOPSY REPORT

Name: ROSENBERG, BENJAMIN Autopsy No.: A-8-79
Hosp. No.: E.R. 0.8478-8 Hosp. Location: E.R.
Age: Admitted: 5/17/79 Expired: DOA 5/17/79
Autopsy Performed: 5/17/79 By: James R. Williams, M.D. M.D.

CLINICAL DIAGNOSIS

DOA

FINAL DIAGNOSIS

1. Status post colostomy for adenocarcinoma of rectum (Biopsy S-239-79)
2. Strangulation of ileal loop 20 cm. from ileocecal valve.
3. Bilateral hydrothorax 300 cc. with distention, proximal small bowel.
4. Severe pulmonary edema and congestion.
5. Coronary arteriosclerosis.
6. Generalized arteriosclerosis.
7. Adenocarcinoma of rectum with metastasis to iliac nodes.

James R. Williams, M.D.
Pathologist

CAUSE OF DEATH

Acute cardiopulmonary decompensation secondary to toxic shock secondary to mechanical strangulation of distal ileum.

BEASLEY, HEWSON & CASEY

ATTORNEYS AT LAW

JAMES E. BEASLEY
WILLIAM C. HEWSON
BENEDICT A. CASEY
KEITH S. EBRSTEIN
DANIEL L. THISTLE
JON C. OHLINGER
ARLENE O. FREIMAN
C. TAYLOR TUNSTALL, JR.
W. BOYD SPENCER, III

5TH FLOOR
21 SOUTH 12TH STREET
PHILADELPHIA, PA. 19107
215-665-1600

*MEMBER NEW JERSEY AND PENNSYLVANIA BAR

October 18, 1979

Mrs. Lena Rosenberg
6310 Algon Avenue
Philadelphia, Pa. 19111

Dear Mrs. Rosenberg:

I have read carefully the newspaper article you left in my office. I agree that this theory of treatment is totally unacceptable. However, I believe the matter falls more in the range of criminal activity than medical malpractice in your husband's case. Since your husband did have cancer, I believe it would be extremely difficult to prove that the care rendered by the potential defendants contributed substantially to his death. It would also be difficult to prove that he did not assume the risk of such unusual treatment.

You might consider discussing the problem with the District Attorney's office.

I am returning herewith the article you left.

Very truly yours,

WC Hewson

WILLIAM C. HEWSON, M. D.
Attorney at Law

WCH:jh
Encl.

Newspaper Articles -
Philadelphia Enquirer
Sunday, Oct. 14, 1979
"He Yearned to Live on air alone, ..."

National Institute of Justice
United States Department of Justice

OKLAHOMA CITY, OKLA., *June 7, 1979.*

POSTAL INSPECTOR IN CHARGE,
Los Angeles, Calif.

DEAR SIR: On Feb. 21, 1979 I ordered 100 Prostin tablets from the Krueger-Ross Laboratories, 3435 Motor Avenue, Los Angeles, California 90034. They guaranteed this product to relieve my prostate problems or they would refund my $9.95. To date I have been unable to get any response out of them. I have written them two letters and attempted to call them but they do not have a telephone number listed as Krueger-Ross Labs.

Since they have been given ample time to reply to my letters I assure they do not intend to honor their guarantee. Enclosed you will find a copy of my check to them, a copy of the guarantee and an exact copy of the order I sent to them last February.

I complied with all the requirements of mailing the unused portion of the bottle of tablets to them.

I am sending you this information so that you can take any action you feel is necessary.

I believe they have been advertising in the National Enquirer.

Sincerely yours,

DON HARBOUR.

P.S.—This letter is being mailed to you June 16, 1979 and I have had no response from these people. Would you be kind enough to inform me of your action on this.

D. H.

JULY 5, 1979.

KRUEGER-ROSS LABORATORIES,
Los Angeles, Calif.

DEAR SIRS: This office has been contacted concerning an unsettled mail order transaction with you. According to the information we have received, Mr. Don Harbor, 5105 Hales Drive, Apt. 140, Oklahoma City, OK 73112, sent you a check dated February 21, 1979 in the amount of $9.95 for your product. To date, Mr. Harbour has not received the refund he has requested.

It will be appreciated if you will check your records regarding the above transaction and take whatever action is necessary to resolve this matter. In order that we may close our files, would you please advise the customer of your findings and furnish a copy of the findings to this office. A preaddressed envelope which requires no postage is enclosed for your convenience in corresponding with my office.

Thank you for your cooperation.

Sincerely,

J. F. WILLIAMSON,
Inspector in Charge.

Enclosure.

JULY 5, 1979.

Mr. DON HARBOUR,
Oklahoma City, Okla.

DEAR MR. HARBOUR: We have received your complaint concerning Krueger-Ross Laboratories, 3435 Motor Avenue, Los Angeles, Calif. 90034.

Since your transaction was conducted through the mails, we are taking the liberty of contacting the subject in your behalf.

It should be understood, however, that the U.S. Postal Inspection Service has no authority to effect refunds or adjustments. As an investigative agency, it is our function to gather evidence and facts in order that a determination can be made if action is warranted under the Mail Fraud and/or False Representation Statutes. Such action may consist of criminal proceeding as authorized by United States Attorneys, administrative proceedings by the U. S. Postal Service, or both.

Thank you for bringing this matter to our attention.

Sincerely,

J. F. WILLIAMSON,
Inspector in Charge.

PRESCRIPTION AND ADMINISTRATION OF SELECTED DRUGS IN A NURSING HOME

A Study

Presented to

the Faculty of the Frances Payne Bolton School of Nursing

Case Western Reserve University

In partial fulfillment of the requirements for the

Degree of Master of Science in Nursing

by

Carol Ann Miller

Approved: [illegible]

[illegible]

Marian Sheafor RN, Ph.D., Chairperson

Date: May 12, 198

CHAPTER I

INTRODUCTION AND LITERATURE REVIEW

Problem and Purpose

Since the advent of tranquilizers and antidepressants in the 1950's, the use of these drugs has escalated to the point that between 1962 and 1971 the sale of tranquilizers and other mood-modifying drugs increased by 136% (Goddard, 1973, p. 161). While studies have been done to determine prevalence rates for particular drugs, research to determine the efficacy of psychotropic drugs has not rapidly progressed, particularly in the area of drugs prescribed for the elderly. The purpose of this study is two-fold: to describe the prescription and administration of tranquilizers and antidepressants to elderly patients in one nursing home, and to identify the reasons nurses administer or withhold a tranquilizer or antidepressant ordered on a discretionary (PRN) basis for elderly nursing home patients.

In recent years attention has been focused on the disproportionately high number of drugs used by the elderly who comprise 11% of the U.S. population, but consume 25% of all drugs (Butler, 1975). The few studies of drug utilization which have been done clearly support Butler's statement that the elderly consume more drugs than the general population; and, specifically, have greater use of psychotropic drugs (Prien, 1975; Parry, Balter, Mellinger, Cisin, and Manheimer, 1973; Guttman, 1977; Zawadski, Glazer, and Lurie, 1978). As Phase I of the Long-Term Care Facility Improvement Campaign, the U.S. Department of Health, Education and Welfare studied U.S. nursing homes to assess the quality of care in skilled nursing facilities (HEW, 1974). Among the most noteworthy findings of this study were that 55.5% of the patients had prescriptions for tranquilizers or antidepressants, and that almost 50% of these were ordered PRN rather than on a set dosage schedule.

Of the few published studies found on psychotropic drug use by the elderly, only one identified the actual drug administration patterns as well as the prescription patterns (Ingman, Pierpaoli, and Blake, 1975). In a survey of patient drug records in one nursing home, Ingman et al. found that the average number of neuroactive drugs prescribed was substantially higher than the average number given due to the high proportion of drugs ordered PRN. In discussing the findings of his study, Ingman states:

> The determinants of drugs actually administered for behavioral symptoms (on a discretionary basis) may lie outside the written record altogether and in the social interactions that characterize human relationships in long-term care — the social matrix including the elderly patient, the nurses, the relatives and the physicians. The answer to the question: "Why did the doctor prescribe this

> drug and why did the nurse give it at this particular time to this particular patient?" often requires a more elaborate inquiry than our research was able to or was intended to provide. (p. 314)

Extensive reading on the subject of psychotropic drugs and the elderly revealed that most literature is oriented toward the role of the physician or pharmacist in drug therapy for the elderly. However, the responsibility for administering drugs, particularly PRN drugs, to elderly nursing home patients lies primarily with the nurse who decides whether or not to give the drug. In one of the few references to the responsibility of the nurse in administering drugs, three nurse-authors (Le Sage, Beck, and Johnson, 1979) summarize the present status of nursing as follows:

> There is currently an increased emphasis on nurses' accountability for their practice, and their role in decision making and diagnosis is becoming increasingly important....Nurses now function independently in the area of prevention, but nursing practice causing alteration is usually a collaborative function with physicians. When the etiology of a drug-related problem is related to phenomena which nurses are educated and licensed to treat, the actual or potential health problem identified is a nursing diagnosis....Although the domain of nursing practice is not well defined, nurses are concerned generally with the total person response to drug therapy. (pp. 63 - 64)

It is hoped that this study will contribute to a better understanding of nursing practice in regard to drug therapy for the elderly. Further, valuable information will be provided, not only about nurses' drug administering patterns, but more importantly, about one aspect of nurses' decision-making role -- the reasons nurses give for deciding to administer or withhold tranquilizers and antidepressants ordered PRN for elderly patients in one nursing home.

Definition of Terms

Terms used in this study were defined as follows:

Tranquilizers are drugs that act on the central nervous system and can be subclassified as antipsychotic (major tranquilizers) and antianxiety (minor tranquilizers).

Antidepressants are drugs that act on the central nervous system and can be subclassified as tricyclic antidepressants, monoamine oxidase inhibitors (MAO inhibitors), and lithium carbonate.

PRN, pro re nata, is a term used to designate drugs which are specified by the physician to be administered on a discretionary basis, when needed by the patient.

Literature Review

Studies related to the use of psychotropic drugs by older people are few in number and diverse in their scope. Great variation exists in important content areas such as population characteristics (e.g., age range, institutionalized, or community-living), and classification of drug categories (e.g., psychotherapeutic, psychoactive, neuroactive, or psychotropic). The literature review for this study was limited to studies with populations or subgroups aged 60 years old or over, and residing either in the community or a long-term care facility, exclusive of state

mental hospitals. In order to facilitate the comparison of research information, six studies which met these criteria are summarized in Table 1.

Although these six studies have obvious differences, the common element in all the findings is the widespread use of psychotropic drugs by the aged. This finding will first be discussed in relation to the studies of community-living aged (Parry et al., 1973; Guttman, 1977); and secondly, in relation to the studies of institutionalized aged (HEW, 1974; Prien, 1975; Ingman et al., 1975). Lastly, Zawadski's survey (1978) which included both institutionalized aged and noninstitutionalized aged will be considered.

Parry et al. (1973) approached the issue of psychotropic drug use by the aged through an extensive survey of U.S. households, using a probability sampling of 2,552 persons aged 18 to 74 years old. Personal interviews consisted of questions about the respondents' drug use during the year previous to the survey. Questions focused on the following information: use of prescription and non-prescription drugs, sources of drugs, reasons for each drug, and frequency and duration of use of each drug. Additionally, the following information was obtained about the respondents: personal and social characteristics, current health status, attitudes toward psychotherapeutic drugs, general values, psychic and somatic symptoms, and methods of coping with psychic stress (Parry et al., 1973, p. 771). Results of Parry's survey will be discussed on

TABLE 1

COMPARATIVE REVIEW OF 6 STUDIES OF PSYCHOTROPIC DRUG USE BY THE AGED *

CITATION	SAMPLE (N)	SETTING & AGES	DRUG CATEGORIES	DATA COLLECTION	RELEVANT FINDINGS
PARRY ET AL. 1973	2,552 2,002 ..... 550	Probability sampling of U.S. households 18-59 y.o. 60-74 y.o.	Prescription and over the counter Psychotherapeutic, including: Maj. tranqs. Min. tranqs. Antidepressants	Late 1970 - Spring 1971 Interviews regarding: use of psychotherapeutic drugs during previous year; sources of, reasons for, duration of, & frequency of each drug	Aged subgroup had highest use of Rx. psychotherapeutic drugs 27% of aged used Rx. psychotherapeutic drugs 13% of females & 29% of males used Rx. psychotherapeutic drugs
GUTTMAN 1977	447	Urban households 60 y.o. & over Mean age = 72 y.o.	Prescription and over the counter, including: Antidepressants Sedatives/Tranqs. Nervous system drugs Sleeping aids	February - June 1976 Personal interviews re: kinds, sources, amt., & frequency of drugs used; symptoms of overdoses &/or side effects; and patterns of alcohol use	13.6% used sedatives/tranqs. 1.1% used antidepressants 50.7% of psychotropic drug users reported they could not perform daily activities without the drugs
HEW 1974	3,458 59 ..... 705 ..... 2,694	288 nursing homes Under 20 y.o. 20-64 y.o. 65 y.o. & over Mean age = 82 y.o.	30 categories, including: Tranqs. Antidepressants Sedatives/Hypnotics	August - November 1974 Pharmacist review of patient charts to record all drug orders current on day of survey	46.9% of the patients had orders for tranqs. 8.6% had orders for antidepressants 45.9% of tranqs. were ordered PRN
PRIEN 1975	2,485 654 ..... 682 ..... 1,149	12 Veterans Administration Hospitals 60-65 y.o. 66-75 y.o. 76 y.o. & over	Psychoactive: Maj. tranqs. Min. tranqs. Antidepressants	February 1974 Record review of all drugs administered on day of survey	37% received at least one psychoactive drug on day of survey 25% received major tranqs. 9% received minor tranqs. 7% received antidepressants
INGMAN ET AL. 1975	131	One 300-bed, long-term and extended care facility Ages not given	Neuroactive, including: Maj. tranqs. Min. tranqs. Antidepressants	Review of drugs administered on 10/1/70 & 8/1/71 to determine: no. & type of neuroactive drugs prescribed with notation of PRN orders	34% had orders for maj. tranqs. 20% had orders for min. tranqs. 11% had orders for antidepressants 53% or neuroactive drugs were PRN 34% of PRN drugs were administered
ZAWADSKI ET AL. 1978	2 million 1,639,000 .... 361,000 .... 300,975 ... 60,000 ... 25 ...	Cal., Medicaid Non-aged 60 y.o. & over Community-living Institutionalized Day Health Program	Top 15 drug expenditures, including: Mellaril Chloral Hydrate Thorazine Haldol Elavil	Fiscal year 1975 - 1976 Cost analysis of Medicaid expenditures for drugs, with individual analysis of top 15 drugs used (N.B., Drug use was measured only by cost data)	Drug expenditures for the aged were more than double the expenditures for the non-aged 5% of drug expenditures for the community aged were for psychotropics, compared to 19% for institutionalized aged

* ABBREVIATIONS USED: y.o. = years old; Maj. tranqs. = Major tranquilizers; Min. tranqs. = Minor tranquilizers; Rx. = Prescription

the following levels of analysis: (1) rate of psychotherapeutic drug use by age subgroup, (2) level of psychotherapeutic drug use by age subgroup, and (3) prevalence rates for females versus males.

Parry's findings regarding the rate of psychotherapeutic drug use by age subgroup revealed that 27% of the 550 respondents age 60 to 74 years old reported use of prescription psychotherapeutic drugs during the year prior to the interview. Further analysis revealed that this 27% rate of use by the aged was the highest rate for any subgroup, with the next highest group (age 30 to 44 years old) reporting a 24% rate of use.

In addition to reporting the rates for each subgroup, Parry measured the levels of use reported by the respondents as "high" (regular daily use for two months or more), "medium" (regular daily use for one week to two months, or intermittent use on 31 or more occasions), and "low" (regular daily use for less than one week, or intermittent use on fewer than 31 occasions). Data about the level of use showed that 9% of the 550 aged respondents and 32% of the 146 aged psychotherapeutic drug users reported a "high" level of use. This finding of 32% is very close to the 31% reported "high" use by the 18 to 29 year old group; but is much lower than the reported 39% and 42% "high" use by the groups age 30 to 44 years old, and 45 to 59 years old respectively (Parry et al., 1973, pp. 777 - 778). From this

data, it can be concluded that while a larger percentage of noninstitutionalized aged than noninstitutionalized younger persons were using psychotherapeutic drugs, the elderly were less likely to use these drugs at "high" levels.

Parry's data related to the prevalence rates for males versus females revealed the following information:

1. 13% of the 1,049 male respondents and 29% of the 1,503 female respondents reported use of prescription psychotherapeutic drugs during the year prior to the interview

2. By age subgroups, the prevalence rates for women were consistently higher than those for men in the same age subgroup

3. By drug category (i.e., major tranquilizers, minor tranquilizers, antidepressants, stimulants, and hypnotics), the percentage of female users was consistently higher than the percentage of male users, except in the category of antidepressants (where the use was equal for males and females)

4. By drug category, sex, and age, the only incidence of a higher rate of use for males was in the 60 to 74 year old age group for the category of antidepressants. In this age subgroup, 4% of the males and 2% of the females reported using antidepressants. (Parry et al., 1973, p. 775)

Guttman (1977) based his study of drug use among noninstitutionalized elderly on personal interviews with 447 residents of Metropolitan Washington, D.C., aged 60 years old and over. The sample came from 23 census tracts selected from the total 627 census tracts in the Standard Metropolitan Statistical Area of Washington, D.C., using a social area analysis approach. Data were collected on the following topics: kinds, sources, amount and frequency

of prescription and over the counter drugs; symptoms of overdose and/or side effects; and patterns of alcohol use. Additional data related to socioeconomic background, decision-making patterns in regard to the use of drugs, and characteristics of elderly psychotropic drug users (Guttman, 1977, pp. 2 - 3). In contrast to Parry's measurement of reported drug use during the year prior to the interview, Guttman measured only those drugs reported taken by the respondents in the 24 hours prior to the interview.

In Guttman's findings, sedatives/tranquilizers were the second most frequently reported type of prescription drug used by the respondents. Of the 447 respondents, 13.6% reported using prescription sedatives/tranquilizers in the 24 hours prior to the interview. In contrast, only 1.1% of the respondents reported using antidepressants. Information about the reported reasons for using psychotropic drugs indicated that 50.7% of those who used psychotropic drugs reported that they could not perform their daily activities without their drugs. In regard to the frequency of sedatives/tranquilizers, 38% of the users reported "daily use," 22% reported using the drugs "one or more times weekly," and 40% reported using the drugs "as necessary" (Guttman, 1977, pp. 4 - 5, 10).

The most extensive survey of psychotropic drug use among institutionalized aged was carried out by the U.S. Department of Health, Education and Welfare (HEW, 1974).

In this survey of 288 nursing homes, 3,458 patient records were reviewed to determine the kinds and number of drug orders current on the day of the survey. Records of all patients were included, regardless of age; however 78% of the patients were 65 years old or over, and the median age of all the patients was 82 years old (HEW, 1974, pp. 3 - 4). Among the most noteworthy findings of the 1974 HEW survey were the following:

1. On the average, each patient had orders for 6.1 prescriptions (p. 15)
2. The category of tranquilizers ranked third in order of the most frequently prescribed group of drugs (p. 16)
3. 46.9% of the patients had prescriptions for tranquilizers (p. 14)
4. An additional 8.6% of the patients had prescriptions for antidepressants (p. 14)
5. 45.9% of the prescriptions for tranquilizers were ordered PRN (p. 28)

While the HEW survey provided data concerning the number of tranquilizers which were ordered PRN, no attempt was made to identify how many of those PRN drugs were actually administered. In fact, this survey was based entirely on the number of drug orders active on the day of the survey, without any reference to the number of drugs actually administered on the day of the survey.

In contrast to the HEW study, Prien's survey of 2,485 patients in 12 Veterans Administration hospitals (1975) was based entirely on a record review of all drugs administered on the day of the survey. No notation was made to designate

which of the administered drugs were ordered PRN, nor was there any attempt to identify the PRN drugs which were ordered but not administered on the day of the survey. Prien reported that 37% of the patients received an antipsychotic, antianxiety, or antidepressant drug on the day of the survey. Additionally, he categorized the patients by diagnosis and found that 56% of the 1,276 patients with a primary diagnosis of mental illness, as compared to 16% of the 1,209 patients with no diagnosis of mental illness, received at least one psychoactive drug on the day of the survey (Prien, 1975, p. 145). By drug category, 25% of the patients had orders for antipsychotic drugs, 9% had prescriptions for antianxiety drugs, and 7% had orders for antidepressants (p. 148).

Ingman's survey (1975) of 131 patients in a 300-bed long-term care facility is the only published study found which reported the number of drugs ordered as well as the number of drugs actually administered. In this study, the patient drug orders for two different dates ten months apart were reviewed by a pharmacist and physician to determine, among other factors, the following: (1) the number and type of neuroactive and non-neuroactive drugs, (2) whether a drug was prescribed on a discretionary (PRN) basis, and (3) whether the drugs were administered or not. It was found that the average number of neuroactive drugs prescribed (2.1) was distinctly higher than the average number administered (1.3) due to the fact that 53.3% of the

prescriptions were ordered PRN. Additionally, during the 24 hour period of the survey, 66% of the PRN neuroactive drugs were not administered (Ingman, et al., 1975, p. 311).

Ingman broadly defined neuroactive drugs to include the following therapeutic categories: hypnotics, analgesics, major tranquilizers, minor tranquilizers, antidepressants, psychostimulants, skeletal muscle relaxants, antiparkinson drugs, autonomic agents, and cerebral stimulants. However, a breakdown of the data according to drug category revealed that 34.4% of the patients had prescriptions for major tranquilizers, 19.9% had prescriptions for minor tranquilizers, and 10.7% had prescriptions for antidepressants (Ingman et al., 1975, pp. 310 - 312).

Unique among the studies of psychotropic drug use by the aged, Zawadski's survey (1978) provided comparative data for aged versus nonaged, and institutionalized aged versus noninstitutionalized aged. The total California Medicaid population of two million recipients was included in this survey, and then subgrouped in various ways. Data was based exclusively on drug expenditures for fiscal year 1975 to 1976, without regard to cost differences or consideration of how many drugs were actually consumed by the Medicaid recipients. Drug profiles were compiled by ranking the top 15 drug expenditures for each subgroup. The specific tranquilizers and antidepressant which ranked among the top 15 drugs were: Mellaril, Thorazine, Haldol, and Elavil (Zawadski, 1978, p. 830). Since no minor tranquilizer ranked

among the top 15 drugs, minor tranquilizers were not included in the drug profiles.

Comparative data from Zawadski's survey revealed that drug expenditures for the aged were more than double the expenditures for the nonaged. Similarly, for the aged subgroups, expenditures for the institutionalized aged were more than double the expenditures for the noninstitutionalized aged. Furthermore, the bulk of the differences for the aged subgroup was due to a much higher level of expenditures for psychotropic drugs for the institutionalized (18.5%) than the noninstitutionalized (4.8%). Another finding was that the psychotropic drug expenditures of the noninstitutionalized aged did not differ from those of the nonaged group (Zawadski at al., 1978, p. 883).

From a review of the six studies discussed above, it is obvious that many questions remain unanswered regarding the prescription and administration of psychotropic drugs for the elderly. Previous investigators addressed the question of how frequently drugs were prescribed for or administered to the elderly. However, no attempt was made to investigate the reasons for prescribing or administering psychotropic drugs for the elderly. This investigator examined how often and why nurses administered tranquilizers and antidepressants ordered PRN for elderly nursing home patients.

Specifically, the two questions addressed by this study were:

1. How are tranquilizers and antidepressants prescribed for and administered to elderly patients in one nursing home?
2. Why do nurses administer or withhold a tranquilizer or antidepressant ordered PRN for elderly nursing home patients?

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CHAPTER II

METHOD

To answer the questions of this investigation, a two-part survey was designed consisting of: (1) a structured review of patient medication records, and (2) the administration of a questionnaire to nurses. This chapter will discuss the following areas of the survey: (1) Design and setting, (2) Protection of human rights, (3) Review of medication records, (4) Administration of the questionnaire to nurses, and (5) Data reduction.

Design and Setting

The survey was conducted in a publicly-administered long-term care facility for adults in a large midwestern city. The facility had 174 intermediate and skilled care beds, however the great majority of the patients were ambulatory and 35 of the patients were mildly mentally retarded. In addition to nursing services and physical and occupational therapies, a variety of recreational, social and therapeutic group activities were provided at this nursing home.

Data were collected during the month of February 1980.

Protection of Human Rights

The proposal for this study was reviewed and unconditionally approved by the Research Review Committee of the Frances Payne Bolton School of Nursing. Additionally, in accordance with the policies of the nursing home where the study was conducted, the administrator reviewed the proposal and approved of the method of data collection. Staff nurses were informed in writing that their participation was voluntary and anonymous (Appendix A). The purpose of these procedures was to protect the human rights of the subjects — the patients whose records were reviewed and the nurses who answered the questionnaire.

Review of Medication Records

Subject Selection

Nursing kardexes were used to obtain the names of all patients aged 65 years old or older, who had resided at the nursing home during the entire month of January 1980. Medication records of these 114 patients were then reviewed to identify patients who had prescriptions for tranquilizers or antidepressants during the month of January. The number of records meeting this additional criterion was 50.

Data Collection

Medication records which met the criteria were reviewed for the following information: (1) the names of eight specific tranquilizers (as used in the 1974 HEW survey)

and the category "other tranquilizers," (2) the names of antidepressants, and (3) the dose of the drugs prescribed with particular note of PRN orders. This information was recorded on a form designed for use in this study (Appendix C). Of the 50 records reviewed, 31 contained orders for a total of 50 set dosage tranquilizers or antidepressants and 19 contained orders for a total of 22 PRN tranquilizers or antidepressants.

The 19 records with orders for PRN tranquilizers or antidepressants were surveyed further to obtain data regarding the administration of the 22 PRN drugs. Each PRN order was recorded on a form designed for this study to demonstrate the following information about the drug: (1) the maximum number of doses which could have been administered during the month of January 1980, and (2) the actual number of doses which were administered during that month (Appendix D).

To preclude the loss or duplication of information, each patient record was assigned a code number. At the completion of the study, the information linking code numbers to the study data was destroyed.

Administration of Questionnaire to Nurses

Selection of Nurses

All nurses — whether Registered Nurses (R.N.'s) or Licensed Practical Nurses (L.P.N.'s) — who administered medications at the nursing home were included in this study.

This decision was based on the policy of this nursing home (and most nursing homes) that all licensed nurses have comparable independence in and responsibility for administering medications and making decisions about PRN medications. In view of this policy, it was important to group these nurses together, without regard to their educational background, in order to answer the question of how nurses make a decision to administer or withhold a tranquilizer or antidepressant ordered PRN for a nursing home patient.

Administrative Design

The Director of Nursing provided a list of 16 nurses who administered medications at the nursing home. She then sent a memo notifying the nurses of this study and indicating her approval of their voluntary participation. This investigator visited the nursing home to personally deliver a letter (Appendix A) and questionnaire (Appendix B) to each of the 16 nurses. To assure confidentiality, a large envelope was placed at each nursing station for the anonymous return of the questionnaires. During the following three weeks, this investigator was frequently at the nursing home to review medication records and collect the questionnaires. By the end of this period, 14 of the 16 nurses had returned their questionnaires.

Instrument Design

The instrument designed for this study to obtain data from the nurses was a questionnaire consisting of four

vignettes describing fictitious patients with prescriptions for PRN tranquilizers and/or antidepressants, followed by open-ended questions related to the nurse's decision to administer or withhold the PRN drugs (Appendix B). The vignettes were designed to reflect four patient situations commonly dealt with at the nursing home. Each vignette described a patient's age, diagnoses, length of stay at the nursing home, behavior, and medication orders for one or more tranquilizers and/or antidepressants. These factors varied for each patient in order to provide a cross-section of patient situations usually encountered by these nurses. Instructions for the questionnaire were as follows: "read the vignettes carefully, WHILE PUTTING YOURSELF IN THE PLACE OF THE NURSE WHO DECIDED TO WITHHOLD OR ADMINISTER THE DRUG(S). Then describe your course of action and the factors which influenced your decision" (Appendix B). After each vignette, space was provided for the nurse to describe her course of action and list one to four reasons for her decision.

The questionnaire was originally designed with the same vignettes; but the course of action was pre-determined (i.e., the decision had already been made to give or withhold the drug), and the nurse was instructed to give reasons for the course of action which was taken. Four nurses employed at a different nursing home pre-tested this original questionnaire. This pre-test demonstrated that the vignettes were well understood, however the pre-determined course of

action regarding the PRN drugs was problematic. The nurses who pre-tested the questionnaire suggested that they may not have agreed with the course of action; thus they were forced to think of reasons for a decision they would not have made if they had a choice. After the results of this pre-test were reviewed, the questionnaire was revised to provide for open-ended choices for the nurse's decision to administer or withhold the PRN drug(s).

Data Reduction

Data from the medication records were grouped using percentages and frequency distributions. Data obtained from the questionnaires were analyzed by individual vignette and also grouped by content analysis.

CHAPTER III

DISCUSSION OF FINDINGS

Findings of this survey will be presented and discussed, first, in relation to the review of medication records, and second, in relation to the questionnaire administered to nurses.

Medication Records of Patients with Tranquilizers and Antidepressants

The following areas of the review of medication records will be considered: (1) Sex and age of the patients whose records were reviewed, (2) Use of tranquilizers and antidepressants by males and females, with a discussion of comparable findings from Parry's survey (1973), (3) Prescription patterns for tranquilizers and antidepressants, (4) Administration patterns for PRN tranquilizers and antidepressants, (5) Comparison of the results of this survey with three previous studies of the use of tranquilizers and antidepressants by nursing home patients (HEW, 1974; Ingman et al., 1975; and Prien, 1975), and (6) Summary of findings.

Sex and Age of Patients Whose Records Were Reviewed

Data were collected about the sex and age of the patients whose medication records were included in this survey.

No information was obtained about diagnoses or other factors. Information about the length of stay at the nursing home was used only to determine whether or not a patient had resided at the nursing home during the entire month prior to the data collection.

Of the 114 patients who were 65 years old or older and had resided at the nursing home during January 1980, 67% were female and 33% were male. The age of these patients ranged from 65 years old to 95 years old. The mean age was 79.6 years old, and the median age was 80.5 years old.

Use of Tranquilizers and Antidepressants by Males and Females

Of the 114 patients whose records were included in this study, the prescription of tranquilizers and antidepressants for the female patients was disproportionately higher than the prescription of these same drugs for the male patients. While 49% of the female patients had prescriptions for tranquilizers and/or antidepressants, fewer (34%) of the male patients had prescriptions for these drugs. Regarding set dosage and PRN orders, data showed that 22 of the 79 female patients (29%) had prescriptions for set dosage tranquilizers or antidepressants, and an additional 15 patients (20%) had prescriptions for PRN tranquilizers or antidepressants. In contrast, 9 of the 38 male patients (24%) had orders for set dosage tranquilizers or antidepressants, and an additional 10% had orders for PRN tranquilizers or antidepressants.

Table 2 summarizes the tranquilizer and antidepressant prescription patterns for the 76 female patients and the 38 male patients whose records were reviewed.

TABLE 2

TRANQUILIZER AND ANTIDEPRESSANT PRESCRIPTION PATTERNS FOR 114 NURSING HOME PATIENTS BY SEX

Prescription Patterns	Female Patients No. & Percent	Male Patients No. & Percent
NO PRESCRIPTIONS for tranquilizers or antidepressants	39 (51%)	25 (66%)
Orders for SET DOSAGE tranquilizers or antidepressants	22 (29%)	9 (24%)
Orders for PRN tranquilizers or antidepressants	15 (20%)	4 (10%)
TOTALS	76 (100%)	38 (100%)

This data can be compared with data from Parry's survey (1973) which is the only study found that examined psychotropic drug use by the aged with data for males and females. Parry found that noninstitutionalized women used more than twice as many prescription psychotherapeutic drugs as noninstitutionalized men. In his survey of 2,552 adults aged 18-74 years old, 13% of the male respondents and 29% of the female respondents reported using prescription psychotherapeutic drugs during the year prior to the interview (Parry et al., 1973, p. 775). In his discussion of the disproportionately high use of these drugs by women, Parry speculated that the higher use might be related to

any of the following factors: (1) more frequent physician visits by women, (2) a higher use of alcohol and marihuana by men, and (3) a higher social acceptance of mild smyptoms of psychic distress — with related physician visits — by women (Parry et al., 1973, p. 775).

Some of the reasons that institutionalized older women in this present study had more prescriptions for tranquilizers and antidepressants than the institutionalized older men might be: (1) physicians are more prone to relate women's complaints to anxiety and/or depression, (2) female patients might express anxiety and depression more obviously than male patients, and (3) since female patients have a high use of tranquilizers and antidepressants before institutionalization, they continue to request these drugs in the nursing home. However, it would be impossible with the data of this survey to go beyond speculations regarding the reasons that institutionalized older women received more prescriptions for tranquilizers and antidepressants than institutionalized older men.

Prescription Patterns for Tranquilizers and Antidepressants

This section will report data from the medication records of the patients whose records were reviewed for tranquilizers and antidepressants. Specifically, the following data will be discussed: (1) Prescriptions by drug

category and drug name, (2) Single and multiple prescribing patterns, and (3) PRN prescription patterns.

Prescriptions by Drug Category and Drug Name

Of the 114 records reviewed, 50 medication records contained a total of 72 prescriptions for tranquilizers and/or antidepressants in the following categories: 31 prescriptions for major tranquilizers, 19 prescriptions for minor tranquilizers, and 22 prescriptions for antidepressants. The names of specific drugs in each category and the frequency of prescriptions for each drug are reported in Table 3.

Single and Multiple Prescribing Patterns

An examination of single and multiple prescribing patterns for tranquilizers and antidepressants found that 35 patients (70%) had single prescriptions for a tranquilizer or antidepressant, while 4 patients (8%) had orders for 2 or 3 tranquilizers, and 11 patients (22%) had orders for a combination of tranquilizers and antidepressants. By drug category, 30 patients (60%) had orders for 1 or more tranquilizers while 9 patients (18%) had orders for an antidepressant alone. Table 4 shows the frequency with which tranquilizers and antidepressants were prescribed singly or in combination.

TABLE 3

TRANQUILIZERS AND ANTIDEPRESSANTS PRESCRIBED
BY DRUG NAME AND CATEGORY
(N=72)

DRUG NAME	DRUG CATEGORY & FREQUENCY PRESCRIBED		
	Major Tranquilizers	Minor Tranquilizers	Antidepressants
Haldol	14 (19.4%)*	na**	na
Valium	na	11 (15.3%)	na
Mellaril	8 (11.1%)	na	na
Thorazine	7 (9.7%)	na	na
Elavil	na	na	6 (8.3%)
Sinequan	na	na	6 (8.3%)
Tofranil	na	na	6 (8.3%)
Serax	na	3 (4.2%)	na
Triavil	na	na	3 (4.2%)
Atarax	na	2 (2.8%)	na
Ativan	na	2 (2.8%)	na
Stelazine	2 (2.8%)	na	na
Librium	na	1 (1.4%)	na
Serentil	na	na	1 (1.4%)
SUBTOTALS	31 (43%)	19 (26.5%)	22 (30.5%)

* Percentages refer to the total number of PRN prescriptions
The sum of the SUBTOTALS equals 100%

** "na" = not applicable

TABLE 4

SINGLE AND MULTIPLE PRESCRIBING PATTERNS
FOR 50 NURSING HOME PATIENTS
BY DRUG CATEGORY

PRESCRIPTION PATTERNS	PATIENTS Number and Percent	
1 tranquilizer	26	52%
1 antidepressant	9	18%
2 tranquilizers	3	6%
3 tranquilizers	1	2%
1 tranquilizer & 1 antidepressant	6	12%
1 tranquilizer & 2 antidepressants	1	2%
2 tranquilizers & 1 antidepressant	4	8%
TOTAL	50	100%

PRN Prescription Patterns

Regarding PRN prescriptions, 22 of the 72 prescriptions for tranquilizers and antidepressants (31%) were ordered PRN. Specifically, the names of the PRN medications and the number of orders for each were: 11 orders for Valium; 5 orders for Thorazine; 2 orders for Atarax; and 1 order each for Ativan, Librium, Serax, and Sinequan. Of these 22 PRN prescriptions, 73% were minor tranquilizers, 23% were major tranquilizers, and 4% were antidepressants. Table 5 summarizes the 22 PRN tranquilizers by drug category.

TABLE 5

PRN PRESCRIPTIONS BY DRUG CATEGORY
(N=22)

Drug Category	Number of PRN Prescriptions	Percent of all PRN Prescriptions
Major tranquilizers	5	23%
Minor tranquilizers	16	73%
Antidepressants	1	4%
TOTAL	22	100%

Further review of the data showed that 84% of the orders for major tranquilizers were written on a set dosage schedule and, conversely, 84% of the orders for minor tranquilizers were written PRN. Table 6 presents the number and percent of PRN and set dosage prescriptions for the categories of major tranquilizers, minor tranquilizers, and antidepressants.

TABLE 6

PRN AND SET DOSAGE PRESCRIPTIONS
BY DRUG CATEGORY
(N=72)

Type of Prescription	Major Tranquilizers No. & Percent		Minor Tranquilizers No. & Percent		Antidepressants No. & Percent	
SET DOSAGE	26	(84%)	3	(16%)	21	(95.5%)
PRN	5	(16%)	16	(84%)	1	(4.5%)
TOTALS	31	(100%)	19	(100%)	22	(100%)

CONTINUED

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By specific drug name, the number of set dosage prescriptions and the number of PRN prescriptions are presented in Table 7. It should be noted that all orders for the most frequently prescribed minor tranquilizer, Valium, were written PRN. In contrast, all orders for the 2 most frequently prescribed major tranquilizers, Haldol and Mellaril, were ordered on a set dosage schedule.

TABLE 7

SET DOSAGE AND PRN ORDERS FOR 50 NURSING HOME PATIENTS BY DRUG NAME (N=72)

Drug Category and Name	Number Set Dosage	Number PRN
Major Tranquilizers:		
Haldol	14	0
Mellaril	8	0
Thorazine	2	5
Stelazine	2	0
SUBTOTALS	26	5
Minor Tranquilizers:		
Valium	0	11
Serax	2	1
Atarax	0	2
Ativan	1	1
Librium	0	1
SUBTOTALS	3	16
Antidepressants:		
Elavil	6	0
Sinequan	5	1
Tofranil	6	0
Triavil	3	0
Serentil	1	0
SUBTOTALS	21	1
TOTALS	50	22

Administration Patterns for PRN Tranquilizers and Antidepressants

Data related to the administration patterns for PRN tranquilizers and antidepressants were analyzed to answer the following questions: (1) How many and what kinds of the PRN tranquilizers and antidepressants were administered during January 1980? (2) What was the frequency of administration of PRN tranquilizers and antidepressants which were administered? and (3) At what times of day were the PRN tranquilizers and antidepressants administered?

Kinds and Frequency of PRN Drugs Administered

Of the 22 prescriptions for PRN tranquilizers and antidepressants, only 7 tranquilizers were actually administered during January 1980. Namely, the administered tranquilizers and number of patients receiving each drug were: 3 patients received Valium, 1 patient received Ativan, 1 patient received Atarax, 1 patient received Serax, and 1 patient received Thorazine. By drug category, 6 of the 7 administered drugs were minor tranquilizers, 1 was a major tranquilizer, and none was an antidepressant. This pattern of administration is consonant with the fact that 16 of the 22 PRN drug orders (73%) were minor tranquilizers while only 5 of the drugs (23%) were major tranquilizers. Table 8 summarizes the results of a review of the frequency of administration for each of the 7 PRN drugs which were administered during January 1980.

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TABLE 8

DOSES OF 7 PRN TRANQUILIZERS GIVEN DURING ONE MONTH COMPARED TO THE DOSES PRESCRIBED FOR POSSIBLE ADMINISTRATION

Drug and Dose	No. of Doses Given	Maximum Possible Doses	Percent of Ea. Order Given
Ativan q. h.s. PRN	31	31	100%
Valium 2 mg. t.i.d. PRN	57	93	61%
Serax 10 mg. b.i.d. PRN	33	62	53%
Valium 5 mg. b.i.d. PRN	27	62	43%
Vistaril 25 mg. t.i.d. PRN	31	93	33%
Thorazine 25 mg. t.i.d. PRN	7	93	7%
Valium 2 mg. b.i.d. PRN	2	62	3%

Times of Administration of PRN Tranquilizers

To identify patterns in the administration of the PRN tranquilizers, a review was made of the times of day at which the drugs were administered. Of the 188 doses of PRN tranquilizers administered, 151 doses (80%) were given at 9 P.M. The remaining doses were administered as follows: 31 doses (16%) were given at 9 A.M., 3 doses (2%) were given at 1 P.M., and 3 doses (2%) were given at 5 P.M. This information clearly demonstrated a much higher frequency of PRN tranquilizer administration during the evening shift, particularly at 9 P.M. when bedtime (h.s.) medications were administered. It should be noted (see Table 8) that the only PRN tranquilizer specifically ordered for

bedtime administration (Ativan q. h.s. PRN) was the only PRN tranquilizer administered 100% of the time.

Because of the finding that a much higher percentage of PRN tranquilizers was administered during the evening shift, the 7 PRN prescriptions were further analyzed to determine: (1) the number of prescribed doses which could have been administered during each shift if all possible doses were given, and (2) the number of prescribed doses which actually were administered during each shift. In the nursing home where this survey was conducted, the schedule for administering medications is the same for PRN orders and for set dosage orders (e.g., a medication ordered "...q.i.d." or "...q.i.d. PRN" would be administered at 9 A.M., 1 P.M., 5 P.M., and 9 P.M.). Given this schedule for the administration of PRN medications, all prescribed doses would have been administered between the hours of 9 A.M. and 9 P.M. in the nursing home where this survey was conducted. Therefore, only the day shift (7 A.M. to 3 P.M.) and the evening shift (3 P.M. to 11 P.M.) were considered for this analysis.

The total number of doses prescribed for PRN administration was 496. Of this total, 279 doses (56%) were prescribed for possible administration during the day shift and 217 doses (44%) were prescribed for possible administration during the evening shift. The day shift nurses actually gave only 45 of the 279 doses (12%) prescribed for possible

administration during their shift. In contrast, the evening shift nurses actually gave 154 of the 217 doses (71%) prescribed for possible administration during their shift. Table 9 summarizes the administration patterns for the PRN tranquilizers by shift.

TABLE 9

ADMINISTRATION PATTERNS FOR 7 PRN TRANQUILIZERS PRESCRIBED FOR NURSING HOME PATIENTS DURING ONE MONTH BY SHIFT

Administration Patterns	Day Shift No.& Precent	Evening Shift No.& Percent	TOTAL for Both Shifts No.& Percent
Doses Administered	34 (12%)	154 (71%)	188 (38%)
Doses NOT Administered	245 (88%)	63 (29%)	308 (62%)
TOTAL Ordered	279 (100%)	217 (100%)	496 (100%)

One obvious administration pattern for PRN tranquilizers which emerged from this data was that a disproportionately high number of PRN tranquilizers were administered during the evening shift, particularly at 9 P.M., as compared to the number of PRN tranquilizers administered during the day shift. Of the 188 doses of PRN tranquilizers which were administered during January 1980, 80% were given at 9 P.M. Since the medications ordered for administration at bedtime are routinely given at 9 P.M. in this nursing home, the question might be asked: Do the nurses substitute PRN tranquilizers for hypnotics to induce sleep?

In addition to the 80% of the administered PRN tranquilizers which were given at 9 P.M., 2% were given during the evening shift at 5 P.M. The number of doses given during the evening shift was disproportionately high considering the fact that only 44% of all PRN tranquilizers were prescribed for possible administration during the evening shift. In view of these findings, the following questions could be posed: Do the patients exhibit more anxiety in the evening? Do the nurses have more time to identify signs and symptoms of anxiety during the evening shift? Are the patients bored in the evening and therefore do they show more anxiety? Do the nurses offer PRN tranquilizers to the patients more often during the evening shift than during the day shift? Do the evening shift nurses administer tranquilizers at 9 P.M. because the night shift nurses expect the patients to be asleep at 11 P.M.? Do the patients request PRN tranquilizers more often during the evening, particularly at bedtime? These questions could be answered empirically and may suggest the direction for another study.

Comparison of the Results of This Survey With the Results of Three Previous Studies

HEW Survey (1974)

Regarding the percentage of nursing home patients in this present survey with prescriptions for tranquilizers and antidepressants, 36% of the 114 patients whose records were reviewed had orders for tranquilizers and 17.5% had orders

for antidepressants. When compared with the HEW survey, a smaller percentage of the patients in this survey had prescriptions for tranquilizers, but a higher percentage had prescriptions for antidepressants. In the 1974 HEW survey, 46.9% of the 283,914 patients had orders for tranquilizers and 8.6% had orders for antidepressants.

Regarding single and multiple prescribing patterns, 80.5% of the 41 patients in this survey with prescriptions for tranquilizers had orders for a single tranquilizer and 19.5% had orders for 2 or 3 tranquilizers. In the HEW survey, a lower percentage (74.2%) of the 133,014 patients had orders for a single tranquilizer and a higher percentage (25.8%) had orders for multiple tranquilizers. In addition, data regarding patients in this survey with prescriptions for antidepressants revealed that 95% of the 20 patients with prescriptions for antidepressants had single orders. Data from the HEW survey showed very similar findings — 95.6% of the 24,544 patients had orders for a single tranquilizer.

Data from the HEW survey regarding the percentage of times a tranquilizer was prescribed PRN showed that 45.9% of the tranquilizers were ordered PRN. This survey showed that a smaller percentage (42%) of the tranquilizers were ordered PRN.

In summary, the following conclusions can be made about the patients in this survey as compared with the patients in the 1974 HEW survey: (1) they received fewer tranquilizers but more antidepressants, (2) their prescription patterns showed more single and fewer multiple orders for tranquilizers, but no significant difference in their patterns for single or multiple antidepressants, and (3) they had fewer tranquilizer prescriptions ordered on a PRN basis. These comparative findings are summarized in Table 10.

TABLE 10

COMPARISON OF SELECTED FINDINGS FROM THE 1974 HEW SURVEY AND THIS SURVEY (MILLER, 1980)

Findings *	This Survey (Miller,1980)	HEW Survey (1974)
Pts. with tranq. Rxs.	36.0%	46.9%
Pts. with anti. Rxs.	17.5%	8.6%
Pts. with single tranq. Rxs.	80.5%	74.2%
Pts. with multiple tranq. Rxs.	19.5%	25.8%
Pts. with single anti. Rxs.	95.0%	95.6%
Pts. with multiple anti. Rxs.	5.0%	4.4%
Tranquilizers ordered PRN	42.0%	45.9%

*ABBREVIATIONS: Pts. = patients; anti. = antidepressant
Rxs. = prescriptions; tranq. = tranquilizer

Ingman et al., 1975

Ingman's investigation of the prescription and administration of neuroactive drugs in one nursing home included 11 therapeutic categories in the classification of neuroactive drugs. This broad definition of neuroactive drugs presented limitations in the comparison of the findings of Ingman's survey with the findings of this survey. However, a breakdown of the percent of patients with prescriptions for neuroactive drugs by selected drug categories showed that: (1) 34.4% of the 131 patients had orders for major tranquilizers, (2) 19.9% had orders for minor tranquilizers, and (3) 10.7% had orders for antidepressants. Comparable findings of this survey revealed that: (1) fewer (23.7%) of the 114 patients had orders for major tranquilizers, (2) fewer (15.8%) of the patients had orders for minor tranquilizers, and (3) more patients (17.5%) had orders for antidepressants.

Prien, 1975

Most of Prien's data was reported as a comparison of one group of patients with a diagnosis of mental illness and a second group of patients with no diagnosis of mental illness. However, a few of the findings for the total sample of 2,485 patients in Veterans Administration hospitals could be compared to the findings of this survey. Regarding prescriptions by drug category, 25% of the patients in Prien's

survey had prescriptions for major tranquilizers, 9% had prescriptions for minor tranquilizers, and 7% had prescriptions for antidepressants. These findings are generally lower than comparable findings from both Ingman's survey and this present survey. Table 11 summarizes the findings of Ingman's survey, Prien's survey, and this survey.

TABLE 11

COMPARISON OF SELECTED FINDINGS FROM INGMAN, PRIEN, AND THIS SURVEY

Findings	Ingman (1975)	Prien (1975)	This Survey (Miller, 1980)
Patients with prescriptions for major tranquilizers	34.4%	25%	23.7%
Patients with prescriptions for minor tranquilizers	19.9%	9%	15.8%
Patients with prescriptions for antidepressants	10.7%	7%	17.5%

In conclusion, this present study (Miller, 1980) and the studies of HEW (1974), Ingman et al. (1975), and Prien (1975) provided comparative data regarding the prescription of major tranquilizers, minor tranquilizers, and antidepressants. However, the following factors should be recognized as serious limitations in comparing the findings:

1. HEW data reflected the number of drug orders active on the day of the survey
2. Ingman's data included the number of drugs ordered as well as administered on the day of the survey

3. Prien's data reported the number of psychotropic drugs administered on the day of the survey

4. This present survey reported the number of major tranquilizers, minor tranquilizers, and antidepressants ordered and administered during the one month prior to the data collection

5. 95% of Prien's sample were male patients

Each of these factors, among others, would have influenced the outcomes of these surveys and therefore must be considered in comparing the findings.

Summary of Findings from the Review of 114 Medication Records

A review of 114 medication records provided data about the use of tranquilizers and antidepressants by males and females, the prescription patterns for tranquilizers and antidepressants, and the administration patterns for PRN tranquilizers and antidepressants. Highlights of these findings were:

1. Of the 114 patients whose records were reviewed, 50 patients (44%) had prescriptions for a total of 72 tranquilizers and antidepressants

2. 49% of the female patients as compared to 34% of the male patients had prescriptions for tranquilizers and/or antidepressants

3. Of the 72 prescriptions for tranquilizers and antidepressants, 43% were for major tranquilizers, 26.5% were for minor tranquilizers, and 30.5% were for antidepressants

4. 31% of the prescriptions for tranquilizers and antidepressants were ordered PRN

5. Of the 22 prescriptions for PRN tranquilizers and antidepressants, 23% were for major tranquilizers, 73% were for minor tranquilizers, and 4% were for antidepressants

6. 32% of the PRN tranquilizers and antidepressants ordered PRN were administered during January 1980

7. 80% of the 188 doses of PRN tranquilizers which were administered during January 1980 were given at 9 P.M. (when bedtime medications were normally administered)

The Nurses and Their Reasons to Give or Withhold a PRN Tranquilizer or Antidepressant

In this section, the following data from the questionnaires administered to nurses will be presented and discussed: (1) Characteristics of nurses who responded to the questionnaire, (2) Reasons nurses decided to administer or withhold tranquilizers and antidepressants ordered PRN for nursing home patients, and (3) Summary of findings from the questionnaire.

Characteristics of Nurses Who Responded to the Questionnaire

Nurses responding to the questionnaire were asked to provide the following information: (1) year of birth, (2) year of graduation from nursing school, (3) number of years working in nursing, and number of those years in geriatric nursing, (4) educational background, (5) regular shift of work, and (6) academic or continuing education programs taken since completion of nursing school. Data were grouped and were not related to the nurses' answers to the vignettes.

Ages of the nurses ranged from 31 years old to 63 years old. The mean age was 45.2 years old and the median age was 44.5 years old. The range for the number of years since graduation from a nursing program was 2 years to 41 years, with a mean of 20.1 years. The number of years working in nursing ranged from 1 year to 41 years, with a mean of 19.3 years, while the number of those years working in geriatric nursing ranged from 1 year to 17 years, with a mean of 7.9 years. Table 12 summarizes the age and years in nursing for the 14 nurses participating in this survey.

TABLE 12

AGE AND NURSING EMPLOYMENT OF 4 R.N.'s AND 10 L.P.N.'s WHO ADMINISTER MEDICATIONS TO NURSING HOME PATIENTS

Characteristics	Range	Mean	Median
Age (in years)	31 - 63	45.2	44.5
Years since graduation from nursing school	2 - 41	20.1	20.5
Years in nursing	1 - 41	19.3	18.0
Number of those years in geriatric nursing	1 - 17	7.9	6.25

It should be noted that the mean number of years since completion of a nursing program (20.1) was only 0.8 of a year more than the mean number of years working in nursing (19.3). This data clearly indicated that these nurses had been actively involved in their nursing careers and had spent

very little time away from nursing since completing their nursing education. Furthermore, they had spent an average of almost 8 years in geriatric nursing. This, too, is noteworthy when one considers that nursing homes became popular in the United States only after the enactment of the Medicare program 15 years ago.

Regarding the educational background of the nurses who responded to the questionnaire, 10 were Licensed Practical Nurses (L.P.N.'s), 3 were Registered Nurses (R.N.'s) who held nursing diplomas, and 1 was an R.N. with a Bachelors of Science in Nursing degree. Their regular shifts of duty were: 6 worked day shift, 4 worked evening shift, and 4 worked night shift. In terms of continuing education courses related to pharmacology and/or aging since completion of nursing school, 9 nurses did not take any courses and the 5 nurses who had taken courses reported a total of 8 courses in pharmacology and/or aging. These 8 courses varied in length from 6 weeks to 1 year, and were taken between the years 1972 and 1978. No nurse reported taking such a course in the 12 months immediately preceding this study.

Reasons Reported by Nurses to Administer or Withhold PRN Tranquilizers or Antidepressants

This section will consider data from the responses of the 14 nurses who returned the questionnaires. It should be recalled that the nurses were instructed to read 4 vignettes describing patient situations they might have encountered at the nursing home where this survey was conducted. They were

then asked to make a decision to either administer or withhold a tranquilizer or antidepressant ordered PRN for each of the 4 fictitious patients described in the vignettes. Lastly, they were asked to report at least one reason for the course of action they chose regarding the PRN medication.

Data from these questionnaires will be reported and discussed in relation to: (1) Responses to each of the 4 vignettes individually, (2) Grouped data for the responses to all the vignettes, (3) Discussion of the reasons nurses reported they would administer a PRN tranquilizer or antidepressant, (4) Discussion of the reasons nurses reported they would withhold a PRN tranquilizer or antidepressant, and (5) Variability of responses. To facilitate a better understanding of the data concerning the nurses' responses, each of the vignettes will be presented before the data are reported and discussed.

Vignette A: PRN Tofranil

> Vignette A
>
> Mrs. Able, who is 63 years old, was admitted to the XX Nursing Home six months ago with diagnoses of Diabetes Mellitus and remote stroke with right paralysis. She had managed her care at home until she became insulin-dependent and was unable to give her own injections. Initially, she socialized with other patients, participated in group activities, and attended daily exercise class. Within the past two weeks you notice she has become quiet, withdrawn, and refuses to participate in any social activities. She has responded to your attempts to talk to her with silence or by stating "There's nothing wrong with me." When she began refusing to eat two days ago, you called her doctor who ordered Tofranil 10 mg., q.i.d., PRN.

In response to Vignette A, 10 nurses reported 15 reasons for administering Tofranil, and 4 nurses reported 9 reasons for withholding the medication. It shoud be noted that the nurses who decided to given the Tofranil reported an average of 1.5 reasons per nurse for the decision. In contrast, the nurses who decided to withhold the Tofranil reported an average of more than 2 reasons per nurse for the decision not to give the medication. In view of this difference, the question might be asked if the decision to withhold a PRN drug is more complex or needs more justification than the decision to give the PRN drug.

The individual reasons given by the nurses for administering or withholding the Tofranil ordered PRN for Mrs. Able are summarized in Table 13.

Regarding these 24 reasons to give or withhold PRN Tofranil, more than half of the reasons for withholding the drug were related to the side effects of the drug. However, of the 5 specific side effects cited, no medical or pharmaceutical literature was found to support the statement that the "side effects of Tofranil are the same as hypoglycemia." In contrast, there is much medical literature to support the statement that Tofranil is "not effective on a short-term basis" (Judge and Caird, 1978, p. 35; Irons, 1978, p. 46; Goodman and Gilman, 1975). Thus, it might be expected that more than one nurse would have reported this as a factor to be considered in the decision-making process.

TABLE 13

NURSES' RESPONSES TO VIGNETTE A: PRN TOFRANIL

	NUMBER
REASONS 10 NURSES REPORTED THEY WOULD ADMINISTER TOFRANIL	
Relieves symptoms of depression or anxiety	6
Will participate in activities/socialize	4
Improve appetite/eating	3
May begin talking about problems	2
SUBTOTAL	15
REASONS 4 NURSES REPORTED THEY WOULD WITHHOLD TOFRANIL	
Related to side effects: can cause confusion & other side effects side effects of Tofranil same as hypoglycemia can cause increased or decreased blood sugar can cause disorientation can cause diarrhea and other side effects	5
Behavior change may be a sign of hypoglycemia	1
Not effective on a short-term; need 12-14 days	1
Would refer to Social Service	1
Consult with doctor for more effective medication, e.g., Stelazine	1
SUBTOTAL	9
TOTAL NUMBER OF RESPONSES	24

Vignette B: PRN Librium

> Vignette B
>
> Mr. Baker is 64 years old, with severe Chronic Obstructive Pulmonary Disease, and had been a patient at the XX Nursing Home for three years. During your shift today he has been pacing the hallway constantly, smoking cigarettes against the doctor's orders, and has been disturbing several of the other patients by messing up their jigsaw puzzle on the hallway table. When you ask him if anything is wrong, his response is "I'm nervous today, that's all, it's nothing in particular." As you are pouring his medications you notice he has an order for Librium 10 mg., q.i.d., PRN

In response to Vignette B, 12 nurses reported 21 reasons for administering the Librium, and 2 nurses gave 3 reasons for withholding the medication. The average number of reasons per nurse for administering the drug was 1.75 and the average number of reasons per nurse for withholding the drug was very similar (1.5).

Individual resaons reported by the nurses for administering or withholding the Librium ordered PRN for Mr. Baker are summarized in Table 14.

Regarding these reasons reported by nurses, 10 of the 12 nurses who decided to administer the Librium stated they would give it to relieve the patient's tension and anxiety. Since Librium, like other minor tranquilizers, is indicated for the relief of short-term, acute anxiety, (Irons, 1978, pp. 27-28) this reason would be appropriate in view of Mr. Baker's behavior. Three nurses chose to administer the Librium with the goal of helping him decrease his smoking which was contributing to his respiratory problems.

TABLE 14

NURSES' RESPONSES TO VIGNETTE B: PRN LIBRIUM

	NUMBER
REASONS 12 NURSES REPORTED THEY WOULD GIVE LIBRIUM	
Relieves tension and anxiety	10
To improve relationships with other patients/staff	6
Help decrease smoking/is harming himself	3
Participate in activities	1
To help him discuss his problems	1
SUBTOTAL	21
REASONS 2 NURSES REPORTED THEY WOULD WITHHOLD LIBRIUM	
May have had bad news that upset him	1
May have something physical wrong and can't describe it	1
May need other medication	1
SUBTOTAL	3
TOTAL NUMBER OF RESPONSES	24

Two of the reasons reported by nurses for withholding the Librium were difficult to understand or interpret. The nurse who stated "Mr. Baker may have had some bad news that upset him" reported this as a reason for withholding the minor tranquilizer, but did not offer any alternative actions for helping him cope with his "bad news" and related anxiety. Secondly, the nurse who stated "Mr. Baker may need some other medication" did not give any indication of what kind of other medication he might need. Nor did she indicate whether this other medication might be for physical problems or to relieve his anxiety.

Vignette C: PRN Mellaril

> **Vignette C**
>
> Mr. Card, 84 years old, has been a patient at the XX Nursing Home for one year. His diagnoses are Arteriosclerotic Heart Disease and Atrial Fibrillation. He is independent in his Activities of Daily Living, but needs supervision because of his confusion and poor mental functioning. During the past week he has been urinating in the sink, taking clothes from his roommate's drawers and flushing them in the toilet, and has thrown food at other patients in the dining room. A psychiatrist evaluated Mr. Card yesterday, concluded he has "Organic Brain Syndrome," and ordered Mellaril 100 mg., b.i.d., PRN.

In response to Vignette C, 11 nurses reported 19 reasons for administering the Mellaril to Mr. Card, and 3 nurses reported 6 reasons for withholding the medication. As in Vignette A, the average number of reasons per nurse for withholding a medication was 2, and the average number for administering a medication was less (1.7). Again, the question might be asked if the reasons for withholding a drug ordered to be given on a discretionary basis are more complex than the reasons for simply administering the drug.

Individual reasons reported by the nurses for administering or withholding the Mellaril ordered PRN for Mr. Card are summarized in Table 15.

Regarding these responses to Vignette C, it should be pointed out that this is the first and only time that nurses reported they would admininster a PRN tranquilizer so that the patient would "be easier to take care of." The very low

frequency of this response (2 of the total 58 reasons to give a tranquilizer or antidepressant) is contrary to the often heard criticism that nursing home patients are tranquilized for the convenience of the staff. However, Mr. Card presented particular difficulties in his behavior and nurses expressed concern about his own safety (2 reported reasons) as well as his relationships with other patients and staff (5 reported reasons).

TABLE 15

NURSES' RESPONSES TO VIGNETTE C: PRN MELLARIL

	NUMBER
REASONS 11 NURSES REPORTED THEY WOULD GIVE MELLARIL	
Relieve restlessness/quiet him	8
Relationships with other patients/staff	5
For his own safety	2
Easier to take care of	2
May be more functional in activities of daily living	1
May be more aware of his actions	1
SUBTOTAL	19
REASONS 3 NURSES REPORTED THEY WOULD WITHHOLD MELLARIL	
Dose too large (for beginning dose)	3
May cause him to sleep too much	1
May be depressed	1
Could agitate his heart condition	1
SUBTOTAL	6
TOTAL NUMBER OF RESPONSES	25

Half of the reasons for withholding the drug (3 out of 6) were based on questions about the particular dose ordered

Additionally, another nurse observed that the medication may cause him to sleep too much. These reasons indicated that the nurses were aware of the need to carefully determine doses (especially initial doses) of psychotropic drugs for elderly patients (Judge and Caird, 1978, pp. 11-12). Although the nurses did not specifically mention Mr. Card's age, the fact that he was 84 years old was most likely a factor in their decisions.

Vignette D: PRN Thorazine, PRN Valium, and PRN Elavil

Vignette D

Mrs. Dart is 86 years old, and was admitted to the XX Nursing Home yesterday with generalized osteoarthritis and "senility." She was transferred from another nursing home with the following orders on her transfer form: "Thorazine 25 mg., q.i.d.; Valium 5 mg., b.i.d.; and Elavil 25 mg., t.i.d." The physician assigned to her has rewritten all the medication orders as "PRN." According to her transfer form she is "pleasant, cooperative, and needs some assistance in her Activities of Daily Living." Mrs. Dart slept almost continuously since she was admitted to the XX Nursing Home and had to be awakened for all her meals. When you saw her this morning she could tell you her name, but did not know what month or year it was, and gave her previous home address when you asked her where she was. She was cooperative with the aides in getting out of bed for breakfast, but fell asleep in the dining room and was brought back to her room and returned to bed. You are preparing the morning medications, and find that all her PRN medications have just been delivered from the pharmacy.

In contrast to Vignettes A, B, and C which each described a patient with one prescription for a PRN tranquilizer or antidepressant, Vignette D described a patient with orders for one major tranquilizer, one minor tranquilizer, and one antidepressant. Although the nurses were given the option of

giving or withholding any of the 3 drugs, all nurses chose either to withhold all 3 drugs or to administer the antidepressant and withhold the tranquilizers.

Table 16 summarizes the reasons 10 nurses chose to withhold all 3 medications, and 4 nurses chose to administer the Elavil but withhold the Thorazine and Valium.

It should be noted that all 4 nurses who decided to give the Elavil and withhold the Valium and Thorazine grouped Valium and Thorazine together in citing their reasons. No reference was made to the fact that Valium is a minor tranquilizer and Thorazine is a major tranquilizer, and therefore one might expect different responses for deciding to withhold or give each of these drugs. In fact, one nurse reported that both "Valium and Thorazine have more severe side effects than Elavil." In view of these responses, the question could be asked if these nurses differentiated between major tranquilizers and minor tranquilizers.

All 4 nurses who chose to withhold the Valium and Thorazine and give the Elavil said they would withhold the tranquilizers because Mrs. Dart was "overly medicated and sedated." Only one nurse mentioned that Elavil has a sedative action. Another nurse reported she would give Elavil to Mrs. Dart "to stimulate her into activity" but did not refer to the fact that Elavil can produce drowsiness, especially in older patients (Judge and Caird, 1978, p. 35).

TABLE 16

NURSES' RESPONSES TO VIGNETTE D: PRN THORAZINE, PRN VALIUM, AND PRN ELAVIL

REASONS 4 NURSES REPORTED THEY WOULD GIVE ELAVIL AND WITHHOLD THORAZINE AND VALIUM	NUMBER
Give Elavil:	
Antidepressant action should help recall & orientation	1
To stimulate her into activity	1
Sedative and antianxiety action should prevent sharp reaction if all 3 medications were stopped	1
SUBTOTAL	3
Withhold Thorazine & Valium:	
Overly medicated and sedated	4
Causing behavior change	1
Have more severe side effects than Elavil	1
SUBTOTAL	6
REASONS 10 NURSES REPORTED THEY WOULD WITHHOLD ALL DRUGS	
Lethargy/sleeping too much/too much medication	8
Not needed	2
Could cause to fall	1
Difficult to evaluate until more alert	1
Too much sedation counteracts the purpose of Elavil	1
Is doing better and more alert, may continue to improve without medications	1
SUBTOTAL	14
TOTAL NUMBER OF RESPONSES	23

The major concerns expressed by the 10 nurses who chose to withhold all 3 drugs were that Mrs. Dart was sleeping too much, was too sedated, and did not need the drugs. While all of these concernes are valid, none of the nurses expressed a concern about discontinuing 2 tranquilizers and an antidepressant for a patient who had been receiving these drugs for an unknown period of time (Goodman and Gilman, 1975; Irons, 1978; Judge and Caird, 1978). It should be recalled that Mrs. Dart was transferred from another nursing home where the orders had been written for "Thorazine 25 mg., q.i.d.; Valium 5 mg., b.i.d.; and Elavil 25 mg., t.i.d." It is interesting to note that no nurse reported that she would call the previous nursing home to find out how long Mrs. Dart had been receiving these medications in order to determine if withdrawal symptoms from any of these drugs might be likely to occur.

Grouped Data From Vignettes A, B, C, and D

To identify patterns in the nurses' reasons to administer or withhold a PRN tranquilizer or antidepressant, their responses to the 4 vignettes were grouped by content analysis. These responses will first be summarized in Table 17, and will then be discussed in the next two sections of this chapter.

TABLE 17

REASONS REPORTED BY 14 NURSES TO GIVE OR WITHHOLD A TRANQUILIZER OR ANTIDEPRESSANT ORDERED PRN FOR NURSING HOME PATIENTS

	NUMBER
REASONS TO GIVE THE PRN TRANQUILIZER OR ANTIDEPRESSANT	
Will relieve symptoms of anxiety/depression, etc.	26
Improve relationships with other patients/staff	11
Promote socialization/participation in activities	6
Prevent harm to patient in relation to physical problem (e.g., diabetic patient not eating due to depression)	6
Help patient talk about problems	3
For patient's safety	2
Will be easier to care for patient	2
Improve level of functioning in daily activities	1
Improve insight into own behavior	1
SUBTOTAL	58
REASONS TO WITHHOLD THE PRN TRANQUILIZER OR ANTIDEPRESSANT	
Patient showing side effects (e.g., lethargy) or might develop harmful effects	24
Medication not appropriate for particular behavior described	3
Dose is too large	3
No indication that patient needs the drug	2
Symptoms may be result of physical problem	2
Alternative action suggested (Refer to Social Service or consult with doctor about a different drug)	2
Patient may be upset by bad news	1
Cannot evaluate until patient is more alert	1
SUBTOTAL	38
TOTAL NUMBER OF RESPONSES	96

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Discussion of Reasons Nurses Report They Would Administer a PRN Tranquilizer or Antidepressant

> The decision to use psychotropic drug(s) as part of the patient's treatment plan is made on the premise that it will be helpful to the patient by alleviating distressing symptoms, increasing ability to cope, and hastening movement toward optimal functioning (Irons, 1978, p. 1).

This statement made by Patricia Campion O'Neill in Psychotropic Drugs and Nursing Intervention (Irons, 1978) provides a basis for examining the 58 reasons reported by nurses to administer a tranquilizer or antidepressant ordered PRN for a nursing home patient. At least 31 of the reported reasons directly reflect the statement by Patricia Campion O'Neill. The remaining 27 reasons reflect nursing goals which are not directly addressed by this statement.

Almost half (26) of the reasons reported by nurses to administer a PRN psychotropic drug were related to O'Neill's stated purpose for using a psychotropic drug for "alleviating distressing symptoms." These responses cited the action of the drug (e.g., "relieves anxiety," or "is indicated for symptoms of depression") as the basis for administering a particular drug. These responses indicated that the nurses not only were aware of the drug action and indication for use of the drug, but also were able to relate this knowledge to the needs of their patients. Additionally, 4 nurses reported they would give a PRN tranquilizer or antidepressant to decrease the patient's anxiety with the specific goal of

enabling him/her to talk about his/her problems or to increase his/her insight into inappropriate behavior. Finally, one nurse reported she would administer a PRN tranquilizer to enable a patient to "be more functional in activities of daily living." This reason clearly reflected O'Neill's goal of "hastening movement toward optimal functioning."

The second and third most frequently reported reasons for giving a PRN tranquilizer or antidepressant — to improve relationships with others and to promote socialization — both reflected the nurses' concern for social needs of the patients. The fact that 17 of the 58 reported reasons considered the social needs of the patients indicated not only that the nurses realized the importance of socialization for nursing home patients, but also that they related this knowledge to their decisions regarding PRN orders for tranquilizers and antidepressants.

The fourth most frequently reported reason to give a PRN tranquilizer or antidepressant was to prevent harm to the patient in relation to his/her physical diagnosis (e.g., "being a diabetic, it is important for her to eat," or "due to his severe COPD, the Librium may help him cut down on his smoking"). This response indicated that at least 6 of the nurses were aware of the interrelationship between a patient's physical diagnosis and mental-emotional state. Further, these nurses decided that a tranquilizer or antidepressant would be helpful in improving the mental-emotional

symptoms which were compounding the physical problems. Additionally, 2 nurses reported they would give a PRN tranquilizer to a patient for "his own safety" in a situation where the patient's behavior could be harmful.

Lastly, 2 nurses reported they would administer a PRN tranquilizer to "make a patient easier to take care of." These 2 reasons — out of the 58 reasons to administer a PRN tranquilizer or antidepressant — were the only 2 reasons that were not directly centered on patient care or patient treatment.

Discussion of Reasons Nurses Report They Would Withhold a PRN Tranquilizer or Antidepressant

In Drug Treatment of the Elderly Patient, the two Physician-Geriatrician authors state that "Prescribing for the elderly must be based on sound clinical principles, to ensure that they are not denied adequate therapy when this is indicated, nor needlessly exposed to potentially toxic drugs." (Judge, T.G., and Caird F.I., 1978, p. 11) Judge and Caird pose the following questions which should be answered before a drug is prescribed for an elderly patient: (1) "What are the undesirable effects?" (2) "Is drug therapy required at all?" (3) "Is the choice of drug correct?" and (4) "Is the dosage correct?" (pp. 11-12). These 4 questions were also raised by the nurses who reported reasons they would withhold a tranquilizer or antidepressant ordered PRN for a nursing home patient.

The question of "What are the undesirable effects?" was addressed by 24 responses which reflected a concern that the patient was already showing or would develop harmful effects from the drug. Additionally, many of the nurses cited specific side effects (e.g., confusion, lethargy, diarrhea). The fact that 63% of the reasons for withholding a PRN tranquilizer or antidepressant were related to the undesirable effects of the drug indicated that the nurses not only were aware of potential and actual side effects, but also incorporated this knowledge into their decision to administer or withhold a PRN medication. This awareness is particularly important for nurses who administer medications in nursing homes because older patients frequently develop serious side effects, especially from psychotropic drugs (Learoyd, 1972; Block, 1977; Eisdorfer, 1975; Salzman, Shader, and Hartmatz, 1975). Furthermore, nursing home patients may not have frequent monitoring by physicians or frequent medication reviews by pharmacists.

Five of the reasons reported by nurses addressed the question of "Is the drug therapy required at all?" Two nurses reported that there was no indication that the patient needed the drug, and 2 nurses reported that the symptoms may be due to a physical problem rather than a mental-emotional problem. Additionally, one nurse reported she "would prefer to use a psycho-social conservative approach first — such as a Social Service referral."

The question of "Is the choice of drug correct?" was addressed by 3 nurses who reported the medication was not appropriate for the particular behavior described. A fourth nurse reported that "Tofranil is not effective as a short-term antidepressant" and suggested she would "consult with the doctor for a more effective PRN — such as Stelazine."

Lastly, 3 nurses addressed the question of "Is the dosage correct?" by reporting that 100 mg. of Mellaril was too large a dose for this patient. No other medication dose was specifically questioned; however, many of the responses reflected a concern that the patient was "overmedicated."

Variability of Responses

Data from the questionnaires administered to nurses varied both in the reported courses of action regarding the PRN medications and in the reported reasons for these decisions.

In terms of the decisions regarding PRN medications, each of the 4 vignettes elicited responses in favor of giving the medications as well as responses in favor of withholding the medications. In each case, at least 70% of the nurses chose the same course of action. This data is presented in Table 18. It should be pointed out that even though all the nurses chose to withhold the 2 tranquilizers ordered PRN for Mrs. Dart (Vignette D), there was still variability in their courses of action regarding the antidepressant ordered PRN for Mrs. Dart.

TABLE 18

COURSES OF ACTION REGARDING PRN TRANQUILIZERS AND ANTIDEPRESSANTS REPORTED BY 14 NURSES

Vignette: PRN Drug	Decisions to GIVE the PRN Drug	Decisions to WITHHOLD the PRN Drug
A: PRN Tofranil	10	4
B: PRN Librium	12	2
C: PRN Mellaril	11	3
D: PRN Elavil	4	10
PRN Thorazine	0	14
PRN Valium	0	14
TOTALS	37	47

The 96 reasons reported by nurses for their courses of action regarding the PRN drugs (Table 17) demonstrated a great diversity of responses. Each vignette elicited a unique variety and number of reasons reported by nurses for giving or withholding the PRN medications. When the data were grouped by content analysis, 17 distinct categories of responses were identified.

It should be noted that the only area in which the number of responses showed no significant difference is in the total number of responses elicited by the vignettes. Each of the 4 vignettes elicited a total of 23, 24, or 25 reasons for the courses of action chosen by the nurses. Table 19 presents the following data for each vignette: (1) the number of reasons for giving a PRN drug, (2) the number of reasons for withholding a PRN drug, and (3) the total number of reasons reported for the courses of action.

TABLE 19

NUMBER OF REASONS REPORTED BY 14 NURSES TO GIVE OR WITHHOLD A PRN TRANQUILIZER OR ANTIDEPRESSANT ACCORDING TO 4 VIGNETTES

Vignette	No. of Reasons To GIVE	No. of Reasons to WITHHOLD	TOTAL No. of Reasons Reported
A: PRN Tofranil	15	9	24
B: PRN Librium	21	3	24
C: PRN Mellaril	19	6	25
D: PRN THORAZINE, PRN Valium, & PRN Elavil	3	20	23
TOTALS	58	38	96

Summary of Findings from the Questionnaire Administered to Nurses

The 14 nurses who responded to the questionnaire provided a great variety of data regarding their reasons for administering or withholding a tranquilizer or antidepressant ordered PRN for a nursing home patient. Because of the diversity of the responses, the wealth of information obtained from each of the 4 vignettes could not adequately be condensed for a summary. However, grouped data will be summarized in this section.

In terms of the number of tranquilizers and antidepressants the nurses decided to administer or withhold, grouped data revealed that the nurses chose to give 37 doses (44%)

of tranquilizers and antidepressants prescribed for PRN administration, and chose to withhold 47 doses (56%) of the PRN drugs (Table 18). They reported 58 reasons for their decisions to give the medications, and 38 reasons for their decisions to withhold the medications (Table 19). When the reasons were grouped by content analysis, 9 distinct categories of reasons to administer the medications and 8 distinct categories of reasons to withhold the medications were identified (Table 17). Nearly half (26 out of 58) of the reasons to give the PRN drugs were related to the action of the drug (e.g., "indicated for the relief or anxiety," or "to relieve symptoms of depression"). Regarding the reasons to withhold the PRN drugs, 63% of the responses reflected a concern that the patient was already showing or would develop harmful side effects.

CHAPTER IV

CONCLUSIONS AND IMPLICATIONS FOR FURTHER RESEARCH AND FOR NURSING PRACTICE

Conclusions

This study was designed to describe the prescription and administration of tranquilizers to elderly patients in one nursing home, and to identify the reasons nurses administer or withhold a tranquilizer or antidepressant ordered PRN for an elderly nursing home patient.

A structured review of medication records of 114 elderly nursing home patients identified a number of patterns for the prescription and administration of tranquilizers and antidepressants for those patients. However, two of the most noteworthy findings were: (1) when compared to male patients, female patients received a disproportionately high number of tranquilizers and antidepressants, and (2) when compared to the total number of PRN tranquilizers ordered for administration during the evening shift and when compared, also, to the number of PRN prescriptions administered during the day shift, a disproportionately high number of PRN tranquilizers were administered during the evening shift, particularly at 9 P.M.

A questionnaire administered to nurses at the nursing home where this study was conducted identified a great variety of reasons nurses decide to administer or withhold a tranquilizer or antidepressant ordered PRN for an elderly nursing home patient. One conclusion drawn from these diverse responses was that almost all of the reported reasons could be directly related to goals of gerontological nursing such as: relieving symptoms of anxiety and depression, promoting socialization, observing for side effects of medications, and improving a patient's level of functioning in his/her activities of daily living.

A second conclusion was related to the responses which were NOT given. Specifically, in response to the Tofranil ordered PRN for Mrs. Able (Vignette A), only one nurse mentioned that Tofranil is not effective on a short-term basis. Also, in response to Vignette D, which described a patient transferred from another nursing home with previous orders for "Thorazine 25 mg., q.i.d.; Valium 5 mg., b.i.d., and Elavil 25 mg., t.i.d.," 10 nurses decided to withhold all 3 medications when the doctor ordered them "PRN." However, no nurse raised the question of discontinuing 2 tranquilizers and an antidepressant which had been administered to Mrs. Dart for an unknown period of time.

Implications for Further Research and for Nursing Practice

Further research could be conducted both in relation to the prescription and administration patterns for tranquilizers and antidepressants for elderly nursing home patients, and in relation to the reasons nurses decide to give or withhold a PRN tranquilizer or antidepressant. As noted in Chapter III, previous research by Parry et al. (1975) revealed a disproportionately high number of prescription psychotherapeutic drugs used by noninstitutionalized women as compared to noninstitutionalized men. Similarly, this survey showed that institutionalized older women had a disproportionately high number of prescriptions for tranquilizers and antidepressants as compared to institutionalized older men. Further research might address the reasons for the higher use of psychotropic drugs by women. Additionally, similarities might be identified between the reasons institutionalized older women receive higher amounts of psychotropic drugs and the reasons noninstitutionalized women receive higher amounts of these drugs.

The disproportionately high number or PRN tranquilizers administered to patients during the evening shift, particularly at 9 P.M., suggests several questions for further research. Investigation of questions such as: Do nurses substitute PRN tranquilizers for hypnotics to induce sleep for nursing home patients? might be indicated. A review of

medication records, similar to the one conducted for this survey, could be done to report the prescription of set dosage and PRN hypnotics, and to determine the administration patterns of PRN hypnotics. Additionally, data could be obtained regarding the patients who receive combinations of hypnotics and tranquilizers at bedtime.

Finally, further information about the use of PRN tranquilizers and PRN hypnotics at bedtime could be obtained through research methods which go beyond a review of medication records. The data from this survey suggest that bedtime is a key time for the administration of PRN tranquilizers to nursing home patients. Important nursing implications might result from more extensive data regarding the use of medications — as well as other "non-medical" nursing strategies — to provide care to nursing home patients at bedtime.

Regarding the questionnaire administered to nurses, this survey might be repeated with a larger sample of nurses. Comparative data could be obtained by administering the questionnaire to two different groups of nurses (e.g., nurses employed at different nursing homes, or a group of R.N.'s and a group of L.P.N.'s). Additionally, with a larger sample, correlations between the responses of the nurses and factors such as their regular shift of duty, their educational background, or the number of years in geriatric nursing, might be identified.

Finally, this survey leads to several implications regarding the quality of care provided for elderly nursing home patients. The number and variety of reasons the nurses reported for giving or withholding a tranquilizer or antidepressant ordered PRN for a nursing home patient was impressive. At least for the purpose of this survey, the nurses did think about the pros and cons of administering PRN tranquilizers or antidepressants. However, nurses did not always differentiate between major and minor tranquilizers and several of the responses regarding the specific side effects of certain medications might not have been accurate. Furthermore, failure of the nurses to question the abrupt withdrawal of 3 psychotropic drugs which had been given to an 86 year old woman for an unknown period of time must be viewed as inappropriate.

Inservice programs might be provided for the nurses to review psychotropic drugs, with emphasis on the specific categories of major tranquilizers, minor tranquilizers, and antidepressants. Additionally, a review should be made regarding problems of dependency and withdrawal in relation to the use of psychotropic drugs over a long period of time.

Lastly, since the evening shift nurses administered a disproportionately high number of PRN tranquilizers as compared to nurses on other shifts, special effort should be made to provide inservice to this shift regarding the administration of PRN psychotropic drugs, particularly at

bedtime. Emphasis should also be placed on the importance of bedtime for nursing home patients and the use of "non-medical" nursing strategies to provide bedtime care for elderly nursing home patients.

This study has provided a wealth of knowledge about the prescription and administration of tranquilizers and antidepressants in one nursing home and the reasons nurses decide to administer or withhold a PRN tranquilizer or antidepressant. It is hoped that through this knowledge nurses will be more aware of the importance of their nursing decisions in regard to drug therapy for the elderly.

APPENDIX A

LETTER TO NURSES AND COVER PAGE

TO: (Name of individual nurse)

FROM: Ms. Carol Miller, R.N.
Graduate student in gerontology nursing
Case Western Reserve University

DATE: February 5, 1980

One of the primary responsibilities of nurses is to decide whether or not to administer PRN medications. I am studying the factors which influence a nurse's decision to administer or withhold a tranquilizer or antidepressant ordered PRN for an elderly nursing home patient.

My study consists of two parts, both of which will be carried out at the (name of the nursing home). One part involves a review of selected patient records which I will be doing on the units. The other part involves a short questionnaire which I am distributing to all nurses who administer medications at the nursing home. Your participation as one of these nurses is purely voluntary, and whether or not you participate will in no way influence your job. Please DO NOT SIGN YOUR NAME. Your return of the completed questionnaire will be accepted as your consent to participate.

I am asking you to fill out a cover page providing background information about your education, experience, etc. and a short case-study type questionnaire which will help me look at factors related to the decision making process. If you are willing to participate in this study, please fill out the cover page and proceed to read the directions. Nurses who have pre-tested this questionnaire have been able to complete it in one-half hour or less. Within the next week I will be at the nursing home during all three shifts, or you may call me at 651-4173, if you need to clarify any items. Attached is an envelope for you to return your questionnaire, and I would appreciate it if you would give it to me no later than February 12, 1980.

When this study is completed I would be happy to meet with the nurses to share the results.

PLEASE FILL IN EACH SECTION

YEAR OF BIRTH _____

REGULAR SHIFT OF DUTY: Day ____ Evening ____ Night ____

EDUCATIONAL BACKGROUND:

L. P. N.	_____	R.N., Assoc. Degree	_____
G.N., Assoc. Degree	_____	R.N., Diploma	_____
G.N., Diploma	_____	R.N., B.S.N.	_____
G.N., B.S.N.	_____	R.N., other (Specify)	_____

YEAR OF GRADUATION FROM NURSING SCHOOL _____

NUMBER OF YEARS WORKING IN NURSING _____

NUMBER OF THOSE YEARS WITH GERIATRIC PATIENTS _____

HAVE YOU TAKEN ANY ACADEMIC OR CONTINUING EDUCATION COURSES RELATED TO PHARMACOLOGY OR AGING SINCE COMPLETION OF YOUR NURSING PROGRAM? _____

IF SO, PLEASE GIVE THE FOLLOWING INFORMATION FOR EACH COURSE:

Year	_____	_____	_____	_____
Length	_____	_____	_____	_____
Content (check one)				
Pharm. only	_____	_____	_____	_____
Aging only	_____	_____	_____	_____
Pharm. & Aging	_____	_____	_____	_____

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APPENDIX B

QUESTIONNAIRE FOR NURSES

Directions for Questionnaire

Each of the following four vignettes describes a fictitious patient at the (name of the nursing home — XXNH). For each situation I have supplied information about the patient's age, diagnoses, length of stay at the XXNH, behavior, and medication orders. Each patient has a physician's order for one or more tranquilizers or antidepressants ordered PRN, and it is up to the nurse to decide whether she will administer or withhold the medication(s).

Please read the vignettes carefully, WHILE PUTTING YOURSELF IN THE PLACE OF THE NURSE WHO DECIDES TO WITHHOLD OR ADMINISTER THE DRUG(S). Then describe your course of action and the factors which influenced your decision.

THERE ARE NO RIGHT OR WRONG ANSWERS, NOR DO I HAVE ANY PRECONCEIVED IDEAS ABOUT WHAT YOU MIGHT LIST AS REASONS. However, a few of the factors which might influence a nurse's decision to give or withhold a PRN tranquilizer or antidepressant might be as follows:

1. The patient will be quieter and easier to take care of;
2. If the patient is less anxious, he might participate in recreational/social activities;
3. Other patients are becoming too upset about the patient's behavior;
4. The family night come in and complain that the patient is too quiet or "snowed under;"
5. Most of the other nurses who work on this floor give the medication;
6. None of the other nurses who work on this floor give the medication.

These factors are given ONLY AS EXAMPLES of things which might be considered by a nurse, and should not necessarily be listed as YOUR reasons to withhold or administer a PRN medication.

VIGNETTE A: PRN TOFRANIL

Mrs. Able, who is 63 years old, was admitted to the XXNH six months ago with diagnoses of Diabetes Mellitus and remote stroke with right paralysis. She had managed her care at home until she became insulin-dependent and was unable to give her own injections. Initially, she socialized with other patients, participated in group activities, and attended daily exercise class. Within the past two weeks you notice that she has become quiet, withdrawn, and refuses to participate in any social activities. She has responded to your attempts to talk to her with silence or by stating "There's nothing wrong with me." When she began refusing to eat two days ago, you called her doctor who ordered Tofranil 10 mg., q.i.d., PRN.

YOUR COURSE OF ACTION REGARDING MRS. ABLE'S MEDICATION IS:

_____

_____

GIVE AT LEAST ONE ANSWER:

List below the reasons you made the decision to give or withhold the medication:

1. _____

2. _____

3. _____

4. _____

VIGNETTE B: PRN LIBRIUM

Mr. Baker is 64 years old, with severe Chronic Obstructive Pulmonary Disease, and has been a patient at the XXNH for three years. During your shift today he has been pacing the hallway constantly, smoking cigarettes against the doctor's orders, and has been disturbing several of the other patients by messing up their jigsaw puzzle on the hallway table. When you ask him if anything is wrong, his response is "I'm nervous today, that's all, it's nothing in particular." As you are pouring his medications, you notice he has on order for Librium 10 mg., q.i.d., PRN.

YOUR COURSE OF ACTION REGARDING MR. BAKER'S MEDICATION IS:

GIVE AT LEAST ONE ANSWER:

List below the reasons you made the decision to give or withhold the medication:

1.

2.

3.

4.

VIGNETTE C: PRN MELLARIL

Mr. Card, 84 years old, has been a patient at the XXNH for one year. His diagnoses are Arteriosclerotic Heart Disease and Atrial Fibrillation. He is independent in his Activities of Daily Living, but needs supervision because of his confusion and poor mental functioning. During the past week he has been urinating in the sink, taking clothes from his roommate's drawers and flushing them in the toilet, and has thrown food at other patients in the dining room. A psychiatrist evaluated Mr. Card yesterday, concluded he has "Organic Brain Syndrome," and ordered Mellaril 100 mg., b.i.d., PRN.

YOUR COURSE OF ACTION REGARDING MR. CARD'S MEDICATION IS:

GIVE AT LEAST ONE ANSWER:

List below the reasons you made the decision to give or withhold the medication:

1.

2.

3.

4.

VIGNETTE D: PRN THORAZINE, PRN VALIUM, & PRN ELAVIL

Mrs. Dart is 86 years old, and was admitted to the XXNH yesterday with generalized osteoarthritis and "senility." She was transferred from another nursing home with the following orders on her transfer form: "Thorazine 25 mg., q.i.d.; Valium 5 mg., b.i.d.; and Elavil 25 mg., t.i.d." The physician assigned to her has rewritten all the medication orders as "PRN." According to her transfer form she is "pleasant, cooperative, and needs some assistance in her Activities of Daily Living." Mrs. Dart slept almost continuously since she was admitted to the XXNH and had to be awakened for all her meals. When you saw her this morning she could tell you her name, but did not know what month or year it was, and gave her previous home address when you asked her where she was. She was cooperative with the aides in getting out of bed for breakfast, but fell asleep in the dining room, and was brought back to her room and returned to bed. You are preparing the morning medications, and find that all her PRN medications have just been delivered from the pharmacy.

YOUR COURSE OF ACTION REGARDING MRS. DART'S MEDICATION IS:

_____

_____

GIVE AT LEAST ONE ANSWER:

List below the reasons you made the decision to give or withhold the medication:

1. _____

_____

2. _____

_____

3. _____

_____

4. _____

_____

APPENDIX C

DATA COLLECTION FORM A

Directions for Using Data Collection Form A

1. On code sheet, record the name, age, and sex of the patient whose record is being reviewed and assign a code number to each record, beginning with number "1," etc.

2. Starting with record number one, review each medication card (the white card entitled "MEDICATION & TREATMENT RECORD") for the month of January 1980.

3. If the medication card contains any prescriptions for tranquilizers or antidepressants, list the exact dose ordered for that patient on data collection form A, under the appropriate drug column. If the drug does not have a designated column, write the name and dose in the block "other" for the category of major tranquilizer, minor tranquilizer, or antidepressant.

4. Place a red circle around any doses written as "PRN."

DATA COLLECTION FORM A

CODE NUMBER	MAJOR TRANQS.	Haldol	Mellaril	Thorazine	Sparine	Compazine	OTHER MAJ. TR.	MINOR TRANQS.	Valium	Librium	Atarax	OTHER MIN. TR.	ANTIDEPRESSANTS	Elavil	Triavil	Norpramin	Sinequan	Tofranil	Lithium	MAO Inhibitor	OTHER ANTIDEP.
1.	XXXXXXXXXXX			25 mg q.i.d. PRN				XXXXXXXXXXX	5 mg t.i.d.				XXXXXXXXXXX								
2.	XXXXXXXXXXX		100 mg b.i.d.					XXXXXXXXXXX					XXXXXXXXXXX								
3.	XXXXXXXXXXX							XXXXXXXXXXX					XXXXXXXXXXX		t.i.d. [illegible]						
4.	XXXXXXXXXXX							XXXXXXXXXXX		10 mg t.i.d. PRN			XXXXXXXXXXX								

EXAMPLE

APPENDIX D

DATA COLLECTION FORM B

Directions for Using Data Collection Form B

1. Using information from data collection form A, review all medication records with orders for PRN tranquilizers or antidepressants. Use the code sheet to identify the patient record with the corresponding code number.

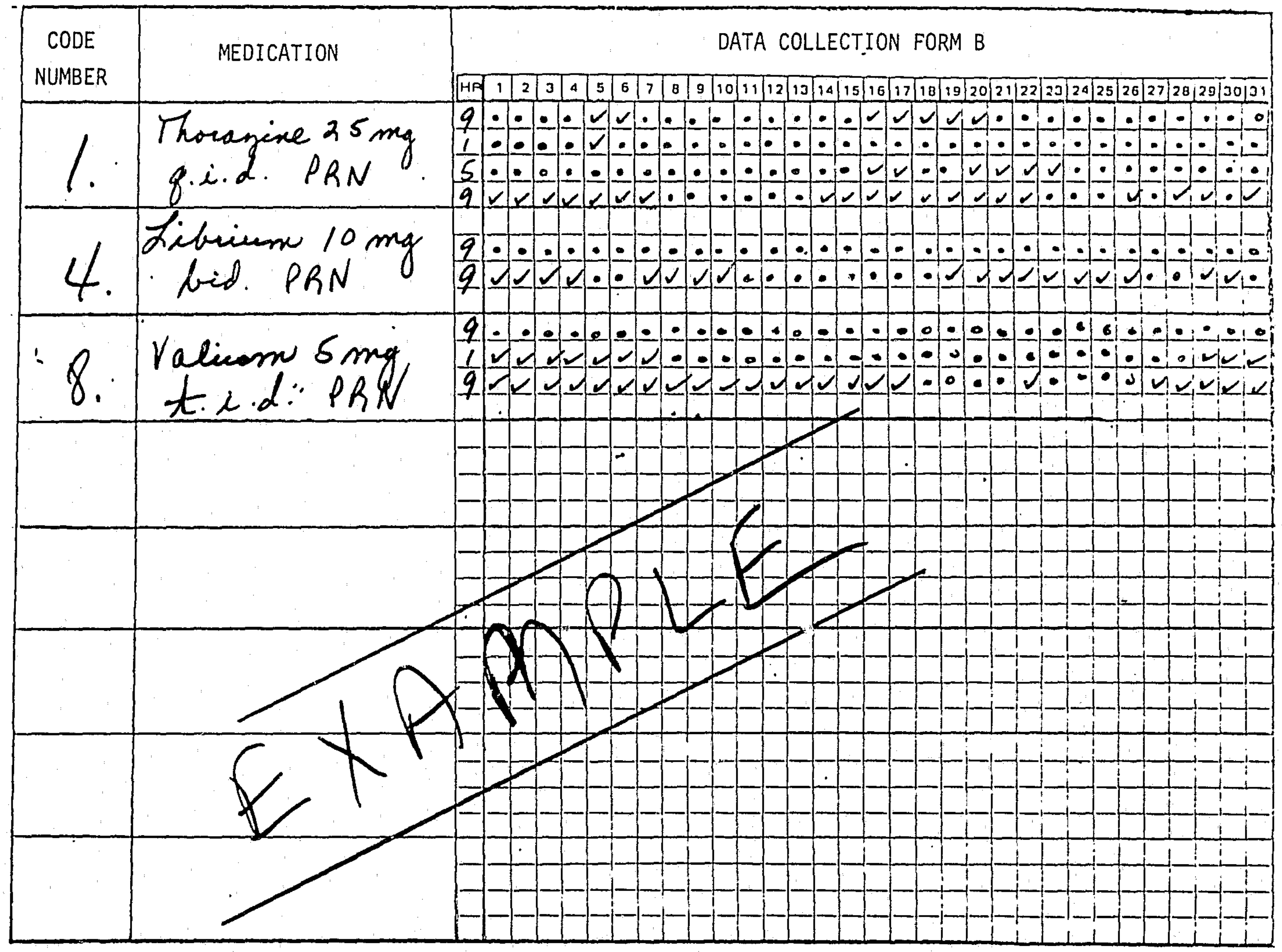
2. For each PRN order on data collection form A, record the patient record number in the column on the left.

3. Record the name and dose of each drug in the "Medication" column, next to the corresponding number.

4. In the "Hr." column, specify the possible doses for the PRN drug as follows:

Order Written:	Hours Given:
... q. 4 hrs., PRN	9 A.M., 1 P.M., 5 P.M., 9 P.M. 1 A.M., and 5 A.M.
... q.i.d., PRN	9 A.M., 1 P.M., 5 P.M., and 9 P.M.
... t.i.d., PRN	9 A.M., 1 P.M., and 9 P.M.
... b.i.d., PRN	9 A.M., and 9 P.M.
... q.d., PRN	9 A.M.
... q. h. s., PRN	9 P.M.

5. Review the "MEDICATION & TREATMENT RECORD" of the patient, and fill in each box of possible doses with a "•" if the nurse DID NOT administer a dose of medication and with a "✓" if the nurse DID administer the dose.



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