

QUACKERY: A \$10 BILLION SCANDAL

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BEFORE THE
SUBCOMMITTEE ON
HEALTH AND LONG-TERM CARE
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THURSDAY, MAY 31, 1984

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON AGING,
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:10 a.m., in room 2318, Rayburn House Office Building, Hon. Claude Pepper (chairman of the subcommittee) presiding.

Members present: Representatives Pepper, Oakar, Derrick, Borski, Regula, Wortley, Daub, Ridge, McCain, Bilirakis, and DeWine.

Staff present: Bill Halamandaris, staff director; Kathy Gardner-Cravedi, assistant staff director; Melanie Modlin, executive assistant; Mark Benedict, minority staff director; Susan Roland, assistant minority staff director; Dr. Lewis Kuller, Robert Wood Johnson fellow; Mary-Lou Stone, fellow; Laurel Hixon, Steve Bernstein, Steve Edstein, Margaret Campbell, interns; and Pat McCarthy, fellow.

OPENING STATEMENT OF CHAIRMAN CLAUDE PEPPER

Mr. PEPPER. The subcommittee will come to order, please.

I can recall, in the days of my youth in Camp Hill, AL, a patent medicine vendor coming through town selling Herbs of Life, a vegetable compound composed of roots, herbs, gums, berries, balsam, and flowers. He said that that would cure colds and almost everything except cancer and I believe maybe arthritis. My staff thought maybe it might cure my cold if I'd drink some of this.

So if any of you want to share some Herbs of Life here this morning—

Mr. REGULA. What is the alcohol content?

Mr. PEPPER. Ladies and gentlemen and my colleagues, this hearing marks the conclusion of a 4-year investigation into quackery and its impacts on senior citizens. The inquiry was initiated in 1980 following a series of hearings which determined health frauds were the most significant of the frauds directed against the elderly.

As a matter of fact, I think it's the lowest type of gangsterism, because it is like the gangster who preys on drug addicts to sell drugs. This group of gangsters preys mostly on the ill, giving them hope of health which they can never realize.

We conclude today that quackery is a national scandal. Billions of dollars—and the estimates range anywhere from \$10 to \$25 billion—is the amount that they rip off each year. Thousands of people are being harmed. Many of our most vulnerable citizens

have the last few precious moments of their lives stolen away from them because they suffer needlessly, and no one seems to be interested in doing anything much about it.

Federal efforts against quackery are minimal and appear to be diminishing. States are also not responsive. In fact, two-thirds of the States do not even have criminal sanctions for these offenses.

I should say that we invited the Department of Justice to send witnesses to testify before us here today. They declined the invitation.

The Food and Drug Administration is devoting about 1 percent of their resources to this kind of quackery and fraud.

For some reason or another, the agency that generally is very alert in trying to prevent wrong and prosecute the wrongdoing, the Federal Trade Commission, seems to be strangely paralyzed in this type of case.

So this report that we released today, that our committee staff has prepared, details the activities of the committee and the subcommittee that led to these conclusions. It represents the combined work of dozens of staff members, medical and scientific experts from across the country, and the cooperation of five Federal agencies. It is the most comprehensive review of quackery, we believe, ever undertaken by any congressional body.

By the way, I do want to commend the Postal Service as the agency of the Federal Government most alert in trying to detect these crimes at their inception and trying to do something to prevent the repetition of that and to punish those who are responsible.

We found quackery has become big business. The immense profitability and apparent absence of risk associated with these practices have spawned a web of interrelated foundations, clinics, and phony practitioners. These people work together—they promote these worthless, so-called cures, identify the desperate, and arrange travel and accommodations, when necessary, to facilitate the fleecing that they perpetrate.

We found the inventiveness of the quacks to be as unlimited as their callousness and greed. Some of the phony products being promoted by these crooks and quacks include cancer cures made of groundup diamonds, a tonic made from the warts of horses suspended in sour milk, and serums drawn from human urine and fecal matter.

We found promoters who advised arthritics to bury themselves in the earth, sit in an abandoned mine, or stand naked under a 1,000-watt bulb during the full moon.

These suffering souls have been wrapped in manure, soaked in mud, injected with snake venom, sprayed with WD-40, bathed in kerosene, and made to pay for the privilege of being afflicted that way.

Others seeking relief have been advised to sprinkle the afflicted area with moon dust or eat raw organs and intestines. Raw brain matter, for example, was said to cure mental disorders like Alzheimer's disease. Raw eye extracts were prescribed for blindness, and raw heart concentrate was suggested for myocardial infarctions and other heart disease.

Wrinkles were said to be eliminated by a process that essentially involved plastering the face with sand and water. Prostate suffer-

ers were told to find relief by sitting on a light bulb. Cataracts, it was suggested, could be treated by eating cheddar cheese.

The committee obtained and reviewed, with the help of cooperative medical experts, hundreds of quack products. They range in nature from the somewhat comical to the deadly dangerous. They range in cost from a few to several thousand dollars.

In all, more than 75 percent of the products reviewed by the committee were found to be dangerous or potentially dangerous.

Less than 5 percent of the products reviewed provided any benefit whatsoever, and that was usually cosmetic in nature and at a price commonly several times higher than comparable commercial products.

Some of the hazards associated with the use of the products reviewed by the committee include the potential of blindness, convulsions, heart palpitations, insulin shock, acceleration of cancers said to be treated, aggravation of arthritic conditions, and death.

We have all sorts of instances of these things. A lady from New Jersey had what appeared to be a cancerous condition in one of her breasts. She went to the regular doctors and was told that if she could have an early operation, the cancerous growth might be removed and she might live.

But she went to one of these quacks. They told her, oh, it wasn't any matter of difficulty to treat her condition. They started giving her some of these spurious treatments that they use, and they made her pay high prices for it.

The result was, they waited so long to do anything about the cancerous condition of her breast, she later had to have both breasts removed. She appears now to have a terminal cancer, which might have been prevented if treated in time.

They perpetrate all kinds of medical frauds to support their false claims. For example, a man from Alabama went over to Nassau to take advantage of one of these spurious cancer treatment programs, and they treated him a while, and took a good bit of his money. Then when he left, they gave him an x ray showing that his cancerous condition was completely healed—he had no more cancerous evidence whatsoever. He came back exhilarated, because he had been able to master and conquer this terrible danger.

It turned out that they were falsifying the x ray. When he went back to a regular hospital, they took another x ray and found out his cancer, of course, was still there, just as one would have expected. So after a period of elation he found himself facing a terminal illness.

There was another fellow from Fargo, ND. He had an arthritic condition of a bad nature, and he went down to one of these clinics in Mexico—where they seem to thrive, I regret to say. They gave him something that resulted in steroids, I believe they called it, climbing around his neck.

The first thing they knew, his neck was twice the normal size, and he came back, fortunately, and went to the Mayo Clinic. Luckily they discovered what it was that they had been giving him and were able to prevent its taking his life.

They finally reduced the swelling and finally cured his body of those steroids, but he just barely missed losing his life on account of one of those spurious treatments.

These quack clinics are becoming quite a big business; they have huge buildings, big hotels, and fine facilities everywhere. They give you the tourist treatment and all that sort of thing, and apparently they are just flourishing, living off the fat of the land, as it were.

We will have witnesses that will tell of their own experiences in being victimized by some of these institutions.

The response of Federal, State, and local enforcement agencies to the physical and economic hazards posed by quackery is inadequate at best. State and local efforts were accurately capsuled by the State attorney general who responded to the committee's inquiry by saying, "Quackery is not a priority."

I regret to say that we have problems in my home State of Florida. Our distinguished Governor—I asked him yesterday if we had any State laws that tried to prohibit and punish for this sort of quackery and fraud. He said that he had vetoed a bill to legalize one of these quackery plants in Nassau, but he was overridden by the legislature.

So I guess one of the reasons that people are not more industrious in trying to promote legislation is because there are a lot of patients who have been somehow or another deceived. Some of them would come in and testify, I guess, that they had been helped by some of these spurious treatments.

So that's the problem with which we are going to grapple in these hearings.

Federal efforts are equally lax. The Department of Justice, apparently under the impression that quackery is still something practiced by medicine men out of covered wagons, reported, "The typical medical quackery case . . . does not lend itself to Federal criminal prosecution." Accordingly, the Department said, its "role and experience in this area is limited."

Now, if anybody wants to sell you some of the things that they sell you, anybody that is in sound mind knows that those things are spurious, and selling them is a fraud, and touting them as a remedy for illness is a double fraud and ought to be prosecuted.

A spokesman for the FDA, the agency with primary jurisdiction for these offenses, saw the problem differently, stating last year that the agency is "simply overmatched . . . there are too many quacks, too skillful at the quick change of address and the product name for the cumbersome procedures of the FDA." At least the FDA has tried to be helpful.

The agency from which we have received the best help has been the Postal Service. You will see all around you the kinds of things that go through the Postal Service.

The Postal Service, you remember, applied to us for subpoena power. Congress chose not to give the Postal Service added subpoena power—which I thought we should have given them—but we did give them additional police power to seize some of these quackery products that pass through the post office before they are lost in the delivery to the individual to whom they are consigned. By that time, it's hard to get them back in court for evidence.

So last year, Congress, as you know, at the urging of this committee, did give additional authority to the postal inspectors to seize a lot of these quack products. That way they have it available as evidence against these quacks.

The absence of an effective deterrent, particularly criminal sanctions, combined with the immense profitability of these activities, is a virtual invitation to those who profit in pain by deceit. We are going to have some evidence here that will demonstrate the extent to which some people have profited by this kind of wrongdoing.

Quackery can no longer be considered quaint or comical. It is a serious problem with a severe impact on our most vulnerable people. It must be met with a determined, concerted response and the commitment of adequate resources. That response must begin with a serious effort to educate the public concerning the hazards of quackery.

To that end, I welcome the testimony of the distinguished witnesses who will appear here today. I am particularly grateful for the courage of the public witnesses on our first panel who have agreed to come forward and share their very interesting and challenging experiences with us.

Mr. Regula, we would welcome your statement.

Mr. REGULA. Thank you, Mr. Chairman.

I ask unanimous consent to have my statement made a part of the record.

Mr. PEPPER. Without objection, it will be included.

STATEMENT OF REPRESENTATIVE RALPH REGULA

Mr. REGULA. In the interests of time, I will be very brief.

I think this is an important matter for several reasons. Quackery not only can result in a waste of money, but it also can result in people not getting adequate treatment. They believe that what is being done for them is helpful, and, as a result, they don't get treatment in time.

It seems to me that the issue which the committee needs to address and the challenge to us as Members of the House is to, one, give adequate authority to the proper agencies, and, two, give them adequate funding.

The statutory authority, I think, has been somewhat ambiguous. We are asking an agency to sort out what is dangerous, what is harmless and what is a great waste of the individual's resources. Yet we have failed to provide adequate funding or regulatory flexibility to accomplish these goals. The aged are the primary consumers of these quack devices. In many instances, these quack treatments result in both physical and financial detriment to the senior.

I think the whole area of psychosomatic medicine is a new frontier. In exploring that area, we are plowing some new ground. This will be a very important hearing, if we can develop recommendations to the legislative committees which would prevent these abuses in the future.

I was interested the other day in reading a story that, in the medical schools now, they are alerting the future physicians and surgeons that even statements made while patients are under anesthetic may well be lodged in their subconscious, and therefore they should be very careful as to what kind of statements are made in an operating room.

But I think it illustrates the power of suggestion that takes place in the field of medicine, and of course all of these devices and cures prey on that kind of an opportunity.

I'm especially sensitive to the problem, having grown up in a rural community where, back at that time, the annual visit of the medicine man was a big social event. You may have gotten a bottle of that this morning Mr. Chairman.

Everyone is looking for the magic cure. That's the environment in which these quackery dispensers prey.

So I hope that out of this hearing we can develop the recommendations as to our role in giving the tools to the Federal agencies.

Perhaps, Mr. Chairman, along with what you are mentioning, the results and the evidence produced here should be made available to the 50 States, because in many instances the regulation of the medical field is a State responsibility.

So I would hope that we can make a point of sharing this evidence and these reports with the 50 agencies—proper agencies in each of the States.

Mr. PEPPER. Maybe we will send our report to the attorneys general of the States.

Mr. REGULA. I think that would be an excellent idea, because it really is a partnership effort on the part of the States and the Federal Government.

With that, I yield.

[The prepared statement of Mr. Regula follows:]

PREPARED STATEMENT OF REPRESENTATIVE RALPH REGULA

In my judgment, the issue of quackery is one of the greatest threats confronting the elderly of America. Conservatively estimated at \$10 billion a year, quackery has become a very profitable industry. No words can express my concern over the treatment the aged have been subjected to by these unscrupulous entrepreneurs.

Not one of us is immune to the effects of prolonged pain and the desperation it spawns to "try anything". Unfortunately, the elderly are the prime financiers of this despicable business. Eighty percent of those over age 65 experience chronic health conditions. This same group, about 11% of the population in 1981, account for about 33% of our nation's total health bill. Couple this increased need for health care with a senior's decreased mobility and it becomes increasingly clear why 60% of the quackery market is made up of the over 65 population.

Perhaps the best way to view this matter is in terms of the definition offered by our distinguished Chairman. The common denominator of these alleged remedies "is the element of conscious deceit and the absence of, and, in most cases total disregard for, scientific proof." It is these misrepresented and fraudulent "gimmicks" which are the subject of this hearing.

Despite a universal revulsion toward these frauds, I believe this hearing will be characterized by an objective tone rather than the "witch hunt" emotionalism it so generously promotes. Many of today's unconventional treatments may be tomorrow's medical breakthroughs. But this fact should not deter our subcommittee from its hard-hitting punch to the nose of quackery.

There are those who have asked how a panel of election year politicians can accurately judge the medical viability of these alleged remedies. I have no illusion of expertise in passing judgment on many of the more complex remedies which lay in the nether word between conventional and unconventional legitimate treatment. Rather, I merely point to the overwhelming evidence that the problem does exist and its high time that we provide the appropriate people with the means to correct the situation.

I would commend the efforts of the Postal Service, Federal Drug Administration (FDA), and the Federal Trade Commission (FTC) in dealing with the staggering burdens of quackery complaints. Legal actions recommended by the FDA has increased by over 250% in the last year. The Postal Service has increased its staff over five-

fold since 1982 to deal specifically with the issue. Also, the FTC has increased its staff and funding level in recognition of the seriousness of the problem.

Well intentioned as these efforts are more must be done. The very life blood of America is at stake. These agencies must be given the resources and regulatory flexibility to deal with the complex and fast-moving health scams. At present FDA can only offer recommendations to the Department of Justice to initiate criminal and civil proceedings against a potential offender. FTC has no authority to bring criminal proceedings. The regulatory ropes binding the hands of these agencies must be removed while insuring the protection of legitimate health care treatment innovations. Up to now, Congress has neglected to grant the necessary authority and funds so that these agencies may effectively act.

Those who prey on the health concerns of the elderly should be forewarned that the business of quackery has come under the scrutiny of Congress. We have declared open war. The vileness of this issue has been branded upon our collective memory and will not cease to exist when the doors of this hearing are closed.

Mr. PEPPER. Thank you very much.

Mr. Daub, we would love to hear from you.

STATEMENT OF REPRESENTATIVE HAL DAUB

Mr. DAUB. Thank you, Mr. Chairman.

I do have several things that I want to say, and I will be brief.

I want to commend you, of course, for the leadership that you have continued to give to our committee to expose manners by which the elderly population is victimized. The Aging Committee began these kinds of investigations more than 6 years ago, investigating the various types of fraud against the elderly.

In 1982, I supported our chairman's bill, H.R. 3973, which made an attempt to curtail fraud perpetrated through the mail. I am pleased that many of the provisions of that legislation were enacted into law last year.

The report on medical quackery which is being released today is another step forward in our efforts, and I want to say parenthetically, Mr. Chairman, that the majority and minority staff should be complimented for the extensive work and good effort they have made to put this report together, and ought to be recognized for their contribution.

Mr. PEPPER. I thoroughly agree.

Mr. DAUB. This report is a documentation of a very comprehensive investigation into health frauds. Health frauds are of particular concern to our committee because it is estimated that about 60 percent of those victimized by this type of fraud are senior citizens.

From the exposure that I have had to this particular kind of fraud, it appears that there are some very basic reasons why senior citizens are particularly vulnerable to this form of abuse.

First, many elderly people are isolated and may not have regular contact with friends or family. As a result, a stranger who makes an effort to personally contact the older citizen easily becomes a friend. The unfortunate fact is, this so-called friend is trusted with the elderly person's savings and often their health.

Second, simply an unfamiliarity with new medical treatments may cause some older persons to believe any number of remedies will cure their illnesses.

And, finally, older persons in general are more trusting. They are brought up in an era—I know it may be hard for some to believe now—where it was an insult to your neighbor to lock your door at night.

With these and other factors considered, it is clear that the quacks, or those whose goal it is to profit at the expense of a vulnerable group of people, have a target well in place. Our hearing today is just a first step toward solving this problem. By increasing the public's awareness, we hope to put a stop to many of these kinds of crimes.

Whether it is through the local or national media, private or public organizations, prevention is going to require a substantially greater effort to educate the people who may be vulnerable. Of course, the Government is capable of doing much of this, and I, too, want to fully meet our responsibility from the Federal perspective.

It is essential also to look toward the States, as our ranking member pointed out, and to local communities and ask them to join with us in this effort to prevent medical fraud.

Again, I want to thank the chairman for his direction in our efforts to improve the quality of life for our older Americans. I look forward today to hearing from a very distinguished panel of both experts and those who have done research in this field as well as some of the people who have been victims of this quackery. It will be very helpful.

Thank you, Mr. Chairman.

Mr. PEPPER. Thank you very much, Mr. Daub. We appreciate your good statement.

Mr. DeWine.

STATEMENT OF REPRESENTATIVE MICHAEL DeWINE

Mr. DEWINE. Thank you very much, Mr. Chairman.

We have a number of witnesses, so I will be very brief.

I think that, as my colleague from Ohio has pointed out, a danger from medical quackery of course is money that is taken from individuals, but the real danger, I think, is the time that is taken from them. Many times, it is precious time, and that is what they need to cure a disease. While they are spending their time on some bogus theory or some method of treating them, many times they are losing the time that they need to get good medical treatment. When you have diseases such as cancer, you cannot retrieve that time later on.

I think that is the most dangerous thing from this type of medical quackery.

I commend the chairman and the staff for the report that is being issued today and for holding these hearings, and I look forward to the testimony.

Thank you, Mr. Chairman.

Mr. PEPPER. Thank you, Mr. DeWine.

Mr. McCain.

STATEMENT OF REPRESENTATIVE JOHN McCAIN

Mr. McCAIN. I would also like to thank you, Mr. Chairman, for holding this hearing.

The litany of outrageous medical frauds that we will hear today and that this committee has heard before, and the need for this body to keep a watchful eye on the practices of shysters, quacks,

and con men, who continue to prey on the vulnerable elderly, is, I think, very important.

I believe the chairman pointed out that the difficulties of enforcement in this area—and they are considerable—should not discourage our efforts but, rather, should act as an incentive to explore, develop, and recommend alternatives that will have the effect of abating the problem of deceitful and willful misrepresentations made to the elderly in the sensitive area of health care.

I would also like to thank the witnesses for taking their time and effort to be with us today and share with us and the American people their thoughts and experiences in the very important areas that we are addressing today.

Thank you, Mr. Chairman.

Mr. PEPPER. Thank you, Mr. McCain.

Mr. DERRICK, would you care to make a statement?

Mr. DERRICK. No; thank you. No, sir.

Mr. PEPPER. Thank you very much.

Mr. Bilirakis, would you like to make a statement?

Mr. BILIRAKIS. No; nothing this morning.

Mr. PEPPER. We thank you very much.

Now then, we have excellent witnesses here today, some very fine panels that have been put together by our very able staff.

We have here for the first panel the Honorable Val J. Halamandaris. He is a past director of oversight and special counsel to the House Select Committee on Aging in Washington.

Next is Mr. Sandvik of Fargo, ND, a victim of a phony arthritis cure.

Mr. Harvey Wachsman, a medical doctor and doctor of jurisprudence, from New York, accompanied by Mrs. Edith Schneider, Fairlawn, NJ, victim of a phony cancer cure.

Mrs. Paulette Peters of Midlothian, IL, accompanied by her son, Mr. Chuckie Peters, victim of a phony cancer cure.

Mrs. Marylyn Medberry of Eugene, OR, victim of a phony arthritis cure and daughter of victims of phony Alzheimer's and arthritis cures.

Mrs. Marcella O'Bryant of Springfield, OR, victim of a phony brain disease cure.

Dr. Carl Barnes, pathologist, Florence, AL, and son-in-law of a phony cancer cure victim.

Dr. Lorenzo Pelly, of Brownsville, TX, a cancer clinic practitioner.

Mr. David Horowitz, consumer advocate of Los Angeles.

That is a distinguished and able panel. Now we will hear them.

The first is the Honorable Val J. Halamandaris, who, you will remember, rendered extraordinarily skillful service to this committee when he was with us on the staff. He was formerly also with the Senate committee.

Mr. Halamandaris, we are pleased to have you.

PANEL ONE, CONSISTING OF VAL J. HALAMANDARIS, PRESIDENT, NATIONAL ASSOCIATION FOR HOME CARE, WASHINGTON, DC, PAST DIRECTOR OF OVERSIGHT AND SPECIAL COUNSEL TO THE SELECT COMMITTEE ON AGING, U.S. HOUSE OF REPRESENTATIVES; HERB SANDVICK, VICE PRESIDENT, CONGRESS, INC., FARGO, ND, VICTIM OF PHONY ARTHRITIS CURE; HARVEY WACHSMAN, M.D., J.D., OF NEW YORK, ACCOMPANIED BY EDITH SCHNEIDER, FAIRLAWN, NJ, VICTIM OF PHONY CANCER CURE; PAULETTE PETERS, MIDLOTHIAN, IL, ACCOMPANIED BY HER SON, CHUCKIE PETERS, VICTIM OF PHONY CANCER CURE; MARILYN MEDBERRY, EUGENE, OR, VICTIM OF PHONY PAIN CURE; MARCELLA O'BRYANT, SPRINGFIELD, OR, VICTIM OF PHONY BRAIN DISEASE CURE; CARL BARNES, M.D., PATHOLOGIST, FLORENCE, AL, SON-IN-LAW OF VICTIM OF PHONY CANCER CURE; LORENZO PELLY, M.D., BROWNSVILLE, TX; AND DAVID HOROWITZ, CONSUMER ADVOCATE, LOS ANGELES, CA

STATEMENT OF VAL J. HALAMANDARIS

Mr. HALAMANDARIS. Thank you, Mr. Chairman.

I must say, it is a great honor for me to be with you today. I want to thank you for those years that you allowed me to sit next to you, and to be the counsel to this committee. It was the greatest honor in my life, and it was a high privilege.

I know of your good work and how much it has meant to the elderly. I'd like to commend you personally Mr. Chairman, and also the other members of the panel, including Mr. Regula and Mr. Daub. I don't think the elderly have any better friends anywhere than the gentlemen sitting on the dais, and I would like to acknowledge that.

Mr. PEPPER. You are doing a fine job, Mr. Halamandaris.

Mr. HALAMANDARIS. Thank you.

My responsibility here is to tell you a little bit about this investigation and how it began—the steps that were taken—and then to quickly demonstrate some of the products for you. This is so that the public can get some idea of the various kinds of products that we obtained through the mail during our investigation. I'll do that shortly.

So with your permission, I'm going to summarize my statement. I will not read the entire statement.

Mr. PEPPER. Do you want the full statement put in the record?

Mr. HALAMANDARIS. Yes, sir, please.

Mr. PEPPER. Without objection, it will be received.

Mr. HALAMANDARIS. The investigation began, as you know, Mr. Chairman, with your questionnaire that you sent the attorneys general and the State departments of consumer affairs, and what we learned is that health care fraud is the No. 1 problem that they face.

Paradoxically, they were doing very little about the problem. They admitted this to us. Some of them were embarrassed, but the fact that so few resources were going into the problem, even though senior citizens account for 60 percent of those who are victimized by medical quackery—this was such a stark finding that

we determined a massive investigation was needed to document why the problem existed.

The next step was to gather facts. The Congress has rather extraordinary resources when it comes to finding fact. We sent questionnaires not only to the attorneys general but to police chiefs, to State departments on aging, action line reporters and senior citizen organizations.

We visited the Federal Trade Commission and looked at their files going back 20 years. We visited the Arthritis Foundation, the American Medical Association, the U.S. Postal Service, the National Cancer Institute, every public and private agency that deals with health care. We examined case histories in their files in great detail.

We asked the Library of Congress to give us a print-out of every study and every report on medical quackery and unproven remedies going back 20 years. We did the same thing with the National Library of Medicine.

I want to give the impression that we cast a rather broad net, all in your name, Mr. Chairman, as the chairman of the committee, gathered an extraordinary amount of data which has been fashioned into this report.

Now I would like to say that—if you will forgive the personal reference—this investigation was very important to me because I'm one of the 40 million people in this country who suffer from arthritis.

I know what it's like to be in so much pain that you cry continuously.

I know what it's like to be in so much pain that combing your hair and walking upstairs becomes an act of torture.

I know what it's like to go from clinic to clinic, to go from doctor to doctor, looking for relief.

I know what it's like to have your family spend every dime that they have or every dime that they can borrow to try to find you some help.

I know what it's like to look in magazines and look at the beguiling ads which somehow suggest that simple remedies are the best.

I know what it's like to send money off and purchase such products only to be disappointed time and time again.

I know what it's like to be in pain, to be deceived, and to be without hope. I've been there myself, and that's why I think this investigation is particularly important, and I have spent so much of my time to see it through.

As you know, the central conclusion of this report is that quackery is a massive and growing problem.

When I was with the Senate Aging Committee, we estimated in 1965 that it was a \$1 billion problem. We now find that the problem has grown by leaps and bounds, and it now costs the public more than \$10 billion a year.

I've been groping for some way to demonstrate that, to get that fact to the American public, and to contrast it with the fact that we are spending so little for legitimate research, to contrast the fact that we are spending pennies for legitimate research and millions on medical quackery.

This is what we spend, Mr. Chairman, on research on senility and problems of the aged per capita—a quarter. Twenty-five cents per every American is what is spent trying to find the answer to Alzheimer's disease, senility, and related problems. It comes to \$60 million a year.

We spend \$80 million—35 cents per every American—on arthritis research.

What we spend on cancer research—thanks to you, Mr. Chairman, and your World Conference on Cancer and Aging is \$4.40 for every American, or \$1 billion a year. These \$4 represent what we spend on legitimate research for cancer.

By contrast, this is what we spend on medical quackery: \$44 for every American in this country is spent on medical quackery in every year.

I hope this demonstration serves to drive the point home. We are spending literally billions of dollars which, if they could be routed into finding some sort of legitimate research, would be to everyone's benefit.

Mr. Chairman, I would just like to say that this \$10 billion estimate is conservative: it does not include quackery which is perpetrated against the younger population. The biggest area of quackery right now is phony diet pills, phony diet cures.

A lot of these products that you see up here—weight reduction devices, belts that you put around the middle that are supposed to make you lose weight—are items sold primarily to young people. We are talking about 5 or 6 billion dollar's worth of quackery in those items alone. We did not include those in our estimate. Again, our primary concern in our report was the elderly and senior citizens.

I'd like to say that it's not just a matter of economic loss, it's a matter of loss of life and the matter of injury, and you are going to be hearing some case examples in just a minute. People die as a result of what some of these quacks do.

The next point I want to emphasize is that this is big business. In the report, we point out, one promoter was making \$110,000 a day on one of his schemes. Another promoter, Mr. Chairman, according to court record, made \$13 million in the scope of 9 months.

Another point that occurs to me is that we all accept the fact that a political candidate can raise millions of dollars through direct mail. We understand that. But somehow we have never put it through our head that the combination of the computer plus direct mail means millions of dollars in the context of medical quackery, and that's what's happening here—literally millions of dollars being made by promoters that rip off the public with impunity. Its a very sad commentary.

I'd like to emphasize also that our primary concern in this report is not what individuals choose to do in the privacy of their own homes.

If you want to chew on old socks, and you feel that that makes your arthritis better, I don't think the public should worry about that. Nor do I think it should be a public concern you tell your neighbor that chewing on old socks makes you feel better.

But about the time that you start advertising in the paper that chewing on old socks is the one and only remedy and cure for ar-

thritis, and you start charging dollars for the privilege of learning the secret, then I think society should begin to be concerned.

I think, even more, we need to be concerned about those that I call the quacketeers, who make it their major business to rip off the elderly, which they seem to do with impunity.

The next point I'd like to emphasize is the fact that those agencies that are supposed to be protecting the public are not doing a thing about it, and that is the saddest part of the story. I take exception to the laissez-faire attitude on the parts of the States that have the primary responsibility for stopping medical quackery. They simply view it as a problem that they can't handle.

I protest the Justice Department's horse-and-buggy mentality when it comes to quackery. They still think quackery is a nickle-and-dime operation. We are talking about a multimillion-dollar racket in 1984 and it's growing at an alarming rate.

Mr. Chairman, things are so bad that con men in prison are taught that if they want to get into a good, lucrative business, where there is absolutely no chance of being caught and prosecuted, the thing to do is to set up a mail-order business and go into ripping off old people. Now, that is a pretty sad state of affairs.

I would like to emphasize again that not only should the Justice Department begin to crack down on some of these people, the Internal Revenue Service ought to express some sort of an interest, because fraud and tax fraud go hand in hand.

It also troubles me greatly that the Internal Revenue Service has not been looking at some of these phony foundations which are nothing more than shells that operate as a means of taking money from the public and diverting it into improper sources.

The real problem there is how does the public tell between what is a legitimate foundation and one of these that is set up purposely to steal money from the public? Again, the Internal Revenue Service has the ability to tell the difference and should make more of a special effort in this area.

Finally, something needs to be said about the tactics of those zealots that tried to block this investigation. They sent scurrilous letters to every Member of Congress saying, "Investigate the investigators." In doing so, those people who impugned the motives of the staff of this committee, tried to divert attention from their own activities and to block the issuance of this report. I believe they have behaved in a very unethical manner. They even went to the point of threatening lawsuits against the committee, the committee staff, and the House of Representatives just because we launched this investigation, which we believe to be in the public interest.

These zealots would have you believe that this committee is in league with the American Medical Association and it is trying to suppress any sort of research or use of unproven remedies. That simply is not the case.

Neither the American Medical Society, nor any other group reviewed this report before it was issued. No one had any control of its findings except the committee and its staff. It reflects the best judgment on the basis of the best information we had at that time.

I suppose, Mr. Chairman, that the next major breakthrough in American medicine might be in this report someplace. I doubt it. But it may be in here.

The only thing the report is trying to say is, if it is so, it has to be established through the mechanism of the scientific method. Let's prove it, before we start experimenting on millions of old people.

But once again I want to emphasize that our primary focus in this report is those folks that I call the quacketeers—the businessmen who go out with malice aforethought to rip off old people, and there are plenty of them. If all we accomplish is to alert the public about these people who are committing direct fraud, the report will be valuable.

In closing Mr. Chairman, I think we have to admit that part of the blame belongs with us up here in Congress, because we have not given the Postal Service the authority that it needs.

The Postal Service is woefully undermanned, and as you know, we have not given them even that rudimentary investigative tool, the subpoena power.

We have given subpoena power to every other Federal agency. We have created inspectors general in every government department. They have civil subpoena authority so that they can get books and records and bring some of these promoters to the bar of justice.

The Postal Service does not have that authority. They cannot get access to books and records.

To sit, as I have done, with the postal inspectors and have them pursue these quacketeers who change mailboxes, who change products, who change names and addresses with the frequency that a snake sheds its skin, is immensely frustrating, but only in this way can you have any idea of what we are up against.

They don't have any computer capability. They can't keep track of the promoters by the millions that are out there practicing fraud on old people. So we need to do something to invest the Postal Service with the subpoena authority to give them the manpower and computer support they need.

What troubles me most of all about the findings in this report is that we seem to be saying in this society today that we have accepted a kind of law of the jungle, that we have survival of the fittest, that we have these predators, who are those I call the quacketeers, and we have their legitimate prey in those who are old and ill. We seem to be resigned of that this is the natural order of things. So what if a few people get ripped off? It doesn't really matter. This seems to be the prevailing mentality today.

By our inaction we offer acquiescence and ratification. We have given the clear signal that it's open season to rip off the elderly. I object to this mindset. We have to do something to reverse the pernicious schemes that are taking millions of dollars from the pockets of our elderly at a time when they can least afford it, and the fact that they suffer injury and they suffer death.

I would like to commend you, gentlemen, and ask that you join in repudiating this so-called law of the jungle as inapplicable to human affairs and to reestablish that Older Americans are our treasure, and that we will do everything possible to protect their interests.

Now I want to show you a couple of the items that we received. We opened over 300 major cases as a result of sending away for

products in your name, Mr. Pepper, and you would think that would have a chilling effect on some of these promoters, but apparently not.

This is the first product and I could hardly wait to receive it, because allegedly it cures cancer, blocks pain, helps you in your business—which is interesting—it also stops your headaches, allegedly heals boils that you may have on your face, makes going to the dentist painless, and also helps arthritis pain.

Now, for a mere \$44, Mr. Chairman, what we received, to our surprise, was a cassette tape recording. I want to play that for you. Now, this is what is supposed to cure all of those items. To me it sounds like whales mating.

[Tape recording of electronic sounds is played.]

Mr. HALAMANDARIS. Do you feel better?

It makes me feel a lot better. I don't know about you.

[Tape continues.]

Mr. PEPPER. They sent the cassette?

Mr. HALAMANDARIS. Yes, sir. That is what we received. And once again, the ads couldn't be more clear about the things that it is supposed to cure.

This one interested me—it was an ad for a herbal birth control. The product turned out to be advice about inserting a vitamin C pill, or a lemon wedge, you know where. The third variation was a series of herbs, such as these, which was supposed to induce an abortion in the event the former method failed.

Well, our medical expert said, first of all, either a vitamin C pill or a lemon wedge is going to be painful and is not going to be very effective. The herbs they said could misfire, causing not an abortion, but birth defects in the child, which is carried full term.

So we are talking about something that could be potentially dangerous. We paid \$5 for this product.

This one, case No. 148, was advertised to heal prostrate problems. I was interested in this, again, because a lot of male senior citizens are troubled with enlarged prostates, which causes them to have to urinate frequently. In some cases, the problem results from cancer, and so you have to be very careful with the diagnosis of an enlarged prostate.

Well, what we received for our money from Wyoming, MN was the so-called "drugless relief." This is it—a piece of paper—that's what came back—with some typewritten advice.

According to this paper, what you do to cure your ailing prostate is to get a kitchen stool, and cut a hole in this stool, about 4-inches long and about half-an-inch wide. Then you mount a light bulb on the bottom of the stool. Then you sit on top of the stool with the light bulb underneath. Our medical experts were outraged.

HEMORRHOID CURE

The hemorrhoid cure turned out to be another piece of paper. This piece of paper is a crudely drawn foot with areas of the heel that you are supposed to massage. You rotate the bottom of your heel on the floor, and that makes you feel better and cures your hemorrhoids. This novel therapy would make big news if it worked,

but of course its ridiculous. This one is a youth cure. It is supposed to reverse the aging process and allegedly it cures epilepsy and hay fever. We thought for sure we had a major scientific discovery on our hands. It cost about \$40. This is what we received in the mail. It is called the Fountain of Youth, and it's nothing more than an old enema bag. It's a colonic, and what is recommended is daily or more than daily enemas.

Now, our medical experts said that daily enemas can be very dangerous. They can upset the salt balance in the body, and that can cause you to be weak, to have dizzy spells and faint; to literally bring about a deterioration of your health.

Then we sent away for this warts cure. What we got for our money here was a piece of paper, which pointed out that there are certain phases of the moon. In the first quarter of the moon, what you are supposed to do is go out in the moonlight and expose your wart, and then you shout incantations to the moon. What you say is, "What I see, take on; what I stroke, take off," and that is supposed to cure your wart.

Well, our medical experts say that most infectious warts disappear on their own anyway—warts that are caused by viruses—and so to some extent the public may be fooled into thinking that this is actually a cure, but it is a rip-off, pure and simple.

HERPES CONTROL

Do you know there is a cure for herpes, Mr. Chairman? Medical science was in the dark until we found an ad in a tabloid. The product and cure turned out to be advice on diet. They said you can control herpes by cutting out chocolate and peanuts. This advice is laughable except for the fact that people are being fleeced by the promoters of this scheme.

Next we responded to an ad offering us an impotence cure. The impotence cure turned out to be this stuff. It says, "Spanish Fly. Just spray it on. Defrost your sex life with Spanish fly." It's mostly water. You can spray all you want, but our medical experts doubt that it will cure impotence problems.

Another example I've brought is an ad which promised an instant facelift without surgery. We paid about \$10 for this which sound like a heck of a deal. What we received are these illustrations showing how to perform a series of facial exercises. You know, you are taught to move your mouth in certain directions and that's their idea of a facelift in the privacy of your own home, for only \$10.

Our medical expert, Dr. Jack Fisher of the Mayo Clinic said this is one of the biggest rip-offs that he has ever seen. The tape that comes with it makes a lot of claims about making you 20 years younger if you do this exercise 5 minutes a day. These claims are false.

Another fascinating one is this herb dial. This is a cure-all, and it basically gave you instructions on how to set up your mail-order quackery business.

There is a series of diseases and problems on the outside of the dial. They correspond to certain herbs that you can prescribe that

are allegedly curative. So you can hang out a shingle and become a doctor of nature if you feel like it.

So let's say that your client's problem is ulcers. All right. We set this here, and it says that the answer to ulcers is valerian root and capsicum. You advise your client accordingly and collect his money.

Well, unfortunately, some of these herbs can be very, very dangerous. There are a number of references in the report that indicate that herbs can potentiate the drugs that people take, and herbs can cause illness, herbs can cause death. So you have to be careful in prescribing them, yet that's what people are taught to do.

Now, I would like to end with one final product, and this one is called the Orgon Energy Accumulator and the Orgon Energy Blanket, and this is a particularly outrageous one because it was introduced in 1934, and the promoter was put in jail in 1956.

Nevertheless, in 1981, we were able to obtain this product through the mail. It cost us \$100. And I'm ending where I began, because this product is so good that it cures cancer, it cures arthritis, whatever happens to ail you, and I want to demonstrate that for you.

Again, of the 300 cases that we opened, we have been successful in putting a good number of people behind bars. This is one case that we were successful in stopping, with the help of the Postal Service.

If you will allow me, I want to demonstrate. I wouldn't ask anybody else to do this; it is too ridiculous.

[Witness puts plastic cone-shaped hat on his head and blanket around his shoulders.]

Mr. HALAMANDARIS. This is it.

In summary, Mr. Chairman, we have got a major problem on our hands. This is no laughing matter. This is no joke. We are talking about millions of dollars that are being ripped off by the unscrupulous people that are quite content to make profit out of the pain of others. I ask your help in stopping the problem.

Mr. Chairman, I'd like to now turn to the other members of the panel and let them address you.

Thank you.

[The prepared statement of Mr. Halamandaris follows:]

PREPARED STATEMENT OF VAL J. HALAMANDARIS, PRESIDENT, NATIONAL ASSOCIATION FOR HOME CARE; AND PAST DIRECTOR OF OVERSIGHT AND SPECIAL COUNSEL TO THE SELECT COMMITTEE ON AGING, U.S. HOUSE OF REPRESENTATIVES, WASHINGTON, DC

Mr. Chairman and Members of the Committee, it is a pleasure for me to be with you this morning to describe the steps undertaken in this 4 year investigation of medical quackery. I believe that this is one of the most important studies I have worked on in my more than 20 years' association with the Senate and the House Aging Committees.

I would like to thank you not only for inviting me here today but also for allowing me to work with you those 5 years in which I served as your Senior Counsel and Director of Oversight. It was a great honor to be able to work with you. Under your leadership, Mr. Chairman, this Committee has done untold amounts of good for the nation's 25 million senior Americans. I commend you for your efforts.

My task this morning is to describe the Committee's investigation and the findings outlined under our report. I will do that quickly, then I want to demonstrate a few of the products which we received through the mail for you. Next, I want you to

hear from citizens who were victimized by phony cures. Finally, I want to talk a little about solutions.

1. This investigation began with a questionnaire to State Attorneys General and Departments of Consumer Affairs. We were struggling with the fact that the elderly make up 11 percent of the population but more than 30 percent of the victims of crime. We knew about violent crimes through other hearings by this committee but what about non-violent crimes?

2. To our surprise, every state in the Union lists fraud as the major non-violent crime being perpetrated against the elderly. Beyond that, the states were unanimous that health care ripoffs were the most frequent and most troublesome kinds of fraud that they encountered. The states told us that about 75 percent of the complaints they received were valid but that complaints were merely the tip of the iceberg. For every one who complained, we were told there were 10 too embarrassed to do so. Paradoxically, little was being done about the problem. Both the Attorneys General and the Department of Consumer Affairs told the Committee that they did not have the manpower needed to properly defend the public.

3. Having learned that health care frauds are the single most important kind of fraud perpetrated against the elderly, we sought to examine why the elderly are so vulnerable. You know the answer. They are sick three times as often, three times as long and their medical bills are three times on average those of their younger counterparts. Those medical bills come at a time when they have on average less than half of the income of their middle aged counterparts. Seniors have very real health problems. They are afraid and sometimes desperate. They grew up in a more trusting, less cynical era. They are afraid of becoming ill and helpless and of "going on welfare." As one confidence man told us, "They make easy marks for the con man."

4. In an effort to develop more information, we did the following:

(a) We sent questionnaires to: Selected Police Chiefs of major U.S. cities, selected District Attorneys, all State legislatures and their health and aging committees, all State offices on aging, and all "Action Line" reporters with major U.S. newspapers.

(b) We sent questionnaires and reviewed all files going back 20 years in the possession of: the Federal Trade Commission, the Food and Drug Administration, the U.S. Postal Service, the National Cancer Institute, the National Institute on Aging, and the National Institute on Arthritis.

(c) We contacted and reviewed all relevant files in the possession of: the American Medical Association, the Arthritis Foundation, and the American Cancer Society.

(d) We asked the Library of Congress and the National Library of Medicine to give us a printout of all books and major newspaper articles dealing with unproven remedies going back 30 years.

(e) We contacted senior citizens directly and through their national organizations.

(f) Next, as you know, the Committee on Aging held six hearings on the subject of medical quackery.

(g) Finally, in cooperation with investigators detailed to the Committee by the U.S. Postal Service, the Federal Trade Commission and the Department of Health and Human Services, the Committee staff searched through literally thousands of advertisements in hundreds of magazines in search of questionable ads touted particularly to senior citizens.

We identified a list of some 60 of the most eminent scientists in the nation and got their approval to serve as unpaid consultants to the Committee. They agreed to help us evaluate the products we sent to them in light of the advertising, and the representations made about them.

5. The Congress of the United States has tremendous resources with which to find fact. We used the tools that were available to the Committee to collect a massive amount of data. This was a laborious search for facts both in order to inform the public but also to present to the Congress in order that it might legislate effectively. Four years is a long time to spend on a study but the topic merited this kind of a careful examination.

6. If you will forgive a personal reference, this study was very important to me because I am one of the 40 million Americans who suffer from arthritis. As a result of an injury, I know first hand what it means to be in so much pain that you cry continuously. I know what it means to be in so much pain that simple acts like combing your hair, and climbing stairs become acts of torture. I know what it means to go from doctor to doctor, clinic to clinic in a desperate search for relief. I know what it means to have your family spend all their income and all they can borrow to help you. I know what it means to be so drugged that you could fall off a building and never feel it. And I know how beguiling magazine and newspaper advertisements can be holding out illogical hope of miracles that never happen. I know how tragic it can be when you learn the ads are a fraud placed by heartless

people who seek to profit from the pain of others. I know how it feels to be deceived, in great pain and without hope. And that's why I wanted to do something about this problem.

7. This voluminous data which was collected was fashioned into this report. The central conclusion of this report is that medical quackery is a massive problem and growing at an alarming rate. In 1965, medical quackery was estimated at \$1 billion a year. Today it costs the nation more than \$10 billion.

This \$10 billion figure reflects quackery targeted primarily against the aged. We found phony cancer cures quite prevalent and place their cost at \$4 billion a year. Phony arthritis cures were next at \$2 billion a year. So-called "youth cures" ranked third and were the fastest growing and perhaps the most curative of the frauds. There were few "cures" promoted that related to heart disease. A tremendous number fell into the miscellaneous category such as prostate cures, gallstone cures, herpes cures and the like. This \$10 billion figure does not include any projection of the cost of quackery perpetrated on the younger members of society. One of the most lucrative areas of all is phony diet pills and weight reduction schemes. We did not find these rackets targeting the aged although billions of dollars are lost to such schemes every year.

8. This \$10 billion loss is particularly tragic when contrasted with the meager amounts spent for legitimate research. We spend some \$80 million on arthritis research, \$60 million to research Alzheimer's disease and problems of aging and \$1 billion a year in search for a cure to cancer. I was looking for some way to dramatize these facts for you. What I'd like you to see is that we spend about 25 cents per person in the United States on vital research related to problems of the aged; we spend only about 35 cents per person researching the cure for arthritis. We spend \$4.40 per person looking for the cure to cancer. This contrasts with \$44 per person that the nation spends on medical quackery.

9. The monetary loss is but one part of the problem. There are thousands of individuals that are injured through reliance on quack remedies and there are thousands of deaths. Such direct injuries and deaths are augmented by thousands of cases in which quackery was the indirect cause. In these cases, individuals decided to forego legitimate medical treatment choosing questionable or unproven remedies instead. You will hear some case histories in a moment.

10. The next point that I want to emphasize is that quackery has become a big business. When we think of the word, we tend to think of slightly comical figures, the pitchman with his covered wagon. Ironically, we all accept the fact that millions can be raised through direct mail for political candidates and somehow, we've never made the connection that millions are being ripped off by modern day con men with their computer mail operations. As noted in the report, court records indicate one promoter was making \$100,000 a day in his scheme. Another promoter made some \$13 million in nine months of operation.

11. I would like to emphasize that there is very little which stands in the way of the modern day quack. As you know the word is used in the report to describe those people who promote false or unproven remedies for a profit usually with the false representation that they will "cure" or aide in the cure of various diseases and problems. There is little in the way of state enforcement efforts. The efforts of the Federal Trade Commission have been singularly unimpressive. The Food and Drug Administration which has the prime authority in this area has been less than impressive. Even though the Committee has been bombarding them with inquiries and notice of this hearing for 4 years, they still spend less than .001 percent of their budget to fight quackery. Only the U.S. Postal Service has made anything like a reasonable effort to fight this kind of fraud but they do not have the authority they need nor do they have the staff.

The Postal Service has within it a unit called the Inspection Service. This agency responds to over 200,000 inquiries every year and up until recently had only 5 investigators assigned to investigate medical quackery. It is ironic that the Congress has not seen fit to give the Inspection Service even that rudimentary investigative tool, the power of civil subpoena. The Congress has given this authority to every other government agency. Every government agency now has an Inspector General whose responsibility is to fight fraud and every IG has been invested with broad subpoena power. The Chief Postal Inspector who was the model for the Inspectors General legislation still does not have the power to require promoters to produce books and records and thereby investigate and put more of these operations out of business.

The Postal Service does not have the computer system that it needs to track the millions of promoters who change addresses, advertising and products like a snake sheds its skin.

12. Given the size of the problem, I find it sad that the Justice Department can respond to this Committee that it is too busy and has better things to do than investigate medical quackery. I think it is unfortunate that the Internal Revenue Service has shown little interest since fraud always carries with it its identical twin of tax fraud. I think it is unfortunate that the IRS has not subjected some of the Foundations which we found to be little more than hollow shells and fronts and purveyors of fraudulent schemes to scrutiny.

13. I find it reprehensible that the States which have the primary responsibility for regulating clinics and medical practice in general have taken such a laissez-faire attitude towards clinics which specialize in false or unproven remedies.

14. Finally, something needs to be said about the tactics of some of the zealots who sought to block this investigation through fear, pressure, misinformation, scare tactics and threats of law suits. These people would have you believe the Committee and its staff have joined in a conspiracy with the AMA to uphold the principles of traditional medicine. This is simply untrue. This report is an objective effort to find fact. No one and no organization reviewed this report or its conclusions in advance. These zealots would have you believe that the Committee and the Postal Service are out to suppress ideas and books and the actions of individuals in the privacy of their own homes. In fact, the Committee is concerned not about what individuals do in the privacy of their own homes nor about what they say or write. Rather, the Committee is concerned by the action of promoters, the people I called "quacketeers" who promote false and unproven remedies for a profit. I abhor the tactics of these zealots who sought to block this investigation and to stifle this report.

In summary, we seem to have accepted in America today a version of the law of the jungle. We seem through our policies to have accepted the law of the survival of the fittest. We seem to be saying that it is the natural order of things to have predators in society, that is the people I call the "quacketeers." We seem to accept the notion that the natural quarry of these "quacketeers" is the aged, the sick and the helpless. Through our inaction in the face of this \$10 billion ripoff, we have given the clear signal to all concerned that it is open season on ripping off the vulnerable aged. Things are so bad that con men in prison are coached to enter the mail order quackery game, soon to be the electronic quackery scheme. It is the one racket available which guarantees you millions in revenues, to affect your gains while wearing the cloak of the healer with almost no chance that you can ever be caught and prosecuted. I reject this policy of inaction and indifference. I do not accept the law of the jungle as applicable to human affairs. I call upon you, the members of this Committee and the Congress to take speedy action to erase this blight on the American conscience.

Mr. PEPPER. I'm sorry. You see the clock back there. There is a vote on. We will have to run over and vote, and then we will be right back. I'm sorry that we will have to interrupt our hearing.

[Recess.]

Mr. PEPPER. The subcommittee will come to order, please.

Mr. HALAMANDARIS, had you completed your excellent statement?

Mr. HALAMANDARIS. Yes, sir.

Mr. PEPPER. I want to commend you on the excellence and comprehensiveness of your statement, also upon being the one who initiated when he was the staff director here—who, when he was the special counsel here, initiated this inquiry originally, and we are so glad that it can be carried on so ably by his distinguished brother, Bill.

Mr. HALAMANDARIS. Thank you, Mr. Chairman. I appreciate that.

Mr. PEPPER. We are very much indebted to you.

Our next witness will be Mr. Herb Sandvick of Fargo, ND, victim of a phony arthritis cure.

Mr. Sandvick, we will be pleased to hear from you.

Speak now right up close to the microphone, so everybody can hear you, please.

STATEMENT OF HERB SANDVICK

Mr. SANDVICK. Members of the subcommittee, ladies and gentlemen, my name is Herb Sandvick, and I am currently vice president of Congress, Inc., a distributorship in Fargo, ND, where I have been employed for the past 38 years.

For the last 30 years, I have been suffering from a disease, ankylosis spondylitis—spinal arthritis. This disease usually affects men between the ages of 16 and 35. Most forms of arthritis inflame only the inside of the joints, but spondylitis also involves a special type of inflammation outside the joints. This inflammation causes a bony outgrowth on the spine which can fuse it solid. You might notice my neck. The inflammation may also affect the shoulders, knees, and ankles. If the neck and the hip become fused in a flexed position, the ability to do even routine activities will be limited.

At times, the pain throughout my body was so unbearable that even the slightest pressure on my back and legs was agonizing. My spine began to fuse. I didn't know it then, but eventually both knees and one hip would have to be replaced surgically with artificial joints so that I could continue to walk.

For years after the diagnosis, the only drug I used was aspirin. Then my arthritis went into remission—a very typical pattern with this disease—but when it returned, the pain was agonizing. The disease grew worse, and conventional treatments brought no relief.

One night, my wife and I were watching television and heard a woman talking about this clinic that supposedly cured arthritis. At first, we were skeptical and hesitant about going, but my pain was so bad that I thought it would be worth any risk. In desperation, I decided to visit the clinic in Mexico.

All the information I had available about the Mexican arthritis clinics indicated how great their treatments were. The news media were reporting the success stories. They didn't report the dangers. Instead, I learned about those firsthand. When I arrived at the Mexican clinic, I received no physical examination. In fact, I never saw a doctor for the entire 2½ years that I went to this clinic. Employees at the clinic dialed a telephone number, and I talked to a Dr. Montez. He only asked me what was wrong with me and if I was taking drugs. After a brief conversation, he prescribed shots and pills, which I later learned contained powerful steroids.

Initially, the drugs made me feel better, so I continued to make the trips to the clinic every 6 months for about 2½ years. The shots at the clinic cost about \$85, and then I was given a supply of medication to take home, which cost about \$250 for a 6-month supply. Also, I might add, the airfare out and the airfare back, North Dakota to Mexico, was rather high. Eventually, the medication took its toll. My body began swelling out of proportion—I think they call it "moon face"—causing my face to puff up and my neck.

One morning I could not drive myself to work, as my health was deteriorating rapidly. I was in so much pain by the time my wife drove me to work that she insisted I get back into the car and see a rheumatologist immediately. The rheumatologist admitted me to the hospital. To relieve the shock of withdrawal, he put me back on steroid drugs at a relatively high rate. Then he gradually began to decrease the dosage. Today my arthritis is carefully monitored by

this same rheumatologist, and with proper medication and a prescribed program of exercise, I keep active and live as normally as possible.

I have since become very active with my local Arthritis Foundation chapter, as its past president and currently as the chapter's government affairs chairman. My special focus throughout all of these activities has been unproven remedies and quack cures. I almost lost my life to a quack cure. Hopefully, I can save the lives of others by sharing my experience.

Thank you.

Mr. PEPPER. Well, thank you very much for that excellent statement.

I'd like to wait until we have heard all the witnesses before we start examining, but just tell us, What kind of a clinic did they have down there? How affluent did it seem to be?

Mr. SANDVICK. It was what we might call a hole in the wall. It was a very small room. Chairs lined both sides. I wouldn't say it was clean. And they had a girl sitting at a desk—slacks on, shirt, and so forth—who took my name and things and put me through the telephone conversation with the so-called Dr. Montez.

Then after I sat back, they took me into another room, and another girl gave me the shots and a couple of pills and sent me to a druggist.

Mr. PEPPER. Well, thank you very much. We will come back to you, Mr. Sandvick.

Mr. SANDVICK. You are welcome.

Mr. PEPPER. The next witness is Dr. Harvey Wachsman of New York. He will be accompanied by Ms. Edith Schneider of Fairlawn, NJ, victim of a phony cancer cure.

Dr. Wachsman.

STATEMENT OF HARVEY WACHSMAN, M.D., J.D.

Dr. WACHSMAN. Mr. Chairman and members of the subcommittee, I'm Harvey Wachsman. I'm a neurosurgeon and a trial attorney, and I'm here with Edith Schneider, who is seated to my left.

Quackery is synonymous with injury and death inflicted by someone who should know better, and suffered by someone who has no real ability to defend themselves. The definition of medical malpractice is the same, except that quackery is intentional while medical malpractice is not.

The fact that a physician is both licensed and a member of the medical society offers no real protection for the patient either against quackery or against malpractice.

A case in point is Emanuel Revici. Dr. Revici is a 1920 graduate of the University of Bucharest and for more than 20 years has been victimizing desperate individuals with his so-called alternative cancer therapy.

On October 18, 1965—almost 20 years ago—in the Journal of the American Medical Association, an article entitled "The Treatment of Cancer by the Method of Revici" made the following finding.

Incidentally, that article was published or authored by members of the faculty of Columbia University, New York University, and Montefiore, which is the Einstein Medical School, as well as a com-

munity hospital, the article contained the following quote: "Based upon the above-mentioned cases, the clinical appraisal group is forced to conclude that the Revici method of treatment of cancer is without value."

Clearly, that was almost 20 years ago, and yet this individual has kept his medical license and has continued to treat patients with a method that can be considered, in its best light, without value and, in truth, fraudulent.

The cases of Edith Schneider, Mrs. Cecelia Zyjewski, and Anna Recce are indicative of this point.

Mrs. Schneider, who is seated next to me, had a small tumor the size of a marble in her left breast and was told by several physicians, after mammography and appropriate treatment, including surgeons, that she needed to have this mass removed, that it was probably a cancer.

Unfortunately, she listened to the radio and listened to Gary Null's program, an individual who proffers these kinds of individuals such as Dr. Revici. Dr. Revici was on the program.

She listened to this individual, went to see him, and followed his advice for a period of approximately 13 months, during which time Mrs. Schneider went back on multiple occasions to Dr. Revici's office, at which time she was given selenium or other drugs such as that, which were to be sprinkled on her food, taken in capsules, and injected.

On each of these visits, she was charged from \$50 to \$75, which would occur almost on a weekly basis, biweekly basis, but certainly frequently. Of course they had no efficacy and never did.

Approximately 13 months later, at a family gathering, fortunately there was a physician, who is a member of the family, who examined her and found that this tumor the size of a marble had spread to the opposite breast and was now the size of a baseball.

During all these visits to Dr. Revici, the only thing they examined was, they'd feel her breast, tell her it's protecting her—this medicine—Dr. Revici would, and in fact all he tested was her urine to see the color of it. What that actually was was a colorimetric test of pH to determine the color, and by virtue of the color of the urine, he would tell her how much selenium to put on her food.

This situation was finally remedied to some degree when, in fact, a member of her family who was a physician saw her. Mrs. Schneider was then admitted to the Memorial Sloan-Kettering Hospital in New York City, where both breasts were removed within a matter of days, and she then underwent x-ray therapy as well as chemotherapy, which caused her at one point to lose her hair.

This tumor had spread to regional nodes, axillary nodes, and of course her chance for survival was markedly diminished.

Mrs. Zyjewski is another case—exactly the same story, except somebody else was on the radio up in Connecticut—New Britain, CT. She had a tumor the size of—and the point is, with respect to Mrs. Schneider, that this was treatable at the time, that there was probably a 50- to 75-percent chance of cure at least, and that's a conservative figure.

Mrs. Zyjewski had a tumor in her rectum, which was again the size of a marble, which again carried a 50- to 75-percent cure rate.

Unfortunately, she saw four physicians, all of whom said that it needed to be removed.

She then went to Dr. Revici. Dr. Revici, over the next 13 or 14 months, treats her, again with the same kind of treatment—with this selenium—sprinkling it on her food, while this tumor eroded through her rectal-vaginal wall, causing feces to come out of her vagina, with spread of this tumor to her back, throughout her body, to her liver, and finally caused her death in November of 1983.

Anna Recce is the same sort of situation as Mrs. Schneider.

This fraudulent and deceptive practice on the part of Dr. Revici perpetuated on these three victims, and presumably many others, has not only achieved improper fees, and, more tragically, has deflected them from standard and predictably successful medical therapy. Their lives literally were sacrificed by virtue of these frauds.

There is a network of these quacks throughout the country. There is an organization called Mankind Research Foundation located right here in the Washington, DC, metropolitan area, in Silver Spring, MD, and run by a Dr. Carl Schleicher.

This individual tells fearful, desperate, and panic-stricken victims of cancer that there is an alternative treatment of cancer and that for a \$1,500 donation to Dr. Schleicher's foundation, he will give them the name of a physician, a licensed physician, who will treat the patient with the alternative mode of therapy.

The name that Dr. Schleicher gives out after the donation of \$1,500 is paid is none other than Emanuel Revici.

Through all these years, Emanuel Revici has been allowed to keep his medical license, has never been brought up on charges before this year, when our three lawsuits were filed against him, and the New York State Medical Society has not deprived him of his membership for his actions but, in fact, has honored him by bestowing an honorary lifetime membership upon him.

Thus, it is clear that the physician members of the medical society do not police themselves. It is obvious that policing oneself is no policing at all.

There is no dispute that Revici has acted far outside the mainstream of established medical standards. He has preyed upon desperate, innocent victims.

Why then the reluctance to take action against him? Why has he been allowed to practice all these many years with total impunity from anyone? Why has he been permitted to dupe, defraud, and deprive unknowing people of life itself?

Because the State has done nothing, the medical society has done nothing, and until a medical malpractice trial lawyer took a stand, no attempt was made to inhibit Revici from practicing his fraudulent methods.

The fact is that because my office brought three lawsuits against Emanuel Revici, together with the ensuing publicity, the New York State Department of Health, Office of Professional Medical Conduct, finally began hearings to remove his license in January of this very year, 1984, which are continuing to the present date and are still not completed, and here it's almost June.

Dr. Revici continues to practice in the face of overt quackery. In truth, at present and across this country, the only real protection the public has against quackery by physicians and medical malpractice is the medical malpractice trial lawyer. The only real deterrent to the individual who preys upon the elderly, the poor, the sick, and others who cannot defend themselves is the medical malpractice trial lawyer.

Criminal sanctions, though well deserved, would in many cases be difficult to prove and, in reality, probably not stop significant numbers of these purveyors of fraud.

The life of an elderly person, if taken away through quackery or malpractice, in most, if not nearly all the States in this Union, has unfortunately little or no economic value. This is due to the wrongful death statutes which specifically limit recovery to pecuniary loss to the next of kin and pain and suffering. Many elderly people are either retired or have a short work-life expectancy, and thus pecuniary loss is either limited or nonexistent.

I would therefore strongly suggest to this committee that legislation be enacted that allows for an element of damages known as loss of love and affection. This element is present in Chairman Pepper's home State of Florida because of the elderly population there. This is a protective device. It is present in one or two other States in this Nation, but it is not present across the rest of this country.

This loss of love and affection as an element of damages for the wrongful death of an elderly person and, further, allow for punitive damages in the event of quackery such as this—this method of compensation and punishment would more likely deter those who have little concern for the life of the elderly and who seek to enrich themselves at the expense of these presently unprotected citizens.

Thank you.

[The prepared statement of Dr. Wachsman follows:]

PREPARED STATEMENT OF HARVEY F. WACHSMAN, M.D., J.D., GREAT NECK, NY

It is a truism that our life and health are our most precious assets. The health care provider (doctor-hospital, etc.) has the responsibility to employ reasonable diligence and current acceptable standards of care for the purpose of protecting our health. The issue that I address is one of "quality medical care". The elderly are especially vulnerable to poor quality care.

How then does one assure quality medical care? It is also self-evident that in order for the health care provider to be appropriately responsive to the needs of the patient that there must be in place a system of adequate "policing" and one of reasonable "accountability". Policing oneself is no policing at all. Accountability must be within some meaningful context.

The subject of policing and accountability have traditionally been left to State licensing agencies in conjunction with the activities of the various State and Local Medical Societies. I do not advocate changing this system. Rather, I point out that there has coexisted a necessary concurrent policing and accountability mechanism—the medical malpractice attorney. It is and has been the medical malpractice attorney who has been the most effective advocate for the individual victim of poor quality medical care. By being an effective advocate for the individual victim, the medical malpractice attorney has the effect of acting as a deterrent factor on behalf of all potential victims.

Recently, I have become involved in a case that I believe is symptomatic of the point that I am making. It involves a physician who, in my view, has been preying on the fears, desperation, and panic of cancer victims. The specific physician that I refer to is Dr. Revici who prescribes a regimen of nutrients to cure cancer. There has never been a single iota of scientific or medical substantiation for this form of

quackery. This fraudulent and deceptive practice perpetrated on the patient, not only unethically achieves improper medical fees, but far more tragically, has deflected a number of patients from standard and predictably successful medical therapy. The cases of Mrs. Edith Schneider, Ms. Cecelia Zyjewski, and Mrs. Anna Recce are indicative of this point.

Edith Schneider, a resident of Fairlawn, New Jersey, was under the care and treatment of Emanuel Revici of New York City, from November 1981 until approximately January 1983. During that time, Dr Revici was treating Mrs. Schneider for a malignant tumor in her breast.

Prior to coming under the care of Dr. Emanuel Revici, Mrs. Schneider had consulted with three physicians who advised her that a mastectomy was recommended for a small, marble-sized lump in her left breast. Fearful of surgery, however, Mrs. Schneider sought the counsel of Dr. Emanuel Revici, a licensed medical doctor, who was highly recommended on a radio broadcast heard by Mrs. Schneider. Dr. Revici's method of treating cancer was heralded as an alternative to conventional cancer therapy. At the onset of her treatment with Dr. Revici, Mrs. Schneider was informed by Dr. Revici that the lump in her breast was indeed malignant and that surgery would only spread the cancer. This finding by Dr. Revici was based solely upon physical examination of Mrs. Schneider's breast. He did not do any biopsy, or aspiration, or mammogram. Throughout her association with Dr. Revici, Mrs. Schneider was treated with various selenium based compounds which she would alternately form into capsules inject into herself and spread on her food. During her course of treatment with Dr. Revici from November 1981 until January 1983, Mrs. Schneider maintains that Dr. Revici did not perform any complete physical examinations on her, except to periodically monitor the color of her urine which would thereby assist Dr. Revici in determining whether to increase or decrease the amount of the selenium based compounds which he had given to her. Dr. Revici reassured Mrs. Schneider that his treatment "would burn the cancer out of her body". Throughout her course of therapy with Dr. Revici, the lump in Mrs. Schneider's left breast grew to the size of a baseball. In view of the fact that the lump increased in size rather than diminish, by happenstance, Mrs. Schneider mentioned the large lump to her physician-cousin at a New Year's Eve party. She was immediately advised to seek surgery.

On January 9, 1983, Mrs. Schneider underwent a radical mastectomy of the right breast, and, thereafter, on January 13, 1983, her left breast was removed after a biopsy revealed intraductal cancer in the left breast. Mrs. Schneider did not return to Dr. Revici's office for any care and treatment.

Edith Schneider's cancer is described as being at Stage III with four of the seven nodes being positive. She underwent 16 radiation treatments with a physician in Manhattan and is currently undergoing chemotherapy with another physician in Manhattan. Her prognosis is quite grim. Edith Schneider is married and has two daughters, ages 19 and 14.

Cecelia Zyjewski, born on August 17, 1917, was a resident of New Britain, Connecticut. In or about December 1981, she was diagnosed as having cancer of the colon. At that time, the cancer was in the polyp stage and was extremely operable. This diagnosis was done by a Dr. Greenberg in Connecticut.

Extremely frightened about the prospect of undergoing surgery, Ms. Zyjewski contacted Dr. Revici after hearing about him on a Connecticut radio talk show. In approximately February 1982, Ms. Zyjewski did consult Dr. Revici who took care of her in the same manner that he cared for and treated Edith Schneider and Anna Recce, i.e., giving her selenium based fluid which she would put onto her foods, make into capsules and inject into herself. Like the other two herein mentioned patients, Dr. Revici failed to perform any physical examinations of his patient other than to monitor her urine for purposes of ascertaining the color (i.e., red, brown, green) in order to determine whether or not to increase or decrease the selenium prescribed by him for her.

On December 25, 1982, Ms. Zyjewski began convulsing and was taken to New Briton General Hospital by a member of her family. Upon arrival in the Emergency Room, Ms. Zyjewski was informed that she did have a rock hard tumor in her back which was inoperable. Indeed, the tumor has broken down the wall of the rectum and she was spilling feces into her vagina. Upon hearing that his patient was in New Briton Hospital, Dr. Revici contacted Ms. Zyjewski and urged her to get out of the hospital because they would butcher her. Additionally, Dr. Revici told her not to take any of the pain medication given to her. Relying on Dr. Revici's advice, Ms. Zyjewski discharged herself and went to see Dr. Revici who presumably prescribed antibiotics for her.

Approximately three months later, in March of 1983, Ms. Zyjewski was admitted to Astoria General Hospital, where she underwent a colostomy. After the colostomy, Ms. Zyjewski's condition rapidly deteriorated to the point where the tumor was about the size of a football pressing on her spine and lower internal organs. Ms. Zyjewski died on November 16, 1983, after approximately one year of severe pain and discomfort.

In May 1980, Anna Recce, a resident of Brooklyn, New York, felt a lump in her left breast. She then went to the Strang Clinic on 34th Street in Manhattan, at which time, a test was performed on her which indicated that she did indeed have cancer and that surgery was highly recommended. Like Mrs. Schneider, she was fearful of the removal of her breast, and, consequently, sought the care and treatment of Dr. Revici. She had heard about Dr. Revici from the WBLI radio broadcast of Gary Null, a nutritionist and research assistant at the Institute of Applied Biology, Inc., which is the organization identified with Dr. Revici. At her October 1980 visit to Dr. Revici, Mrs. Recce was informed by Dr. Revici that he could indeed treat her, and, in fact, could cure her and that he would protect her. Indeed, Dr. Revici referred Mrs. Recce to a physician who thereby admitted her to the Boulevard Hospital where a biopsy was performed as well as two cobalt treatments. Thereafter, Mrs. Recce was under the care and treatment of Dr. Revici continuously until May 1983. His "care and treatment" of Mrs. Recce consisted of physically examining her breast, looking for changes of color in her urine, and prescribed selenium based compounds for injections and for ingestion on her food, similar to the treatment which he gave to Edith Schneider.

In April of 1983, Mrs. Recce complained to Dr. Revici of severe, excruciating pain in the back of her neck. She was informed by Dr. Revici that the cancer was "burning its way out" and that she was indeed getting better. Nonetheless, around Memorial Day 1983, Mrs. Recce became violently ill, doubled over in pain, and was rushed via ambulance to New York Hospital where she remained for three weeks.

Since that time, Mrs. Recce has been undergoing chemotherapy and her cancer has, unfortunately, metastasized. She has been informed that she will have to undergo chemotherapy for the rest of her life. Her life expectancy has been dramatically diminished.

Breast cancer is the most prevalent form of malignancy among women. Indeed, early diagnosis and surgical treatment produce a cure rate as high as 90%. Dr. Revici urged Mrs. Schneider and Mrs. Recce against surgery; instead, he prescribed nutrients. The result was a massive growth in the tumor as well as spread, thereby making their prognoses tragically grim. Aside from the obvious personal tragedy, one should be aware of the enormous expense that has been incurred in a relentless effort to treat this now metastatic disease.

Of great interest is the fact that Dr. Revici's methods and modus operandi are not recent discoveries. He has been perpetrating these deceptions upon patients since the mid-1950's. He is a member of the New York State Medical Society. He has become a charter member of the New York Academy of Medicine. He has been and is currently under investigation by the New York State Department of Health and Office of Professional Medical Conduct. Neither the State Department of Health nor the state and local medical societies ever took any action against him—in spite of actual knowledge of his activities—until the medical malpractice attorney got into the act.

Dr. Revici's quackery is further illustrated by his bogus drug "Bionair" (bio=living; air=air). Bionair was ostensibly employed as a drug treatment for addicts. This therapy was given at the now-defunct Trafalgar Hospital in New York City. Needless to say, this was a useless treatment. Indeed, Trafalgar Hospital was closed when it was discovered that fraudulent Medicaid claims were being made by users of "Bionair".

It was only after legal action was taken on behalf of Mrs. Schneider and two other similar victims that New York State initiated hearings against Dr. Revici in order to determine whether or not his license should be revoked. In fact, these hearings which commenced in January, 1984 are still on-going—with no determination having yet been reached.

Dr. Revici's unorthodox methods were condemned as early as 1965 in a study printed in the *Journal of the American Medical Association* which concluded that "the Revici method of treatment of cancer is without value."¹

¹ JAMA, Oct. 18, 1965, vol. 194, No. 3, p. 166.

One must be reminded that the action now being undertaken against the Dr. Revici by the "authorities" is predicated, in reality, on rather simple and clear cut medical issues. Dr. Revici is prescribing a mode of therapy for which he is the originator and the only advocate. There is no scientific basis to support his theories other than his own studies. There are no disinterested advocates of his therapy; he is praised merely by his own students and patients over whom he has a Svengali-like influence. He is acting far outside the mainstream of established medical standards. He is preying upon desperate, innocent victims. Why then the reluctance to take action against him? Why has he been allowed to practice all these many years with total impunity from anyone? Why has he been permitted to dupe, defraud and deprive unknowing people of life itself?

The important point to be made, is that the "quality of medical care" is a subject which is not always as clear cut and definable as the Revici debacle. There necessarily must exist standards of medical care. Departures from these standards of medical care may produce tragic results to a patient every bit as great as those which affected Mrs. Schneider. Yet, these standards and departures, though equally tragic, may nevertheless be more subtle and less clear cut than the Revici matter. If the State and Medical Societies had heretofore taken no action in something as patently negligent as the Revici matter, what then may we expect on matters that are more subtle and less clear cut?

If a doctor is convicted of a crime; is a blatant established alcoholic or drug abuser; or sexually abuses his/her patient, then one may count on the Medical Society to take action. However, one may be equally assured that the Medical Society will take no action against a doctor who may be repeatedly negligent in the care of his patient.

We have successfully prosecuted three cases against a certain doctor who, in each instance, misdiagnosed a breast cancer, believing that it was a cyst. Sadly, in two of these three cases, the injured party, the victim, died. In not one of these instances did this physician refer the patient to a specialist or recommend a biopsy. Now this is a physician who is ostensibly working within the mainstream of medical practice. This is a physician who in each instance claimed that in his best medical "judgment" the condition appeared to be a cyst and required no biopsy. This is a physician who was unquestionably wrong in each instance and more importantly, in each instance, failed to advise the patient that the safer alternative was biopsy. Each of these patients suffered from metastatic spread of the cancer and two have died after enduring excruciating pain. Their cases are no less tragic than that of the aforementioned Revici victims.

We successfully obtained a monetary award from this physician on all three cases. This was the only recourse available. Who would the advocate of these patients have been had there not been the malpractice attorney? The New York State Department of Health did investigate one of these cases and did not even order a hearing with respect to this physician.

It is the plaintiff's medical malpractice attorney who has the experience, expertise and incentive to act as the vigorous advocate if not the only advocate on behalf of the health care victim. State licensing organizations invariably lack this kind of incentive, experience and motivation. Physicians do not like to police one another. It is a fact of life that must be recognized.

There is a natural tendency to "let sleeping dogs lie". Stirring things up is not generally the way of the medical profession. One of the most glaring examples of this type of phenomena concerns the cerebral palsy victim. Specifically, cerebral palsy that occurs due to events around the time of birth is never diagnosed at that time. Signs and symptoms develop much later, and invariably are attributed to "natural causes". The financial, physical and emotional burden of the cerebral palsy victim impacts not only on the individuals and their families but on society as a whole. Yet much of organized medicine, as well as such prestigious organizations as United Cerebral Palsy have, indeed, been content to "let sleeping dogs lie". It is the medical malpractice attorney who has uncovered many instances of medical and hospital neglect that directly caused these tragic permanent disabilities. Instead of the parents and family, as well as society at large, shouldering the burden of these tragic victims, the successful malpractice case has caused the negligent health care provider's insurance company to shoulder the financial burden. In addition, adequate compensation has been furnished in many instances. It is obvious that these cerebral palsy victims have become an increasingly greater burden on society as they age. Simple justice demands that applicable blame be fixed, and restitution be made.

A Rand Corporation study published in the prestigious New England Journal of Medicine (Doctors, Damages and Deterents: An Economic View of Medical Malpractice, Vol. 298, No. 23, pages 1282-1289, June 8, 1978) states as follows:

"Damages awarded in a malpractice suit must be viewed not only as compensating the victim but also as deterring health care providers from negligent behavior. Economic analysis of the malpractice system indicates that awards can send a signal to providers that informs them how much to invest in avoiding mishaps * * * [f]indings of negligence are seen not only as redressing past wrongs but also as giving providers an incentive to avoid future careless injuries. Viewed in this way, the malpractice system and its problems dramatically change character. The negligence system makes a great deal more sense if it is understood primarily as a means to deter careless behavior rather than to compensate its victims. By finding fault and assessing damages against a negligent provider, the system sends all providers a signal that discourages future carelessness and reduces future damages. Thus, litigation beyond providing a means to redress the loss and suffering caused by carelessness, signals potentially negligent people that it will cost them more to be careless than to invest in an appropriate level of prevention. Damages awarded to a victim induce potentially negligent people to compare the cost of avoiding an injury with the cost of paying for it.

"With an effective malpractice signal, the potentially negligent physician would be stimulated to invest more time for no increase in pay because he probably could not set his fees higher than those of his more competent colleagues.

"In practice, the negligent physician may modify his behavior in one of several ways. The doctor who tends to skimp on history or physical examination or to rush through procedures must take the time needed for more careful work. But increasing his investment of time on each case may be insufficient. An inadequately trained physician is notified by the damages awarded that he should invest in further training. The cost of training must then be amortized over future cases. Alternatively, a physician may abandon procedures that he is not competent to perform, even though these procedures are relatively more remunerative than others in his practice.

"The ideal negligence system is achieved only when every noteworthy incidence of malpractice leads to a claim, and every valid claim to a full award."

This Rand study bespeaks the significance of the medical malpractice attorney in our society. Those victims of malpractice who have the knowledge or wherewithal to question the actions of their physicians are able, in many instances, to obtain monetary restitution for those acts of negligence perpetrated upon them. Monetary restitution, however, will not breathe life into a person who died as a result of her physician's failure to timely diagnose and treat her cancer nor will it reattach the limb of a victim whose physician failed to detect and treat an infection in his limb nor will it raise the I.Q. level of a brain-damaged infant who was deprived of oxygen for a few minutes during her birth. Yet, these very physicians are able to continue in their medical practice with no stigma whatsoever. They are simply, perhaps, inconvenienced for a few short days during the trial and, thereafter, they can resume their normal lives. They need not wear any scarlet letter on their chest. They are not chastised by their medical societies or licensing boards. Should we allow this to continue? In our litigious society, is there no other way to seek redress to sue? Without the malpractice attorney, there is no other real protection, for the public, from those who engage in quackery and shoddy medical practices.

I thank the Committee for allowing me this opportunity to address them.

Mr. PEPPER. Thank you very much for your very courageous and very able statement, Dr. Wachsmann. We appreciate it.

Our next witness will be Mrs. Paulette Peters from Midlothian, IL, accompanied by her son, Chuckie Peters, victim of a phony cancer cure.

Mrs. Peters—you, or you and your son—we would be pleased to hear from you.

STATEMENT OF PAULETTE PETERS

Mrs. PETERS. Thank you.

In March of 1978, our son, Chuckie, 7 years old, was first diagnosed as having leukemia by doctors at Wyler's Children's Hospital in Chicago.

Following the diagnosis, my husband and I were presented with an explanation of the treatment to be used to produce and maintain a remission in our child. We agreed to the treatment plan.

The following weeks proved to be a very traumatic time for our son. He had spinal taps, bone marrow aspirations, bone marrow biopsies—all very painful. He also was introduced to large amounts of chemotherapy drugs and radiation treatments.

After some prodding from friends, we went to a nutritional consultant, hoping to find a way to build up our son's body from the devastating effects of the treatments and the drugs. We started Chuckie on a nutritional program which included vitamins, herbs, fresh fruits and vegetables, among other things.

The nutritional consultant also suggested that we contact a retired doctor in Texas, Dr. Robert Baldwin, who administered a special German preparation of vitamin A that was seemingly valuable in enhancing the immune system of cancer patients.

The nutritional consultant called Dr. Baldwin, and we were soon convinced to start Chuckie on this therapy around September of 1978.

At the same time, we were told about a Dr. Harold Manners who treated cancer victims with a metabolic therapy, including the use of vitamin A and laetrile.

In November, I attended a health convention at which Dr. Manners was one of the speakers. Following his talk, I was thoroughly convinced that this was the way to go, and I ran up and explained Chuckie's situation. He said I should get Chuckie into the American International Hospital in Zion and that Dr. Davis would be the doctor to talk to.

A few days later, I called Dr. Davis and scheduled an appointment for Chuckie on December 6. That day, while waiting to see Dr. Davis, we talked to patients who were terminally ill, from all parts of the country. They told us about the debts they had incurred coming to this hospital. It was a last resort. Later we spoke with Dr. Davis, who agreed that Chuckie should continue taking vitamin A and going to Wyler's Children's Hospital until they set up their own program for him. We agreed that American International would be best for Chuckie in his office, as he confirmed our hope that Chuckie would eventually be taken off chemotherapy without any injurious side effects. Dr. Davis told us he hoped that he had caught Chuckie in time before any irreversible damage from the chemotherapy drugs had taken place. He also advised us that we should order laetrile right away and begin treating our son with it. We were told to order 30 vials and given a list of distributors.

The first thing we did when we got home was to call these different distributors of laetrile. Our first encounter was with a very shady sounding character who sold laetrile as a side line. He told my husband to meet him at a warehouse at a location my husband felt totally unsafe going to. The man then replied it would be best to meet during the day. The transaction was to be strictly a cash basis sale. Well, we crossed that distributor out. The next person we talked to was a woman whose husband had died from cancer, but she still had about 20 vials of laetrile that she would sell to us cheap. She promised they were all still good. Needless to say, we crossed that one out, too.

Finally, we located a more professional sounding business, Cytox Corp., in Dallas, TX. We ordered the 30 vials of laetrile at \$9 per vial, and this was just the beginning. It was to be shipped to us c.o.d. within that week.

At the end of the week, Chuckie developed an infection in his finger which led to blood poisoning. We immediately took him to Wyler's Hospital, where he was admitted. I requested a meatless diet and revealed to the dietician that Chuckie was receiving megadoses of vitamins. The dietician related this to Dr. Wilson, a hematology doctor, and he talked to me at length about the possible side effects of giving megadoses of vitamins to Chuckie, especially the vitamin A. Dr. Wilson was very, very convincing in his argument that we should not put Chuckie on Dr. Manners' metabolic therapy. So we decided against changing hospitals and using laetrile, but we did stay with the vitamins and diet. We figured they couldn't possibly do any harm, even though it was against our doctor's wishes.

After leaving the hospital, I called Dr. Manners and explained what I was doing with Chuckie. I told him of our doctor's urging to take him off the megadoses of vitamins, to which Dr. Manners' reply was, I should stay with it. I also asked Dr. Manners if he would completely back me in what I was doing, and would he also talk to my son's doctors if they so requested. He said he most definitely would. That week, two of the doctors tried to contact him, but he was unavailable.

In October 1979, a year after having started Chuckie on the vitamin A therapy, he started having waves of nausea and much itching of the skin. On October 23, 1979, I got a call from his school to come and get him. He was very nauseated, along with having a severe headache. He started vomiting repeatedly at home and was unable to hold anything in his stomach. The day after, the headaches continued, as well as the wrist and the skin pain. The pain progressed in the days to come to such a point that he could hardly walk. Sensitivity to light increased to where the room had to be darkened. He then started showing signs of muscle spasms in his right arm. It would jerk downward as he tried to feed himself. Each day brought more and more pain. He couldn't walk at all, and the touching of his arms and legs brought screams of pain.

At this time, I wrote to Dr. Baldwin—I couldn't reach Dr. Manners—asking again for reassurance about the vitamin A and also the vitamin C we had him on and informing him as to what was happening to Chuckie. He did assure me the problems Chuckie was experiencing had never been noted by him, nor did he ever read of them in relation to the vitamins.

After a thorough examination and blood tests were done on Chuckie at Wyler's Hospital, excessive levels of calcium were found in Chuckie's blood, a resulting factor of vitamin A toxicity. He was immediately admitted to the hospital and an IV started to help flush out the calcium from his system. Leukemia relapse was immediately ruled out by a spinal tap procedure. A brain scan and a body scan were scheduled. The brain scan showed swelling in the cranial areas, and the body scan revealed extra bone growth, causing much bone inflammation, the reason for the extreme amount of pain he was experiencing. One doctor made the comment after

looking at the x rays how Chuckie's bones looked like lit up Christmas tree lights. The only relief he had from the pain was through various pain medications. First, doctors tried Tylenol with codeine, then demerol. After a while, these had no effect on the pain. They administered methadone in combination with other pain killers; they eventually had no effect. The doctors were beside themselves, not knowing what more they could do to help relieve this horrible pain. Then, by the grace of God, Chuckie started showing signs of improvement, less pain, and his appetite started picking up.

Two days later, he was released from the hospital, but he was unable to go back to school for 2½ months. Almost half of this time, we carted him around in a wheelchair. His thinking capabilities and concentration were minimal for a time. His weight loss was almost 10 pounds. Our son was a shell of what he was a few months before. The 3 years on the chemotherapy program never yielded the amount of pain that he experienced during that 3½ months of pain from vitamin A toxicity. We don't know what the benefits of this vitamin A therapy were. We saw much of the negative effects, which almost cost our son his sight, which almost cost him normal brain functions, which almost cost him his life.

We have run through the gamut of quacks in attempting to help our son. Not only laetrile, not only vitamin A, but coffee enemas were also recommended to use as treatment for leukemia.

As incredible as all this sounds, parents with young, helpless children, elderly persons, and the like, become desperate for treatment alternatives and find themselves at wits' end. It is these desperate people—the young in my case, as well as the old—on whom these peddlers of quackery prey.

The vulnerable should be protected, and these magical cure artists should be stopped. People, including my son, were injured by their reckless activities, and that just should not occur.

I hope our tragic experience with an unorthodox and unproven cancer treatment will serve to alert others to the dangers associated with such experimentation. We are the lucky ones. Chuckie is alive. Others have not been as lucky.

But when I told Chuckie we were coming to Washington, DC, to tell our story, his eyes lit up, and his comment was, "Mom, perhaps it is like you said. Good can come from evil." And I hope our being here will facilitate that statement that good certainly can come from evil.

Thank you.

Mr. PEPPER. Is that Chuckie on your right?

Mrs. PETERS. Yes; it is.

Mr. PEPPER. Can you hear us, Chuckie? Can you hear me?

Mr. PETERS. Hm-mm.

Mr. PEPPER. Well, you are a fine young man, and we hope the Lord and all good forces will restore you to health, so you can enjoy life as you should be able to do, as a fine young man. We hope the Lord will bless you, and we are glad you came here today.

Mrs. PETERS. I might add, Chuckie has been off all drugs for 2 years, and he is considered cured.

Mr. PEPPER. I see. Well, thank you very much, Mrs. Peters.

The next witness we have is Ms. Marilyn Medberry of Eugene, OR, victim of a phony cure for chronic pain and the daughter of

victims of phony Alzheimer's disease and arthritis cures. We are pleased to have you, Ms. Medberry. I had the privilege of being on the "Good Morning America" show this morning with Ms. Medberry, where I thought she made a very fine statement.

Ms. MEDBERRY. It was a privilege to appear with you, Mr. Chairman.

Mr. PEPPER. We are happy to have you here today.

STATEMENT OF MARILYN MEDBERRY

Ms. MEDBERRY. Chairman Pepper and members of the committee, I am Marilyn Medberry.

In December of last year, I sent Chairman Pepper a letter and a report I prepared which describes the way my family and I have been victimized by a quack who advertises himself as "an internationally known physician operating clinics around the world." "I feel compelled to send you this report on medical quackery," I said at the time.

I have spent 3 years researching a corporation that my family has fallen victim to. I have spent the past year trying to initiate a national investigation. These people are currently still in operation, and I have been unable to successfully do anything about it alone.

My stepfather has Alzheimer's disease, which, as you know, is an incurable brain disease. My mother has a very painful form of arthritis. I have chronic back pain related to five major spinal operations.

Sometime in 1981, my mother informed me of a casual contact with a local businesswoman in Eugene, OR, where we live. My mother said this woman spoke highly of the medical treatment offered by a doctor in Mexico. This woman, Doris Powell, said the doctor had helped many people and cured illnesses not helped by orthodox American medicine. She said that she knew about this doctor because she personally had gone to his clinic and been helped. That she had been cured of being a hunchback and her daughter cured of manic depressive illness.

Subsequently, Mrs. Powell came to our home to explain more about the clinic. She told us that the person offering the treatment was a physician, Dr. Bruck, who was licensed to practice medicine in every major European country. He was said to speak 11 languages and to belong to the most prestigious medical societies.

The miracle treatment was described as IBR—immuno biological regeneration—which was said to be the most up-to-date and scientifically based therapy to fight aging and revitalize the human body, that it was licensed in every other major country in the world except the United States; and widely used in those countries. That Dr. Bruck was licensed to practice medicine in many countries. They said IBR was designed to regenerate, stimulate, revitalize, and repair the immunological system of the human body. Mrs. Powell gave us copies of a newspaper article explaining the serum and with a photograph of Mrs. Powell with Dr. Bruck. This was to verify the treatments were genuine.

Some of the conditions it was said to treat include osteoporosis, arthritis, angina pectoris, hemorrhoids, pleurisy, gastric ulcers, diabetes, wrinkles, and many more chronic and more acute human ail-

ments. Mrs. Powell also told us the serum had made a "break-through in arresting cancer and actually curing it."

Based on what we were told, we—my stepfather, mother, and I—agreed to travel to Tijuana for treatment. Mrs. Powell handled all travel arrangements for us. We were given reservations on a flight to San Diego and then left on our own, along with others much more ill, to make our own way to Tijuana. Mrs. Powell originally made arrangements to meet Dr. Bruck in Canada. She met us in Canada, but treatments were canceled because authorities would not let him into the country. We were then sent to Mexico.

We found that the clinic in Tijuana was not a medical facility at all but an abandoned building without medical equipment. We were not examined or given a physical examination. In fact, the doctor didn't even lay hands on us. We were all told that we needed the serum based on a medical questionnaire we had filled out in Oregon provided by Mrs. Powell, and had to be returned and signed by her, or you could not get the serums.

When I questioned Dr. Bruck about this, mentioning the form of arthritis which my mother was suffering from, I was told, "Arthritis is arthritis," meaning all diseases are treated the same, and he laughed in my face.

The serum was sold for \$1,000 per injection, with a minimum of two injections per patient. Each additional injection currently available is \$250 per ingredient. We were told in advance that payment had to be paid in cash, cashier's check, or traveler's check. In all, my family spent about \$8,000 before realizing the miracle they were promised was a hoax. Only later did I learn just how much we had been deceived. The woman who told us about the clinic and arranged our travel—Mrs. Powell—was really a recruiter for the clinic and paid a commission as I was informed by the past administrator of this corporation. The world renowned physician was not a doctor at all, and never had been, yet practices medicine in nine countries.

This corporation earns \$150,000 to \$300,000 per day at these clandestine clinics in the business of killing people.

For the past 3 years now, I have investigated every aspect of this clinic and this so-called doctor. Contrary to their claims, this thymus serum has not been approved or tested for use in Italy, where it is being used. Nor has it been tested and approved in Germany, nor Switzerland, or any of the other countries where it is being used and advertised and injected into American citizens. Dr. Bruck cannot be found in the Swiss Medical Yearbook. The Swiss Health Center, where he is said to practice, is in fact a beauty corner dealing in hair styling and cosmetics. Similarly, he is not registered as a medical practitioner in England or any other country I have documented, and his treatment is unknown there. He is not registered as a medical practitioner in England, and the research facility that he advertises in his brochures as being based in England is nonexistent.

Research on the drugs being used indicates they are not safe for human use. In this country, the only authorized use of placenta products—which is just one of the many drugs offered—I was informed, is used only in cosmetics. The FDA told me that the substance has not been approved for the treatment of any medical con-

dition. My mother purchased \$510 worth of placenta in Mexico, Doris Powell also sold her additional drug vials at her insurance agency in Eugene, as she did with my uncle as well.

In my opinion, Chairman Pepper, as I wrote you in December, quacks are much more dangerous than they are being perceived. I feel that all of our Government agencies I have talked with underplay the problem and demonstrate lack of professional responsibility. I feel that someone with arthritis paying \$300 for 10 rectal suppositories—one of the treatment regimens prescribed at Bruck's clinics, among many, many others—that will supposedly effect a cure, and going off all of their other prescribed treatments—as they are instructed to do—is much more important and should be a lot higher on our priority list. He told me to flush my blood pressure medicine down the toilet.

Dr. Bruck is a career criminal and director of IBR, Inc., now going by the name of Immuvita, Inc. I can see how easily he makes his money. That is why I submitted this information to you and agreed to testify here today.

I have been led to believe that a citizen such as myself can make a difference. I have tried to go through all proper channels, to no avail. I hope your committee will take this seriously and do something to help me with this problem.

Thank you. I am grateful to you Chairman Pepper, your staff, and this subcommittee for allowing me to be heard.

Mr. PEPPER. Well, thank you very much, Ms. Medberry. You are to be warmly commended for the diligence and thoroughness that you exhibited in tracking down and exposing this very profitable racket that was being perpetrated upon people, and we appreciate very much your coming and telling the story here.

Ms. MEDBERRY. Thank you very much.

Mr. PEPPER. No doubt there will be some questions of you a little bit later.

The next witness is Mrs. Marcella O'Bryant of Springfield, OR, victim of a phony brain disease cure.

Mrs. O'Bryant, we would be pleased to hear from you.

STATEMENT OF MARCELLA O'BRYANT

Mrs. O'BRYANT. Thank you, Senator Pepper and members of the committee.

My name is Marcella O'Bryant. I'm 62 years old. I have two children, and six grandchildren, and two great-grandchildren. Since 1976, I've been in and out of the hospitals, and in 1979 I collapsed, and the doctors said that the tube from the brain to the spinal column was plugged—blocked, and they put me in a ventricle shunt and told me that I probably had 5 to 10 years to live. I had to give up my real estate and insurance business and try to seek help.

In 1981, I saw an article in the paper about a clinic in Mexico. Doris Powell was being interviewed, and she told the paper that she had not aged in years; this doctor had discovered a way to reverse aging; it was a fountain of youth.

I talked to a friend, Doris Brunton, in Eugene, OR, and agreed to go with her to Tijuana. I had to give the agent, Doris Powell, \$800

in advance and a deposit of—I took \$1,200, that had to be in a cashier's check, with me to Mexico. I had to pay my own airfare and other travel expenses to Tijuana, Mexico.

When we got to the clinic, the doctor didn't even examine me. He asked what my condition was and gave me a shot of serum. I had two shots. The next day I got another shot. And then he told me he was going to spray something on my body, and instead of spraying it on my body, he said he'd spray it on my clothes, and this he did. He said this would take care of me, and it did.

When I went through the check stand at the customs office, all the bells rang, and they examined everything I had and carried. They thought I was carrying something to blow up the place.

Senator Pepper, I've never been so disgusted in my life. By the time I walked in, I had a feeling that this clinic was nothing, and I felt I had been robbed, and have tried to put it out of my mind.

I lost \$2,500-plus for nothing. My husband and I had scraped money to make the trip and pay for the treatment that turned out to be all fake. He even suggested that they have the ventricle shunt removed.

I know of a lot of other people who have been taken this way, and this man and his crew are still advertising and defrauding people out of their hard-earned money. I hope that you can make them pay for the blood money that they have drained from innocent people who are desperate for help, and if I can do anything to keep somebody else from going through what I have gone through, I'll be happy to do it.

Thank you.

Mr. PEPPER. I just want to add, I know you speak about people who are desperate. I remember when the doctor who was treating my wife, who had cancer, with chemotherapy, came and told me that they had lost control of the cancer and he knew of nothing else to do.

When a person is in that desperate position, they are so vulnerable to somebody that comes along and says, "I know what can be done that will save your wife."

Mrs. O'BRYANT. Right.

Mr. PEPPER. Fortunately I knew enough about this kind of thing that I didn't fall for a lot of this quackery. But I did ask the doctors—I said, "Is there anything else that you have not yet satisfactorily proven on the market that you think might do some good?" "Yes," he said, "we have something." "Well," I said, "let's try that."

Now, of course, these were reputable doctors from the University of Miami. But it shows how desperate people are when they come to the end of the road and how vulnerable they are to this kind of vicious profiteering that people beguile them with, offering false promises and hope.

Well, thank you very much, Mrs. O'Bryant. We appreciate your—

Mrs. O'BRYANT. I appreciate being able to come here.

Mr. PEPPER. Well, thank you very much. Have you finished your statement?

Mrs. O'BRYANT. Yes, I have.

Mr. PEPPER. All right.

Now, the next witness is Dr. Carl Barnes. He is a pathologist in Florence, AL, and the son-in-law of the victim of a phony cancer cure.

Dr. Barnes, we are pleased to have you with us.

STATEMENT OF CARL BARNES, M.D.

Dr. BARNES. Thank you, Chairman Pepper and other members of the committee.

I am here today basically to relate the experiences of my father-in-law, Eldon Brown, of Athens, AL, who unfortunately was the victim of a phony cancer cure and who unfortunately can't be here because he died about 2 months after he was told he was cured.

In 1982, my father-in-law was diagnosed as having unresectable, incurable, widely disseminated adenocarcinoma of the lung, and that essentially his condition was terminal. As could be expected, the family was distraught, and we began to grasp at straws and looking into alternative modes of treatment, and the first experience I had with this was the Greek Cancer Cure, Inc.

At the request of my father-in-law, I obtained some information on this from the National Cancer Institute, and it became evident, on reading through this material, that this was pure quackery, and I convinced my father-in-law at that time that that was the case.

But soon thereafter, some of the local press in Huntsville, AL, carried some stories on Dr. Lawrence Burton and a clinic in the Bahamas called the Immunology Research Center with regard to the so-called immunoaugmentive therapy. Once again, my father-in-law called upon me to try to get more information—specifics about this. About that time, and possibly still today, there was a toll-free number, 1-800-IAT-HELP, where one could call and speak to someone about this.

I did this, and I couldn't receive any specific information about the types of lung cancer they treated. They didn't know anything about the stage, the manner, or spread of the cancers they were treating, and it became evident to me that, how can you say you are curing people of equivalent diseases when you don't even know what you are treating? When I tried to get specific answers, I would get evasive answers—for example, "Our computers are down."

I expressed my concern about the validity of any claims they made, but nevertheless he pursued it further, and another family member called and was told over the phone, essentially, "Yes, come down here; we can help you."

Soon thereafter, he left for the Bahamas, and he was essentially there 8 weeks, during which time he received this material by injection, which, it was claimed, dissolved the tumors.

His main complaint or symptom had been pain from the tumor. It had metastasized to the bones, and sometimes that produces a fairly exquisite pain. Now, when he went down there, he knew that he was having pain due to metastatic tumor of the bones, but he was told—and in fact, it's in their literature I have here—to go off pain medication and to begin the serum injections, and that the serum injections, if they work and dissolve the tumor, will cause pain. So he went down there knowing he had a tumor growing in

him causing pain, and through a pretty good ploy, he came back convinced that the pain he was having was a cure.

In addition, he had one chest x ray taken while he was there, from which he was told the tumor was shrinking. This was approximately 3 weeks or so into his treatment. Now, I have them here. Unfortunately, they won't demonstrate very well, but there's a technical problem with the film they took in that it is overexposed.

Without putting it on an x ray viewbox, it is not eminently evident, but the film is overexposed, which has the technical problem of making masses appear smaller than they really are, when a chest x ray film is taken with too much radiation.

When, upon his return, I encouraged him to go to Fox Army Hospital—he was retired Army—in Huntsville, AL, and have another chest x ray made, and I showed the before-, during-, and after-treatment films to several radiologists, who corroborated that they could see no objective evidence of any shrinkage in the tumor, despite the fact that they told him in the Bahamas the tumor had shrunk.

I was then faced with the unpleasant task of telling my father-in-law for the second time that he was dying. He essentially went through the process of accepting that two times.

It was interesting that they came back with a total euphoria—both he and his wife—that he was cured. They told everyone they saw he was cured. Then, when they realized that they had been fooled, it was really a shock, and, of course, one doesn't go around telling people that you have been fooled, usually, and that is generally the way the word about this type of therapy, I think, spreads.

He died July of 1983, approximately 2 months after he returned.

Now, in addition to the emotional turmoil and being away from the rest of the family for essentially a half of the remaining life he had, this cost them approximately \$10,000, including travel and lodging, for this phony cancer cure.

At the time, I rationalized it by saying, well, he was a dying man anyway, and perhaps it didn't do any harm. But then again, maybe it's tragic for a person to spend the last few weeks of their life receiving a bogus cure and leaving one's widow with \$10,000 less that they certainly could have used.

But what really bothers me most of all is what has been alluded to by some of the other witnesses. When people are put in these stressful situations, particularly parents and families of older people, you do grasp for straws, and I worry that people are going to deny traditional and proven forms of therapy for these bogus promises, and I sympathize with them, and I appreciate your giving me the time to express my feelings.

Mr. PEPPER. Dr. Barnes, you have told us that in the case of your father-in-law, this quack clinic over in Nassau in the Bahamas not only didn't do any good, but did a lot of harm. They lied in the way they manipulated the x ray to make him believe that he was cured when he came back home, and they made him spend \$10,000 and spurred his hopes of life, when it was all just a fraud. That's the basis of it, isn't it?

Dr. BARNES. Mr. Pepper, with regard to the x ray, I could only reach two conclusions. Either they are extraordinarily incompetent

or deceitful, and I really don't know which, but it would be one of the two.

Mr. PEPPER. Well, they told him that the cancer was cured, didn't they?

Dr. BARNES. That's correct. They told him that the tumor was dissolved.

Mr. PEPPER. In other words, they read the x ray to justify their statement that the cancer was cured, so they must have known what the x ray actually showed, and how they would need to change it to get the desired results.

Dr. BARNES. Yes, sir. I felt that telling him that the pain he was having was the immuno-augmentive therapy doing its work was particularly deceitful.

Mr. PEPPER. Well, thank you very much for another sad story, Dr. Barnes.

Dr. BARNES. Thank you.

Mr. PEPPER. We have another able witness, Dr. Lorenzo Pelly of Brownsville, TX, a cancer internist in private practice.

Dr. Pelly, we are pleased to have you.

STATEMENT OF LORENZO PELLY, M.D.

Dr. PELLY. Thank you, Chairman Pepper and members of the committee.

Disease Within A Disease, the Universal Health Center Cancer Clinic fraud.

My name is Lorenzo R. Pelly, and I'm engaged in the practice of internal medicine in Brownsville, TX, which borders Matamoros, Mexico.

One year ago, chance brought me face-to-face with practitioners of so-called "unorthodox medicine" as well as many of the desperate victims and families of those cancer sufferers who had fallen into hands of what I considered to be one of the worse tragedies ever to befall the Nation's health field. I have spent the past year observing as part of a small ad hoc team, investigating the case of Universal Health Center, a clinic in Matamoros, Mexico, which provided worthless therapy to hundreds of sick and dying Americans of all ages and backgrounds, and which charged each patient thousands of dollars for the promise of a quick and harmless cure for the disease.

Universal Health Center is owned and operated by James Gordon Keller. Note that I have written this in the present tense, because Mr. Keller, in spite of two restraining orders, one in Baton Rouge, LA, and another in the State of Texas, is still implementing his hoax in Tijuana, Mexico, at this time.

The Universal Health Center gives his patients injections of suspect and unproven substances, prescribes diets and medicines, and performs other medical procedures without benefit of license or any formal medical training.

I became acquainted with Keller after one of his patients came to the emergency room of the hospital on which I was on duty. The patient was a 44-year-old female schoolteacher with advanced breast cancer, which she treated herself with a microbotic diet in

hopes of starving the cancer, which resulted in her malnutrition, but continued growth of the tumor.

I met Mr. Keller that afternoon, who he claimed, had had a melanoma resected from the face and claimed that the tumor had spread to the rest of the body. Treated with chemotherapy without good results, he claimed he received laetrile, DMSO, and Tumor X, a substance found to contain aminoacids which were of unproven efficacy.

This is only his own account, and I suspect that he was cured with the surgery, if anything.

I gave blood to one of his patients, who in my own opinion was anemic, and suddenly I received several more cancer patient referrals. Most of them, though by no means all, were terminal.

For example, Mr. Keller once referred me a 7-year-old girl that had acute lymphocidic leukemia for a blood transfusion. The mother was terrified at the girl's receiving chemotherapy, due to adverse comments by some of her friends regarding the side effects and how poor the results were. The side effects can include: loss of hair, nausea, vomiting, diarrhea, skin rashes, et cetera, et cetera. The girl was bleeding from the nose at the time that I saw her, due to a low platelet count, and as it turned out, she had severe anemia. The most important finding in this case was that the little girl had the kind of leukemia that responds nicely to chemotherapy, with cure rates of 50 percent or better for her age group. With these facts, I set out and contacted the Federal Bureau of Investigation, the American Medical Association, and the Texas State Board of Medical Examiners, and they responded unanimously that it was out of their jurisdiction. You can imagine the frustration that I experienced.

Mr. Keller was telling these people that Tumor X could cure 80 percent or more cancer cases provided there was no previous conventional chemo or radiotherapy, and about 50 percent if conventional therapy was previously used. He also misled the patients by telling them that x rays to the body would interfere with the efficacy of Tumor X and that high blood counts would potentiate Tumor X. Keller also told the patients that herbs and carrot juice, as well as coffee enemas, were helpful in the cancer eradication.

I promptly realized the clever way he was deceiving these innocent patients. It is a medical fact that anemia can cause weakness and tiredness, and when transfused, the patients felt better. Since he would give his shots soon after the transfusions, the patients felt a sense of well-being that was attributed to Tumor X. By not allowing the patients to be x rayed, no one had a visual evidence of the resolution or progression of the disease.

The dangers in these kinds of deceptions are, No. 1, some cancers are quite curable with surgery, chemotherapy, or radiotherapy. However, delaying the treatment by applying unorthodox therapies such as Keller's would permit the cancer to progress to a stage where conventional treatments would not be effective.

Applications of injections of substances of dubious sterility may cause further infections.

Applications of enemas in cancer patients already dehydrated may lead to death, and some of the cancer patients may have infections and other complications not directly caused by the cancer and

not easily detected by untrained individuals, and this, if not treated promptly, can also lead to death.

The moral and legal issues of deception by false claims about diagnosis and cures as well as the charging of inordinate amounts of money for the application of these dangerous methods in already financially troubled families are also of great concern.

The Congress of the United States has a responsibility of enacting laws that could be easily enforceable by appropriate organizations that would protect these innocent victims.

The medical associations and other agencies in the health fields should jointly work with the lawmakers to enact and enforce these laws, and they should also inform the people and physicians on how to deal with these problems.

The above-mentioned organizations should try to work in conjunction with their counterparts in Mexico to eliminate the sanctuary that presently these clinics occupy.

As this report was being prepared, we conducted a telephone survey, inquiring about the well-being of the patients we had seen of Mr. Keller. Of them, more than 90 percent are now dead.

Thank you.

Mr. PEPPER. Thank you very much, Doctor, for your very able and very vivid presentation.

Our next witness, and the last witness on this panel, is Mr. David Horowitz, consumer advocate, of Los Angeles, CA.

Mr. Horowitz, we are pleased to have you.

STATEMENT OF DAVID HOROWITZ

Mr. HOROWITZ. Thank you, Chairman Pepper.

I first of all should say that I have spent 15 years investigating this area, working closely with your committee, with the Federal Trade Commission, with the Food and Drug Administration, with the U.S. Postal Inspection Service, with the U.S. Consumer Product Safety Commission, and many other agencies that work with senior citizens and quackery.

But before we start, Mr. Chairman, I have been sitting in here listening to what I call a litany of horrors, things that should be corrected, and I just would like to ask—I know you don't do a roll-call, but is there a representative here from the Department of Justice?

Mr. PEPPER. No; the Department of Justice was invited to participate today and declined.

Mr. HOROWITZ. All right. Is there anyone here from the Federal Trade Commission?

Mr. PEPPER. They will appear later.

Mr. HOROWITZ. They will appear later, but they haven't heard the stories that we have listened to.

What about the Food and Drug Administration?

Mr. PEPPER. They are represented, you see.

Mr. HOROWITZ. So, we do have at least one representative from one agency that should have listened firsthand to the testimony that we have all had a chance to hear this morning.

Mr. PEPPER. Is anyone here from the Postal Service?

Yes; there are several back there.

Mr. HOROWITZ. They have been fantastic, Mr. Pepper, in dealing with the things that we have brought to them, and I know the things that the committee has brought to them.

But what I find out there in terms of senior citizens and quackery—that senior citizens who complain about being treated by quack doctors and quack cures, by law enforcement agencies, are basically treated as little children who have no common sense.

They are often not listened to. The only people who listen to them are the rip-off artists who sell them the various cures and the various therapies that do nothing for them.

Mrs. Peters said to me before her testimony this morning, "I cannot believe that things like this are going on today." Well, I think most people in the United States can't believe things like this are going on today, and that's why we receive tens of thousands of letters from seniors as well as ordinary citizens of the United States.

As I looked around the room, one thing that struck me is that most of the material that we see here is advertised in legitimate magazines, in legitimate newspapers, who do not check out the products that they are advertising, who do not even ask for samples of the products, who do not know whether they are quack cures, whether they are on the up and up, whether the doctors who advertise in these publications are even licensed to practice medicine.

That, I think, is one of the major problems that is confronted by all of us in the area of trying to deal with quackery, and that is to get the publications that we are all exposed to and radio and television to be able to have some set formula of checking the practices of some of these places that advertise. So, that's a little absurd.

Mr. PEPPER. I don't believe that the FBI goes into this sort of thing either very much.

Mr. HOROWITZ. You mean the Federal Bureau of Investigation. Well, I can tell you, it's not only the FBI. I have brought cases to local district attorneys who have said, "Sorry, we can't deal with this."

It is small potatoes for most local law enforcement people to deal with quack devices or things that will remove weight in 24 hours, or things that will grow hair, or some cancer cure clinic that opens up somewhere, until somebody actually dies and by then they have lost a life and it is a little too late.

As I said, Mr. Pepper, quackery and senior citizen problems basically get short shrift and are low on the totem pole of most of the law enforcement agencies in this country, with the exception, as we mentioned, of the U.S. Postal Inspection Service, which seems to be right on top of it.

But most people still perceive quackery as something quaint, comical, and harmless. Even in this room today, we look around here like it's a carnival of quackery. Everybody is coming and shooting pictures of all these things that are around, as if it is the first time that many people have even seen it.

Most people don't know that these alternative health products are developed by people without any scientific training. These promoters say they have medical training. They adopt impressive-

sounding titles that have no real meaning in order to sell credibility that doesn't exist.

Quack products which, by definition, lack scientific support, are sold with testimonials and promises, as you can see here, none of which are usually checked out. Most people don't know these promises are rarely made in good faith or that they are even ever fulfilled.

The people who provide the testimonials with which these products are sold either never had the incurable disease that the product is said to have treated, or paid employees, or shills of a company.

Most people don't know the foundations—the so-called foundations supporting alternative remedies like some of the quack cures that we have heard about this morning are often funded by—or are fronted by people who are just acting as shills for quacks. They don't know about referral fees and the self-interest of the seemingly disinterested charitable foundations who continue to go on in this country raising millions and millions of dollars unchecked by law enforcement.

Most people don't know what the bulk of money donated to these organizations goes for. They don't know to check with places like the Better Business Bureau or with local funding organizations to see what the money is raised for.

What is said to be a charitable purpose usually, I have found, in the investigations that we have had in conjunction with Federal agencies, have ended up to be nothing except groups that ended up lining someone's pocket with a lot of money that was maybe never even reported for tax purposes.

In some cases, 90 percent of the funds that were generated, that I have found, by some of these so-called alternative foundations serves no purposes other than enriching the promoters, who go off and use the money for whatever they want.

Most people simply don't know that these so-called cures have never been proven effective in any way or been checked out. They have never met the scrutiny of scientific review. In fact, most have been proven ineffective once they have, and I wonder whether the AMA is here.

Is anyone from the AMA here?

Good. I'm glad you are, because I really think that the AMA has to become more active also in bringing the information to the public, not only to the seniors of America but to the public, and they are trying hard and fighting a losing battle, I might add, in a lot of cases.

Most people simply cannot comprehend the limitless deception of these quacks. The sick and the desperate, as we have heard here this morning, are particularly vulnerable. They hear what they want to hear from people with a financial interest that are making them believe.

Most people have never had the opportunity to track the victims of these quacks or to find out what they have done. They have never had reason to assess the long-term benefits and harm of these questionable cures.

No one brags about being fooled. No one wants to confess rash acts. No one wants to face fear that is going to make them vulnera-

ble, as we found at these hearings. The few brave people who have come forward are really brave to do it.

For most people, I find, once they have been fooled, the only effective remedy is to try and forget about it, and in some cases, for the members of the family, it is very difficult to forget about the death of a loved one who has been fooled by one of these quacks.

The cons are too clever. The law enforcement agencies, I find, are too disinterested, and the laws are too limited to provide relief. The rip-off artists have always known that the risk of preying on the old and the ill can only mean cash without anyone questioning.

Mr. Chairman, you estimated quackery is a \$10 billion problem. I've got to tell you that I feel that your estimate is a very conservative estimate by the kind of mail that I receive. The true total is probably ten times what you estimate.

But the impact in human terms is even greater than the money. Thousands of people are being conned, they are being scammed, they are being bilked and swindled out of the last precious moments of their lives, their peace of mind, and their legacy in elaborate, organized quackery schemes.

The problem is just too staggering in size and complexity for any law enforcement agency to really get into except on a full-time basis, and something must be done now.

The simplest, most important thing we can do is to inform the public, but how do we do it without the proper funding and the proper Government organizations that are going to become involved in a way that it is going to be meaningful?

We need to stiffen penalties, and we need to increase enforcement efforts. That's a little difficult when you don't have the support of Government agencies like the Department of Justice or giving the Postal Service the added subpoena power that it needs.

But our first priority must be to let the people know about the dangers of quackery. I believe that educational programs defining the dangers of quackery have to be dramatically increased by the professional organizations like the State medical organizations, the county medical organizations, and the American Medical Association; that is going to be the key at the beginning.

We should also consider developing a clearinghouse on unproven methods similar to what your committee is asking for. I think this is a must—a referral source where the people can obtain independent information about the value of health and these quack products that are on the market.

Thank you, Mr. Chairman.

Mr. PEPPER. Well, thank you very much, Mr. Horowitz, for your excellent statement. We commend you and your organization for what you have done to make the public aware of the fraud that is being perpetrated upon them and the magnitude of that fraud.

We will consider whether or not there might be a commission set up, or whether we should give general authority to some agency or agencies of the Government, and the like.

But what you have said has been extremely helpful to us, and we appreciate it.

I'm advised that the Federal Trade Commission is represented here. Will anyone who is from that agency hold up their hand?

There are two or three people over there.

Thank you very much. I am glad you are here.

Now, then, we have completed the panel, and it has been an excellent one, and I want to commend all of you for the high quality of your statements.

Let's run through as fast as we can the questions of the members of the subcommittee, so we can move on to three other excellent panels that we have here.

Mr. HALAMANDARIS. Mr. Chairman, if I may, I have another engagement, and I'm going to have to excuse myself.

I would like to just commend you all for what you are doing. The vital thing is not what we have done but what you are doing, and I commend you for your efforts.

Mr. PEPPER. Well, thank you very much, Mr. Halamandaris.

We repeat, it was you, while you were with our committee, who initiated this inquiry and brought it forward with a great deal of momentum, and we are glad your able brother can carry it on with the rest of our staff.

Ms. OAKAR, would you care to question the panel?

Ms. OAKAR. Thank you, Mr. Chairman, and I want to commend Val also before he leaves.

We miss you, Val, but—not that brothers take each other's places, because you both are terrific, but you started the ball rolling. It's great to see you again.

Dr. BARNES, you mentioned that there were some x rays that were shown. Do you have those x rays with you?

Dr. BARNES. Yes.

Ms. OAKAR. Do you want to hold them up and let the committee see?

So they gave you phony x rays. Is that pretty much what happened—your father-in-law, rather?

Dr. BARNES. I don't know if I would call them phony in the sense that it's not an x ray of him, but it is misrepresentative in the sense that if one varies the technique in which an x ray is taken and uses a higher amount of x rays, essentially it overexposes the film, and it has the effect of making things look smaller than they really are.

Ms. OAKAR. I see.

Dr. BARNES. And so the film looks very black and dark in this instance.

Ms. OAKAR. But that's not the real picture, as it were, in other words.

Dr. BARNES. And it makes comparing films like comparing apples and oranges sometimes when there is so much variation.

Ms. OAKAR. Do you want to hold that up just for a second for the committee?

Thank you very much.

Dr. BARNES. This is April. This is after he came back. This is the one taken in the Bahamas. It is very dark. And this is one prior to treatment. You can see the difference in the technique.

Ms. OAKAR. Yes.

Dr. BARNES. You can see some lines and shadows.

Ms. OAKAR. So it was very misrepresentative really.

Dr. BARNES. Yes; correct.

Ms. OAKAR. Mr. Horowitz, I was struck by your comment about advertising, and I am aware of your work and have seen you on TV and other areas. You mentioned the phony advertising and the fact that one quick thing that we could simply do is inform the public.

What are we going to do, though, about the fact that we do have false advertising on not only these magazines but the major networks?

I have some concerns, for example, about the phony insurance policies that the stars are advertising. Because people trust these individuals, they go out and buy these policies which are just rip offs.

You know, we live in a free society. How do we balance the freedom with the restriction?

Mr. HOROWITZ. Well, first of all let me say, on television—which is an area that I know quite a bit about—that in order for any advertising to be accepted on a network-owned or network station, affidavits must be filed with the television network, and those affidavits are checked very carefully about the truth of whatever that ad is—that they are going to deliver whatever that policy says it is going to deliver, and if you find that any of the policies—and I know the policies you are talking about—if you find that any of those are not really doing or delivering what they say they are delivering—those insurance companies—then I would go to network standards and practices at each of the individual networks and let them know.

We have had cases where we have looked at commercials for products which have not delivered what they said they delivered, and standards and practices, after conducting whatever kind of investigation they did, yanked those commercials off the air.

So I don't think it's the greed motive to get it on the air. I think they have to believe the affidavit, which is certified, and if that affidavit isn't correct, they can pull the commercial.

But even more importantly, the Federal Trade Commission—we have some representatives from the FTC here today—should be made aware of it, because one of the powers they have, even though it was almost taken away by Chairman Miller, is the power for checking out substantiation of commercials and products that are on television, and they would be the first place to go to—would be the FTC.

In terms of newspapers, there is nothing you can do. Major newspapers like the Washington Post, the New York Times, the Chicago Tribune, the Los Angeles Times, have certain standards and practices for ads that are put in those papers, but they are few in number compared to some of the supermarket tabloids where many of the ads that I am looking at come out of, or magazines, which are hit-and-miss magazines which have no standards and will accept any advertising.

Several months ago, I had a conversation with Mr. Fletcher, who is the Chief U.S. Postal Inspector, about such advertising, and the Postal Inspection Service has really been trying to clamp down on them, but there's not a lot they can do without having subpoena power to go in and do it.

One of the proposals that Mr. Pepper and the committee are trying to get is subpoena power for the Postal Service. It would not

only help in terms of quackery, but I think it would serve to help the American public because of all the rip offs there are in just mail-order advertising.

Ms. OAKAR. Let me just—I don't mean to cut you off, but I do want to ask a few other questions.

Mr. HOROWITZ. Oh, I'm sorry, but I mean I could go on—

Ms. OAKAR. That's all right.

The only thing I would dispute is that not everyone is in a position to verify whether somebody has lied in their statement for advertising.

You are surely not suggesting that all the advertising that is on television, et cetera, is true, because we all know that's not true.

I think what you are saying—

Mr. HOROWITZ. But if you know that as a fact, I would let the Federal Trade Commission know about it, because they are the group that can go after them, because—

Ms. OAKAR. Well, let me tell you, the committee has made tremendous recommendations, and you have suggested some of the recommendations, which are very similar, and which the committee has expanded.

For example, the committee recommends that FDA make a major commitment to protecting the public safety. Now, some of us have been trying to get FDA to do its job for a long time. We had a very important hearing on diet pills containing PPA. They are still advertising those pills like gangbusters on television and in every major magazine and just about every newspaper.

Mr. HOROWITZ. You mean Phenylpropanolamine.

Ms. OAKAR. That's right. And that's about the diet pills. And we had all kinds of cases in which people suffered and were victimized by these pills. FDA could do its job very simply by continuing that study on PPA and completing it. It has only taken them 15 or 20 years. And they don't do their job.

So the real question is—

Mr. HOROWITZ. But Ms. Oakar, let me tell you something. When you are dealing with diet pills, you are dealing with diet pills, and I can name 15 brands that are being sold over the counter in drug-stores, being manufactured by major drug companies in this country—

Ms. OAKAR. Right.

Mr. HOROWITZ [continuing]. And are being sold in supermarkets. You are dealing with a mammoth lobby that has a lot of bucks to spend to slow things down.

Ms. OAKAR. Well, you don't have to tell this Member that, because we went through great trauma to even have a hearing. And thanks to the courage of my chairman, we had that hearing, and we are still working on it, and we are still trying to get FDA to do its job.

I did want to ask Mrs. Peters one quick question.

You mentioned the vitamin E substance that your son was taking.

Mrs. PETERS. Pardon me? What was that?

Ms. OAKAR. Vitamin E. Was it a vitamin E substance?

Mrs. PETERS. Vitamin A.

Ms. OAKAR. Vitamin A substance.

Did you feel that there was anybody that you could talk to, who could give you an opinion as to whether you were on the right course?

As the chairman mentioned and you mentioned, we have all had people in our families that have suffered from acute diseases. You know, you are in such anxiety over that—and other members of the panel might want to respond—did you feel that there was anyplace you could go to find out whether what you were trying to do for your son would work.

Was there any consumer group, or did you have any avenue to go to, or was there just nobody to go to?

Mrs. PETERS. Well, to be perfectly honest with you, I didn't think that there was a need to go to anyone, because I felt perfectly safe in using this.

Well, the preparation was called Bio-A-E-emulsion. I did feel perfectly safe in using it for my son. I didn't think there would be any harm coming from it. It was a vitamin.

Ms. OAKAR. Yes, it's a vitamin. And what we are seeing is that the various Government agencies, that should be protecting you from things that you think are perfectly safe, aren't really out there.

Doctor, you are shaking your head. Did you want to comment on that?

Dr. PELLY. Well, the comment is that I think that the patients, per se, the individuals that are subjected to these quacks—quacketeers—should be also studied.

I think it is almost becoming, in the cancer area, a cult, where a patient is treated in Brownsville, goes to the Bahamas, goes to Tijuana, and keeps believing that these methods are efficacious.

I spoke last night to the first cancer patient that I saw of Mr. Keller, and he—I have a tape recording of his conversation, and he stated to me that there was only one problem with Tumor X—that it can stop the cancer but cannot cure it. By that he meant that you have to take Tumor X continuously for it to contain the cancer.

So I think that we have a real problem, and I strongly believe that it is going to perhaps be easier to control the quacketeer than those that are subjected to the problem.

Dr. WACHSMAN. Can I comment on that for a moment?

Ms. OAKAR. Yes.

Dr. WACHSMAN. It seems to me that many of these cancer quacks are related to the health food faddists and people who propagandize the fact that vitamins are wonderful, and they treat things—people like Carlton Fredericks who has been on radio for some 40 years on WOR, and who has been stating for 40 years about his nutritionist background when, in fact, all he is is a Ph.D. in communications and had two biology courses.

The point is, this entire health food circus that goes on causes people like Edith Schneider and others to believe that these things are safe—as Mrs. Peters—that they are vitamins; they are OK.

The truth is, this leads them into the situation where they will believe that something is treatable, that these vitamins or these megadrugs are in fact going to be helpful. The truth of the matter

is that they are not helpful. The truth of the matter is, it's a fraud upon people.

All these health food centers throughout the country that sell vitamins in mass numbers and have people like Gary Null, who has, again, no background in nutrition, who is a research scientist in the Institute of Applied Biology, which is Dr. Revici's basic place that his research has been going on for years—he is not a research scientist.

There has never been any, and the fact is that this is continuing, based upon the fact of people believing in these health foods and believing that these things are really going to help them, and therefore it's quite safe, as Mrs. Peters pointed out, to give her son vitamin A in megadoses when in fact all it does is does harm rather than help.

Ms. OAKAR. My point was, Doctor, that we don't have a mechanism. We have a few little government programs—and I think Mr. Horowitz was suggesting this also—beyond law enforcement and new laws, and we all have introduced bills to try to get these agencies to do their job.

We don't have widespread educational program—a consumer hotline, if you will—so that when people go off and try to get a remedy, and they are desperate, they can at least have some authority to check with.

The little that it would cost our government to do something like that—to educate our people, to make them feel more secure in what they are doing, and to tell them if they are on the right track—is something that I think is so do-able, that wouldn't get entangled in the legislative process, and we are not doing that.

I do think that some of the independent groups like AMA and the nurses and other groups could do more than they are doing, also.

Mr. HOROWITZ. Ms. Oakar, if I could bring up a point here, there is a mechanism available in the Federal Government that is totally not being used, the President does have a special assistant on consumer affairs.

Ms. OAKAR. Right.

Mr. HOROWITZ. It is an office that has, one, no statutory power, obviously; it is an office that basically does not really have a staff to get anything done, except for some informational stuff; and I think the logical place to start as the clearinghouse that Mr. Pepper and the committee are asking for is to have an effective consumer office in Government with somebody heading it who could get some of these educational programs going right now.

Virginia Knauer, as you know, is the head of that office, and most of the stuff that's coming out of there is just strictly pap, some educational stuff, mostly ceremonial, and really not of broad or general interest to the mass of people who should know about the kinds of things that we were discussing here today. I think that's the place where we could start.

Ms. OAKAR. But you have to have the framework, Mr. Horowitz, whereby the people working for Government and the administration really are advocates for the consumer, and that's the problem that I see.

I see FDA—and I don't say this lightly, but I see FDA protecting these drug companies when they ought to be removing some of these products that are on the market, and warning people about the use of other products that are not even regarded as quackery type products. It's just the run of the mill products that you buy, like vitamin A, that we just realize now have killed some of our children.

Mr. HOROWITZ. But Ms. Oakar, you also know that several times—at least four times that I know of—maybe it's three times—that a super consumer protection agency was proposed before the Congress, and each time it went down to overwhelming defeat, and it was something that was supported very heavily by not only the consumer interests in this country and people like Ralph Nader and Dr. Fields and people over at the Health Research Group, but by many others in the Congress who felt that it was an important thing to have, and every time it came up before the Congress—including some of the people in this room—it was defeated.

Ms. OAKAR. I sure agree with that, and we ought to resurrect it. Thank you very much.

Mr. PEPPER. Thank you very much.

Before I continue the questioning, it was an inadvertence of mine that I didn't give Ms. Edith Schneider—who accompanied Dr. Wachsman, an opportunity to make any statement.

We would welcome anything you would care to say, Ms. Schneider.

STATEMENT OF EDITH SCHNEIDER

Ms. SCHNEIDER. I just want to keep other people from making my big mistakes.

I know that this doctor is still practicing, and it distresses me greatly that other women and other people will go through the same pain that I did, and I just hope that people will be deterred from this course.

Mr. PEPPER. Well, thank you very much. That's eloquent testimony, Ms. Schneider, and we appreciate it.

Mr. Regula, any questions?

Mr. REGULA. Yes. Thank you, Mr. Chairman.

Dr. Horowitz, I'm interested in your talking about a consumer agency. You are in California. As you well appreciate, the licensing of doctors is done by the States. The medical practice is State responsibility.

I'd be interested in what you have accomplished by way of a consumer agency in the State of California, since it would be much easier for people to have a hot-line, if you will, or toll-free line to Sacramento.

Have you accomplished anything there along the lines you are suggesting at the Federal level?

Mr. HOROWITZ. Let me just say this, Mr. Regula. In California, which is supposed to be a place where a lot of these health faddists, health food places, clinics—you know, the clinics below the border like the clinic where Steve McQueen died, who was suffering from cancer—

Mr. REGULA. Right.

Mr. HOROWITZ. One thing California has that many other States don't have is probably the strongest consumer protection agency anywhere, a consumer protection agency, incidentally, that was started by a Governor whose name was Ronald Reagan.

I wish I could see the same strength through the medical societies and through—we have a board of medical quality assurance, which is in regions of California, which is totally accessible to anyone who wants to go and speak before them.

The board is made up of M.D.'s, all licensed, who listen to complaints, who adjudicate complaints, and who go after the quacks, if they are quacks. There are not only heavy fines, but there are doctors in California who are having their licenses suspended all the time for practicing quackery.

I wish that example could be an example that could be followed across the rest of the United States.

There are other States that do that, but I think using California as an example of strong consumer protectionism—an excellent example, which, as I say, was set up by Governor Reagan. I wish we could say the same thing in Washington today with President Reagan.

Mr. REGULA. Well, of course, the success of California would perhaps indicate that the appropriate remedy is with the States, since they do the licensing and since the State government is close to the people.

What success have you had, if any, in stopping the cross-the-border flow? That is part of the problem.

Mr. HOROWITZ. That has been very difficult. The California Medical Association and the county medical associations have done an excellent job of educating the public about it.

The problem is that California and Arizona seem to have one of the largest senior citizen populations anywhere in the United States, with the exception of Florida, Mr. Pepper's turf, and people come from all over the United States, who are not Californians or who are not living in Arizona, and pass through those States into these clinics below the border, despite the fact that the medical societies there are promoting as much as they can, through educational means, the fact that these clinics are quack clinics, and you shouldn't rely on them, and the drugs that are being used haven't been tested.

But there is also a certain feeling of ambivalence about testing of drugs because of the drug testing process that takes place through the Federal Government, through the FDA, and the amount of time taken.

So people will try anything when they are desperate and terminal in order to see if it works, because they feel they have nothing to lose.

Mr. REGULA. Dr. Barnes illustrated that clearly with his father-in-law.

Mr. HOROWITZ. Exactly, and that is also part of the problem.

I mean, I wish there was some way that we could beef up the FDA's testing program so that it doesn't take as long as 7 to 10 years. And I know you always bring up the example, or the FDA brings up the example, of thalidomide and thalidomide testing and how, you know, it was never allowed to be sold in this country but

it was sold in places like Germany and, of course, we know the results of inadequate testing.

But I think there has to be some way to speed up the testing and looking at these drugs so that people who might be terminal or might not be terminal can be helped by some of either cancer drugs or arthritic drugs, or whatever—that we just fund those agencies more, which is always saying, hey, what's going to cure it? Cash. But even more than cash, I think what could help do something is commitment to reorganization of the agency so the process can be speeded up.

Mr. REGULA. Excuse me. It was Dr. Barnes' father-in-law, but it illustrates the point that desperate people will seek out all possible forms of treatment despite their perceived legitimacy. Dr. Wachsmann, as a neurosurgeon and trial attorney, you are particularly competent to answer my next question.

On the malpractice issue, do you think that we should recommend either to the States or expand the parameters of the malpractice statutes at the Federal level to help address this problem of quackery?

Dr. WACHSMAN. I believe that the only protection that the public has at present is the medical malpractice system. There really is nothing in place. The States—and I am licensed to practice medicine in some eight States, including California and Florida and licensed to practice law in at least four others.

The fact is that in California, there is a mechanism at least for taking away licenses. There is this board of quality assurance, and it is in Florida.

However, most other States do not take away licenses, do not investigate malpractice. The medical societies, by and large, do not investigate malpractice. Certainly the AMA does nothing.

The only mechanism in place at present is the medical malpractice system, which has caused recertification, relicensure of physicians, continuing medical education, and a concern on the part of physicians.

We have written a national text in malpractice, a three-volume text, which is the legal text, and the fact is that we review cases and try cases across the country, and we find in the areas where there are no malpractice suits, in rural areas, in States out of the way, the fact is that in those States, in those places, the malpractice is much worse; the care that is given is much lower.

There is a national standard. People are trained throughout the United States as physicians, and the board certification is a national standard, and clearly, where there are malpractice suits, there is a tendency on the part of the physicians to be more careful, to be more concerned, and perhaps not take chances with their patients' lives.

Certainly when it comes to quackery, such as Dr. Revici and others of his ilk, the only way that anything happens is by virtue of somebody doing something about it, and it ends up being the malpractice trial lawyer who does it, because the States generally do nothing, and certainly the medical societies do less.

In the State of New York, the medical societies last year—there was something like a total of 712 complaints to the Department of Health of the State of New York. Of those complaints, 16 were

from the State medical societies, and there are 61 counties in the State of New York; therefore, 1 complaint for every 4 counties in the State of New York; and those were related to drug addiction, to people who were alcoholics, to people with mental incompetence and problems of that sort, and not for malpractice.

It is not investigated by anyone unless the malpractice lawyer is there, and to remove the protection that the public has at present—at least to some degree they have at least someone advocating for them—would be to allow this to continue and to enlarge.

Mr. REGULA. Last question. Dr. Pelly, you mentioned the fact that there are potential medical breakthroughs in many of the peripheral unconventional treatments that come along. Do you think it would be well if there were some central, perhaps federally sponsored, assessment agency that could look at potential cures or potential procedures rather than reject them out of hand in case that 1 in 1,000 does have some efficacy?

Dr. PELLY. Mr. Regula, I don't think I said that there is potential on the methods that I have seen. I think that there are outright nonefficacious methods.

If there was any potential efficacy in a medication, perhaps in another country in Europe, then the FDA should look into that, and I think Mr. Horowitz mentioned something about expediting the study of new drugs. However, of the methods we probably have discussed today, I doubt seriously there is any potential for any kind of use in human beings.

Digressing just one second from your question, I also would like to mention that I contacted the IRS, and when we were talking with the IRS about the agencies present here, I would like to ask, is the IRS present here? I think that that would be an instrument to curtail some individuals that are making millions of dollars, and those are not accounted for.

Mr. REGULA. A lot of them are out of the country. Is that correct? That's part of the problem.

Dr. PELLY. I should mention that Mr. Keller last year gave booster shots of Tumor X to 10 patients in Las Vegas, NV. He gave two shots per patient, and he charged \$150 apiece. So that is not necessarily the case.

Mr. REGULA. Thank you, Mr. Chairman.

Mr. PEPPER. Thank you very much, Mr. Regula.

Mr. DeWine.

Mr. DEWINE. Thank you, Mr. Chairman.

Mrs. Peters, first of all, I want to thank you very much for coming today; I appreciate your testimony.

Did you make any complaints to a medical association or to any other State licensing board concerning the doctor that was involved in your case?

Mrs. PETERS. No; I did not. To be, again, honest with you, I was just so overwrought with what had happened to Chuckie, I wanted to put it all behind me. I didn't.

Mr. DEWINE. To your knowledge, that doctor is still practicing?

Mrs. PETERS. Oh, yes, he is. The doctors involved are. In fact, Dr. Manners, who I thought was a practicing doctor—medical doctor—was not. He is just a doctor of biology. Dr. Baldwin, of course, is

retired. These other people that were involved are still practicing in their firm of nutritional consulting.

Mr. DEWINE. This Dr. Manners, did he indicate to you that he was a medical doctor, or did you just assume that, or did he in any way lead you to believe he was?

Mrs. PETERS. Well, he did not, but he didn't say anything to the contrary either.

There were a lot of people that I do know who thought that he was a medical doctor. In fact, when I was talking to somebody who owns a health food store about him, she was very much surprised to find out that he was not a medical doctor.

Mr. DEWINE. I have a question for Mrs. O'Bryant and I believe one of our other witnesses in regard to Doris Powell. Was Doris Powell ever charged with any kind of State offense, such as theft by deception?

Mrs. O'BRYANT. No; not to my knowledge, she hasn't.

Mr. DEWINE. Did you make any complaint, or did anybody make a complaint to a local police department or local district attorney?

Mrs. O'BRYANT. No; I didn't; Mrs. Medberry may have.

Mr. DEWINE. Mrs. Medberry, did you make a complaint?

Ms. MEDBERRY. Yes; yes.

Mr. DEWINE. And who did you make that complaint to?

Ms. MEDBERRY. I not only made a complaint, I have made complaints to just about everyone you can make complaints to, starting from the bottom up to the FBI and everybody else.

What I want to share—if I might take the time to do this, a brief list of allegations that I uncovered in my research in this past 3 years and presented these allegations, as you can see, and as Chairman Pepper and the committee know, I have quite a volume of evidence, and it's all verifiable.

Here is what I uncovered. Evidence exists for the following objectionable activity. Now, as I give you this evidence and what was taking place with IBR and Immuvita, I want you to keep in mind that everywhere I presented this, no one felt it was a priority issue.

Mr. DEWINE. OK. My time is limited, as is yours, as is the chairman's.

Ms. MEDBERRY. OK.

Mr. DEWINE. My question is what—I think we see the case that you made. I don't have any problem—

Ms. MEDBERRY. Yes; but I don't think you know how large the case really is.

Mr. DEWINE. OK. I don't have any doubt that you have a case. My question is, What reaction did you get when you presented it, and who did you present it to?

Ms. MEDBERRY. I started out with lawyers, and my State senator, for guidance as to whom had jurisdiction. I did not know what to do.

Mr. DEWINE. How about law enforcement officials?

Ms. MEDBERRY. The board of medical examiners, the board of pharmacy, FBI, Department of Health and Human Services, the Inspectors General, the Attorney General's Office, FDA, FTC, consumer organizations, Ralph Nader and others.

Mr. DEWINE. Did you—let me interrupt you. Did you—

Ms. MEDBERRY. I couldn't get appointments. I tried to see the DA, and I could not get an appointment. You can't get past staff who react with disbelief. I had been advised it was not a matter for local police.

Mr. DEWINE. You couldn't get in to see the DA?

Ms. MEDBERRY. No; I couldn't get anyone to listen to me. I was becoming afraid because I had received intimidating phone calls from corporation staff.

Mr. DEWINE. OK. And everywhere you went, your reaction was what?

Ms. MEDBERRY. Their reaction was, "It isn't of interest to us," or "It isn't in our jurisdiction," or, "We are too busy; it is not a priority case," "We do not know if your complaint has any merit," yet no one would look at the evidence. "We don't have enough staff," "We don't have any money," "If people are that gullible, it's really their own fault." "There are so many quacks—that you can't really do anything about it anyway, so we go after the vitamin shops, that's our priority," and "Most quacks don't harm except financially."

I was told by one member of the FDA, "Well, after all, Marilyn, you must understand, we only test and approve or disapprove of drugs and devices; we are not a police agency," "We are too busy," "It's not important enough," "You don't have a case, the laws and Medical Practices Act does not cover this type of problem."

Mr. DEWINE. OK. That's shocking and it strikes—

Ms. MEDBERRY. It's shocking, and it's just—

Mr. DEWINE. It strikes me, as a former prosecuting attorney, that this is a pretty good case, it would seem on what you have said about theft on deception.

Ms. MEDBERRY. I asked them; I said, "Because it involves so many violations and laws, it comes under the jurisdiction of many agencies," I have tried to initiate a coordinated investigation to really get something done; because it is too massive a problem for one agency to stop this crime.

This is an international corporation with its offices all over the United States of America. There is not a State in this country that is not involved and has theft, and cannot initiate an investigation—because no one has the time. The California Health Fraud Council had tried to help and deserve credit for that. I received their support a short time before this hearing.

Mr. DEWINE. OK. Thank you very much.

One last question, Mr. Chairman.

Dr. Wachsman, you have made a pretty good case for the malpractice attorney, and basically I think your point is that that is a deterrent effect, or can be a deterrent effect, in a community—a few of these lawsuits. I don't question that at all. I would agree with you.

It would seem, though, that if we are going to rely completely on malpractice attorneys and malpractice suits, that what we are going to continue to see is a very uneven enforcement and uneven deterrence of this particular problem.

What is the problem, Doctor, with the medical profession policing itself, and what is the problem with each State getting tougher on the quacks? Why won't that, or why can't that, take place?

I just am troubled by your comment that we are going to have to rely completely on people like you. I'm sure you are doing a good job, but a lot of folks are going to fall in the cracks, as the people who have testified today, and we are not going to have the uniform system of deterrence.

Dr. WACHSMAN. I can't agree with you more. I believe to rely just on the medical malpractice lawyer is obviously not enough, particularly with the amount of problems, with the number of situations that we see here today, but the fact is that with respect to medical practice, people have a great tendency—anyone—not to police themselves, not to be overly critical of themselves, unless there are economic factors involved.

In medicine, we see—and I have seen this across the country—that physicians, when they criticize other physicians, it's generally the economic factors. There are four orthopedic surgeons in a place and along comes a fifth orthopedic surgeon, and he's going to take cases away from them, so then they look at his practice very carefully and try to exclude him.

The same thing happens in surgical specialties, because money is involved. It happened in neurosurgery across this country and has happened on multiple occasions.

To say that the societies should police themselves—the medical societies—would be very nice and would be the same as saying that perhaps we should have juries in this country made up on medical malpractice cases of just physicians.

In Alaska, may I add, they had a medical malpractice system of a panel which consisted of three physicians. There was never a finding for the plaintiff at any time, in any place, under any circumstance. They finally ruled it unconstitutional.

The fact is that people have a great tendency not to police themselves. We have reporters, we have people in the press to perhaps police people that are in government. We have a check and balance system in our Government to police each other. We have the Congress and the executive branch and the Supreme Court and the judiciary to police each other. You must have a counterbalancing system.

How do you take care of all these problems? There are multiple ones. I think one of them is taken care of, to some degree, by the medical malpractice lawyer. Some of these other problems have to be taken care of by virtue of the Federal Trade Commission, perhaps some of this false advertising and misleading advertising.

Perhaps also the Communications Commission should be involved with television and radio false advertising that goes on. Perhaps all of these agencies—the FDA.

But the truth is that too many of them have inbreeding again. Too many of these agencies are involved with people who are involved with industry, who are people who are in industry, or become in that particular area when they get out of the FDA, or whatever particular commission they are on, and there is too much of that inbreeding.

Unless there are people outside of the group, outside of that place to actually administer, to look at it, to police it, to oversee it, nothing happens. That's why it's a good thing that you people are

doing this to oversee what is going on in this country with regard to quackery and problems like this.

Mr. DEWINE. Thank you very much, Doctor.

Mr. Chairman, I guess the most shocking thing to me out of this testimony is that even with these particular witnesses, where the spotlight is now on them and on the quackery, that the quackery still continues even in their specific cases—maybe not in their cases, but the same doctors, the same quacks, that preyed on them are continuing to prey on someone else today as we hold this hearing in Washington. That's what's shocking.

Mr. PEPPER. Thank you very much, Mr. DeWine.

Mr. Ridge.

Mr. RIDGE. Thank you, Mr. Chairman.

Senator, I know that, you have a couple more panels so I'll try to expedite my questions because we do have many more witnesses we want to hear.

Dr. Barnes, I was particularly intrigued by your story, inasmuch as you are a physician and pathologist. I'm sure you probably had some reservations in the back of your mind about this Bahamas clinic. Did you express those reservations to your father-in-law?

Dr. BARNES. Yes; I did.

My first opinion was, I tried to be scientific about it, and I told him, "I really don't know what it has to offer," but all my efforts to find out any specific information were frustrated.

One example. Some of Dr. Burton's literature makes a great deal of noise about how medical literature in the United States regarding cancer uses statistics to produce biased results. Well, that's very interesting, but when I called him, they couldn't give me any statistics about his results whatsoever.

Things like that led me to question any veracity to his statements.

Furthermore, as an aside, I think someone asked a question earlier about some way to compile information about these alternate modes of therapy. I think that would be very useful, because one of the most frustrating things to me was that I could not find out any information. I didn't know whether he was curing 90 percent or curing 0 percent, and I wanted to—

Mr. RIDGE. Well, I think your testimony has been particularly commendable and very powerful inasmuch as most of the victims of quackery do not have a son-in-law or daughter-in-law in the medical profession, and in spite of your concern and in spite of the expression of your reservations, the attraction and the vulnerability was still so great that he went to the Bahamas anyhow.

Dr. BARNES. Thank you.

I think one of the things that works to the quack clinic's advantage is that in the stages of dying, one of the stages is animosity, and when you harbor some animosity toward people—and I certainly felt some of it because I was a physician, and I felt guilt about not being able to do anything, or the physician couldn't do anything for my father-in-law.

Then when someone comes along and holds out a hand and says, "Come to me; I'll help you," then the obvious result is, they go.

Mr. RIDGE. Thank you, Doctor.

Mr. Horowitz, a lot of the cases that have been highlighted by today's testimony resulted from person-to-person contacts where people are actually pulled into the system of quackery. I'm sure in your position as a consumer advocate there is a lot of mail order quackery, and I'd just like you to comment on the extent of your experience. Just give us some highlights, if you would, please.

Mr. HOROWITZ. It's endless. I mean, the ads that we are looking at here—the Postal Service can go in finally, find the post office box, the mail drop, for whatever the quack cure is. By then, the people who have operated the business are gone with the money, and they've opened up a mail drop somewhere else. I mean, there just isn't the speed that they need to get in there.

But I find that it has proliferated to a point today that it is greater than I have ever seen in the 15 years that I have been investigating things like this, and it has crept into legitimate magazines—I mean the mass circulation, weekly magazines, as well as the special magazines, the tabloids that you find at the supermarkets. I mean it is just over everywhere. It is in senior citizen magazines.

I'm not talking about magazines like *Modern Maturity*, which is put out by the American Association of Retired People—they are very careful about what they advertise—but in specialized senior citizen magazines I see the same kinds of advertising that I see here. It has just proliferated to a point where it has become like the dust in the air, and it seems impossible to stop it.

With the mail that I receive, I mean, I'm not shocked any more. We know that we are going to get the mail. What frightens me is the fact that the public is not aware enough and doesn't have the information enough to look at this garbage and say, "Hey, it's not going to work," or pick up a telephone and call their family physician, or call the local medical society, or even the Better Business Bureau—which in some areas is better than it is in other areas—and say, "Do you have any complaints?" or pick up the phone and call the local postal inspector and say, "Do you have a file of complaints against this outfit which says that it can grow hair on a bald head?" or whatever the remedy is.

Here again, it's the fact that the public doesn't know. You hammer away and hammer away and hammer away.

I think part of that reason is that in the school system itself we have not developed a curriculum that really makes an impact on young people in consumer awareness, and obviously the senior citizens, who were busy fighting our world wars, who have lived through the Depression, who have raised families, and haven't had the time to go through any education system, are far worse off than the young people.

So it's something—I'm sort of rounding out the answer by saying that there is a proliferation of this stuff. There isn't enough education on the part of the public. But I also think the public is not using common sense, and the only way to develop that common sense is through education and awareness.

Mr. PEPPER. Mr. Ridge, would you yield a minute?

Mr. RIDGE. Yes; I would be happy to, Mr. Chairman.

Mr. PEPPER. Would you agree Mr. Horowitz, that the tendency of a lot of people is to believe that anything they see in print is true?

Mr. HOROWITZ. It's true. As a matter of fact, you know, Mr. Pepper, as well as many folks in Washington know, that people will adopt an editorial point of view after reading the editorial in the newspaper.

So, if you have educated people who will do that, if you have people who are unaware and uninformed, they see something in print, and they think, because it is in print, it is true. But you can't fight that as much as the basic awareness. But that is an excellent point.

Mr. RIDGE. Thank you very much.

Thank you, Mr. Chairman.

Mr. PEPPER. Thank you, Mr. Ridge.

Mr. Bilirakis?

Mr. BILIRAKIS. Thank you, Mr. Chairman.

In the interests of time, sir, I won't necessarily go into any questions but maybe just express some of my thoughts.

I think in addition to the comments that you made about people believing what they read and that sort of thing, we can't overlook the fact that I imagine many of the reasons why people probably would not inquire of their doctor and of the Better Business Bureau and what not is because they basically know that there is going to be an effort made to turn them off, an effort made that they should not take vitamin A, an effort made that they should not go to Tijuana and whatnot, and they know the answer before they would ask the question.

We have seen here a real litany of cases of fear, fear of dying, loss of hope, loss of faith, and grasping, reaching out for just anything.

I guess I can't imagine unless you go through it, and, God willing, I never will—the fear that Mrs. Peters must have felt and the concern of losing her son and just grasping for anything that might be of some help. That is something we just can't overlook, and I'm just not sure, really, what we can do about that, other than to work.

You know, educating the public is important, and yes, we should do that, but I think we have got to almost go to the source, and that is these quacks, these people who are actually preying on this fear and on this loss of hope.

Mr. HOROWITZ. But, you know, highlighting some of the cases that you have heard here this morning and the tens of thousands of cases like this across the United States is one way to send people a pretty powerful message and one way to make them aware.

Mr. BILIRAKIS. Yes.

Mr. HOROWITZ. And the educational process, I think, can do that. I think the medical societies can do that. There are now specialists on television who do medical reporting. We have them in newspapers; we have them in magazines. I think all this is possible to do by just highlighting.

I think this hearing, in itself, is highlighting problems that do exist, and I think the people who maybe watch this hearing, wherever they see it or report it, might get a germ of something that they never thought about.

So, I would say we should also continue hearings like this and continue pumping out the information.

Mr. BILIRAKIS. Mr. Horowitz, there is no question about that—the fantastic knowledge and the education that we Congressmen receive as a result of hearings like this. It helps us to be able to better convince our colleagues who don't have the benefit of it as far as Alzheimer's disease, and matters such as this are very important. But Dr. Pelly of course said it, and that is that you are the Congressmen and it's basically up to you.

Yes, I do agree with Mr. Regula that the State medical societies should place more emphasis on policing themselves and on these problems, but sometimes the job is not getting done there, and then maybe it's up to the Federal Government to get involved. So I don't know.

This is a committee that hears a lot of profound things, and yet it's not a legislative committee; for some reason, it's not empowered and doesn't have the statutory authority to create legislation, and I oftentimes wonder about that, and maybe we should take another look at that, Mr. Chairman. But it is significant.

You know, we talk about quackery, and we have heard and seen so many instances of it here today, and we all laughed at a couple of those things that Mr. Halamandaris pointed to, and yet, they were sad, they certainly weren't funny, even though we all laughed.

You know, there is quackery of other sorts, too. We have a letter being circulated throughout America right now putting fear into people that their medicare is in jeopardy and asking for donations, \$10 and above, and isn't that a form of quackery, too?

So these are all things that this committee—yes, we should continue to hold these hearings, but let's follow up and maybe create a clearinghouse and possibly start some legislation wherever it is necessary, along with the AMA, I might add. I think that anything that we might do that does not bring the doctors into the picture would be very, very wrong on our part.

Thank you very much, Mr. Chairman.

Mr. PEPPER. Thank you, Mr. Bilirakis.

I want to thank you all very, very much, panel one. You have been an outstanding panel. You were very generous and kind to come here and give your time today to this important presentation. I want to acknowledge now, this morning, the Washington Post had a good article on quackery on page 3. USA Today show has a good article also. I imagine there will be good articles in other newspapers all over the country. I think the New York Times also covered it, which indicates that the press is trying to cooperate with us to try to inform the people of the dangers of this quackery.

We are especially grateful to the the visual media, television. Up to 20 or more stations, I think, have been here today to cover the proceedings. As you know, that will give an enormous circulation to the witnesses' testimony today, to the people in the country.

At the very least we hope we can get the people to start asking questions and making inquiry of responsible people, and understanding that it is a waste of money, and sometimes a dangerous thing to do, to fall into the hands of these quacks, who are only trying to exploit their illness or their fear in order to make money.

So thank you all very much again. We appreciate it.

Mr. PEPPER. Now we will call panel No. 2, please. As your names are called, will you please come up to the table.

Mrs. Helene Brown, vice president of the American Cancer Society of Los Angeles and chairman of the Unproven Remedies Committee.

Mr. Dr. Floyd Pennington, vice president, education group, Arthritis Foundation of Atlanta, GA.

The Honorable Frank Williams—Dr. Frank Williams, the distinguished director of the National Institute on Aging, who is accompanied by Dr. Edward L. Schneider, associate director of the National Institute on Aging and head of Biomedical Research and Clinical Medicine.

Dr. Williams and his office have always cooperated with us in every way they could.

Dr. Harrison L. Rogers, Jr., speaker of the house of delegates of the American Medical Association.

We appreciate their being represented.

Ms. Helen O'Rourke, Council of Better Business Bureaus, Arlington, VA.

First we will hear Ms. Helene Brown. We are very pleased to have you, Ms. Brown, and we welcome your statement.

PANEL TWO, CONSISTING OF HELENE BROWN, VICE PRESIDENT, AMERICAN CANCER SOCIETY, LOS ANGELES, CA, AND CHAIRMAN, UNPROVEN REMEDIES COMMITTEE; FLOYD C. PENNINGTON, Ph.D., GROUP VICE PRESIDENT FOR EDUCATION, ARTHRITIS FOUNDATION NATIONAL OFFICE, ATLANTA GA; HON. T. FRANKLIN WILLIAMS, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING, NATIONAL INSTITUTE OF HEALTH, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY EDWARD L. SCHNEIDER, M.D., ASSOCIATE DIRECTOR OF THE NATIONAL INSTITUTE ON AGING, AND HEAD, BIOMEDICAL RESEARCH AND CLINICAL MEDICINE; HARRISON L. ROGERS, JR., M.D., SPEAKER, HOUSE OF DELEGATES, AMERICAN MEDICAL ASSOCIATION, WASHINGTON, DC, AND HELEN O'ROURKE, VICE PRESIDENT, COUNCIL OF BETTER BUSINESS BUREAUS, ARLINGTON, VA

STATEMENT OF HELENE BROWN

Ms. BROWN. Thank you, Chairman Pepper. It's a delight for me to be here as well. I must commend you and tell you that you are a most courageous group. This is not an easy matter to deal with.

My name is Helene Brown. I live in Los Angeles, and I currently serve as the vice president of the American Cancer Society.

In my professional life, I am the director of the Division of Cancer Control at the Jonsson Cancer Center UCLA. Since the Board of Medical Quality Assurance in California was brought into the conversation this morning, I would like to tell you that I serve on one of the committees of the Board of Medical Quality Assurance.

I have a prepared statement that has been given to you.

Mr. PEPPER. Without objection, your statement will be admitted in the record.

Ms. BROWN. Thank you very much, Mr. Pepper.

I'm going to deviate from that a bit because I think there have been some questions raised this morning that I might shed some light on.

I believe that our dependence upon the law and upon education are two excellent aims. I have no quarrel at all with the passing of laws and legislation.

I can only point out that laws are good tools, but in the long run, they do not completely answer the question or solve problems. The only thing that will is a well educated public. By a well educated public, I'm not talking primarily of the lay public, but I am also pleading to educate the professional public and the health care team. A good deal of this problem, unfortunately, is their responsibility.

Today breast cancer diagnosed in its early stages has a survival rate that approaches 90 percent. If the public and the profession made this a well-known fact, I cannot see anyone resorting to a quack remedy for as curable a disease as that.

Cervical cancer has a survival rate approaching 82 percent, colorectal 77 percent, and other cancers are similarly improving rapidly.

Quackery, in my opinion, is a new dimension in murder. The promotion of unproven remedies for cancer patients seeks to deny cancer patients the types of treatment that we know, and have absolute evidence of today, can provide them the best opportunity for cure or remission.

I want to tell you a little bit about the American Cancer Society program, because I was shocked and surprised to note that none of those testifying today called an American Cancer Society office for information.

For years, we have had a Committee on Unproven Methods of Cancer Management. Let me tell you what that committee does. It collects and distributes material on unproven methods of cancer management, diagnosis, treatment, and cure. The unique collection that we have, containing voluminous file material, is one of the principal repositories of such material in the world.

I'm very complimented at this point in time at being the chairman of that committee. We serve as a central coordinating force in this field.

We discuss legal matters, professional education, public education, public information, and public issues, and we do so at a regular meeting at least three times a year.

We publish statements, and I have given your committee samples of those statements. The most common statements that we currently published are given free of charge to anyone who calls an office of the American Cancer Society. There are thousands of offices listed in the white pages of any telephone directory.

We discussed Dr. Burton's cure this morning. We have had a statement published about his methods, warning cancer patients against it. It has been available for many years.

We discussed Dr. Revici. We have a statement on macrobiotic diets. We have a statement on laetrile, Dr. Livingston's vaccine, the Gerson, diet DMSO, antineoplastins, the Greek Cure, and so forth.

We have published all of them. They are available.

At the beginning of each statement in large, broad, capitalized letters is the following: "After careful study of the literature and other information available to it, the American Cancer Society has found no evidence that treatment with"—whatever the treatment is, immuno-augmentive therapy, or whatever—"results in objective benefit in the treatment of cancer in human beings. Lacking such evidence, the American Cancer Society strongly urges individuals afflicted with cancer not to participate in treatment with such treatment," and they are named. The remainder of the statement puts forth all of the evidence that we have on file.

If we pass too many laws and become too stringent from a legal point of view, we are going to stop research in this country. Let us not forget that bona fide, valid research is also the use of unproven methods of cancer management.

We must carefully weigh and measure the risks and the benefits. The quacks know that we, in the pursuit of cures, are using treatment which may not work. It's a very gray area and fine line when someone greedy tries to profit by hiding behind the word "research." We must consider this aspect before passing laws which may harm research.

I would suggest that the Food and Drug Administration might think about releasing drugs, experimental drugs, drugs that may in fact show promise, to ill patients, to patients who may in fact be dying, under a different set of circumstances than they are releasing them to well patients, where side effects make a difference.

If I were dying of breast cancer today, I honestly wouldn't give a darn about a side effect that might take place 10 years from now. I would want to try an experimental drug. I believe the FDA has a method of dealing with the problem. They have addresses it.

In addition, we need stepped-up programs of professional education. Cancer may not always be curable, but let me tell you, it is always treatable. For any member of the health care team—physician, nurse, psychologist, or other telling a patient, "There is nothing more than I can do," is opening the door for that patient to go seeking a miracle in the hands of a quack.

Our health team today is clearly inadequate in the way in which we manage cancer. First, because we can't cure it 100 percent of the time; second, because in spite of the improving survival rates, our treatments are still harsh. There's nothing easy about surgery, radiation, chemotherapy, immunotherapy, or any combinations of these.

The result is, however, that we do cure patients, and we on the health team have an obligation to hold the hands of the patients and their families in a considerate, time-consuming, compassionate, clear manner. I am sorry to tell you that many of the patients that I talk to, who use all of these things that you see before you, have done it because the health care team has abandoned them.

They did not speak clearly. They did not tell them what to expect. They did not tell them that there are hills and valleys, that it takes time, and physicians—the whole health care team needs to take time to explain to the patients, to touch them, to explain again, and again, and again. On the first visit, a patient is told he has cancer, he doesn't hear one other thing. If the physician has his hand on the door knob, ready to leave the room as soon as he is

finished talking, we on the health care team are offering another patient to another quack.

The Federal Government supports a Cancer Information Service with an 800 number, 1-800-4-CANCER. Anyplace in the country, one can dial that number, and reach into the National Cancer Institute. They will answer any of your questions and send you any booklets about cancer that anyone should desire. They will tell you where to get a second opinion. They will give you the information that will help to dissuade the public from using the unscrupulous.

The contracts for the Cancer Information Service supported by the National Cancer Institute are due to expire on November 30. Unless somebody takes some swift action, this resource may in fact be phased out. We have some action we can take today in assuring that this does not happen.

Mr. Chairman, I want to tell you again that you have the people on your side. Most patients who choose the promises of the purveyors of false remedies and hopeless cures are under the impression that they are not going to suffer any side effects and that they are going to find any easy, simple way to cure cancer. It just isn't so, and with hearings such as this, I think you have done the nation a tremendous service.

The American Cancer Society, as you can see, has resources to put at your disposal, and I'm pleased to tell you that we are with you every step of the way.

Thank you so much for giving us this opportunity.

[The prepared statement of Ms. Brown follows:]

PREPARED STATEMENT OF HELENE G. BROWN, VICE PRESIDENT, AMERICAN CANCER SOCIETY, AND CHAIRPERSON, UNPROVEN METHODS OF CANCER MANAGEMENT, ACS NATIONAL BOARD OF DIRECTORS

Mr. Chairman, my name is Helene Brown. I live in Los Angeles, and currently serve as Vice President of the American Cancer Society, and Chairperson of the ACS Committee on Unproven Methods of Cancer Management. This work is my voluntary activity to which I devote about 20% of my time. Today I represent the 2¼ million American Cancer Society volunteers as well as the contributing public who mandate our work through their support, which this year is in an amount exceeding \$225 million.

Professionally, I am the Co-Director of the Division of Cancer Control of the Jonsson Comprehensive Cancer Center at the University of California at Los Angeles (UCLA), and a Senior Lecturer at the UCLA School of Public Health.

There are more than 100 kinds of cancer. Cancer of the lung caused by cigarette smoking, for example, is not the same as leukemia in a 2-year-old child. Leukemia is not the same as breast cancer. Cancer is a complex family of diseases, primarily of older age groups.

Today, people diagnosed as having cancer have a relative survival rate five years after diagnosis of 48%. This is higher than it has ever been, and it continues to improve. Breast cancer diagnosed in its early stages now has a survival rate approaching 90%; cervical cancer 82%; colorectal cancer 77%. Others are similarly high.

The promotion of unproven remedies for cancer patients seeks to deny the cancer patient the types of treatment known to provide the best opportunity for remission or cure. Cancer patients are being exploited at a time in their lives when they are least able to turn away from the lure of false promises.

Individuals select unproven methods of treatment either in place of, or in addition to conventional therapies due to fear, superstition, false hopes for a quick and easy solution to a complex problem promised by unproven methods promoters.

Time is the achilles heel of cancer. When a proponent of unproven remedies lures a patient away from valid treatment he or she is depriving that patient of the opportunity for cure or significant prolongation of life. This is wrong and must be stopped.

The most common unproven methods being used today are: (1) Immuno-Augmentative Therapy (IAT), (2) Macrobiotic Diets, (3) Laetrile, (4) Dr. Livingston's vaccine, (5) Gerson diet, (6) Dimethyl Sulfoxide (DMSO), (7) Antineoplastins, and (8) The "Greek cancer cure" of Hariton Alivizatos, M.D.

I have provided the Committee with individual statements on these methods based on analyses done by the American Cancer Society. As you will note, each of these statements opens with the American Cancer Society position on the method. I will read the one referring to Immuno-Augmentative Therapy.

"After careful study of the literature and other information available to it, the American Cancer Society has found no evidence that treatment with Immuno-Augmentative Therapy results in objective benefit in the treatment of cancer in human beings. Lacking such evidence, the American Cancer Society would strongly urge individuals afflicted with cancer not to participate in treatment with Immuno-Augmentative Therapy."

Some of these "remedies" are, in addition to being ineffective against cancer, potentially harmful to humans. However, even if they do not directly cause injury by themselves, when they are used instead of valid therapy they significantly reduce the patient's chances of survival.

The emotional trauma associated with raising false hopes is cruel and debilitating. The financial costs of being lured to unproven methods can bankrupt a family.

While we can gather anecdotal information and provide warnings and educational programs for all persons, the American Cancer Society has had a difficult time gathering valid data on the extent of the problem. It would be of great value to the ACS and to the American people if this Committee would conduct a thorough investigation of the use of unproven methods of cancer management in this country. We would be pleased to use the information you develop to include in our programs of educating the public about the problem.

We believe that you have the people on your side. We believe that most patients who choose the promises of the purveyors of false treatments are under the impression they will suffer no side effects and will experience a simple, easy way of curing cancer. We also believe that after they learn the unhappy truth, if they could, they would come forth freely to denounce those who promised the simple solution and led them away from treatments known to be effective. Unfortunately, most of these people are in the graveyards—they did not get that chance.

The trauma brought about by patients choosing unproven methods goes farther and deeper than the unfortunate victim. It strikes the families and friends as well.

The American Cancer Society has led the fight against unproven methods of cancer management and their purveyors, but we are constrained by limited resources and our many other obligations. We do all that we are able to pursue tips and complaints about unproven methods, but that is not enough.

Mr. Chairman, you Committee has the authority and the duty to investigate the promoters and purveyors of unproven methods of cancer management. We can assist you as to who they are, where they operate, what their claims are. Our unproven methods files are open to this Committee. We can direct you to physicians who treat the dying patients when they return in desperation, hoping that they will be able to benefit from valid treatments. They rarely can.

Mr. Chairman, I speak to you from troubled personal experience. As the Chairperson of the American Cancer Society's National Board Committee on Unproven Methods of Cancer Management, I am the person to whom many desperate people call for help—cancer victims who suddenly realize how hopeless their chances are, having chosen the simple promises of metabolic, or vitamin, or nutrition therapy, or some other unproven method—who are now hoping against hope that something can be done for them, and if not, that those who diverted them from a real chance for remission or cure are exposed for what they really are. This Committee can help the American people in this cause, Mr. Chairman, and we urge you to do so.

Please accept our deep appreciation for your interest in this cruel problem, and please accept the willingness of the American Cancer Society to do all that we are able to aid you in your efforts.

Thank you.

Mr. PEPPER. Well, Ms. Brown, you have given us a magnificent statement, and we are grateful for your presence here today.

You have given us a great many facts and a great many valuable assurances that mean a lot to a lot of people. I just told our staff director, "Be sure to remind me about this expiration of that service" that you tell about. We will see what the trouble is. I reckon

the money is about to run out, or something, but we will look into the matter and see if we can't do something about it.

Ms. BROWN. Thank you very much.

Mr. PEPPER. We are delighted to do it. The American Cancer Society has made an enormous contribution to the battle against this tragic disease.

You know, it seems to me that if over 400,000 people were being swooped up by some monster coming into our country, we'd arouse our people and we'd say, "It's not a matter of money; we are going to conquer this monster that's taking half a million of our people every year."

Ms. BROWN. Mr. Pepper, it's one of the most serious social evils that we have in our country.

Mr. PEPPER. I knew several Senators when I was in the Senate who died of cancer, who voted against appropriating more money for research and said the Government couldn't afford it. But I think our Government can afford what is necessary for our people to survive.

I just wish I could hear all of this fine panel. Unfortunately, I have to excuse myself and go over to another meeting, and I have Rules Committee meetings right after lunch. There is some important legislation coming up this afternoon.

Fortunately, we have in attendance one of the finest members of this committee, Ms. Mary Rose Oakar—will you be able to stay—you and Mr. Borski?

Ms. Oakar and Mr. Borski, on the majority side here, are deeply interested, as are my colleagues on the other side, and they have agreed to stay, too, as long as they can. So there are going to be some very representative committee members here to hear you.

And remember, there is a reporter over there taking down every word you say. It will all, in a little while, be properly printed up and available for the edification of the American people.

This is a distinguished panel, and I wish I could hear every one of you give your important testimony, but you may be sure, I'll ask the staff to give me a summary of what each one of you said, so I'll have the gist of your testimony that I can read.

So thank you all very much for coming. We are profoundly grateful to you, and we'll try to consult with knowledgeable people like you to see if we can't do something that will be helpful to the people.

As I said, I know the Governor of Florida told me yesterday in Tallahassee when I was there, when I asked what laws the State of Florida had to try to prohibit this kind of thing, "Well," he said, "you know, I vetoed a bill that authorized the continuation of this clinic over in the Bahamas"—which reference has been made to here today. "The legislature overrode my veto."

So sometimes all public authority doesn't support the efforts against quackery, but we will find some way to do more than has been done in the past; I'll assure you of that; and we appreciate your help.

Ms. Oakar, will you please take over?

Ms. OAKAR [presiding]. Thank you, Mr. Chairman.

I think we all owe you a debt of gratitude for having these hearings.

Ms. Brown, I'd just like to say that you might be interested in knowing that the committee—my chairman has agreed to have a hearing on a subject that is of great interest to me—breast cancer—because people, particularly women, are not aware of the options they have, and they are scared to death. You mentioned the 90-percent cure rate, and I think this is really important. So that will be coming up in the future, and I am sure we will want to have you back.

Ms. BROWN. I would love the opportunity. Thank you.

Ms. OAKAR. Thank you.

Our next witness is Dr. Floyd Pennington, who is the group vice president for education, Arthritis Foundation, national office.

What I would like to ask the witnesses—because I guess we really are behind, and you are probably delayed also—is, if there is a way that you can summarize your statement, then you can give us some time to question you, and we can get on to making sure that we hear from everyone today.

Dr. Pennington, thank you very much for being here.

STATEMENT OF FLOYD PENNINGTON

Mr. PENNINGTON. Thank you, Ms. Oakar, and I will summarize my comments and leave the text of the comments for you. I believe you already have that.

Ms. OAKAR. We will put your entire statement in the record, because the record is very important to us. Thank you.

Mr. PENNINGTON. Like the American Cancer Society, the Arthritis Foundation also has a very active program against arthritis quackery, which, according to the committee report prepared for you, is probably close to a \$2 billion a year business. We can estimate that a fair amount of that money goes out of the pockets of the elderly in this country.

Unlike the American Cancer Society, the 36 million Americans that suffer from the arthritides have few opportunities to look forward to cure at the present time. This makes them great prey for people who are trying to hustle hope disguised as a medical cure, as a device that will assist them in managing their arthritis, or in something that will help them overcome the tremendous pain and potential disability that they are facing.

Statistically, 90 percent of all the people in this country who have arthritis, will sometime during the course of their disease, turn to one of these remedies. Why? Simply because of many of the things that have already been stated, including the distrust of the medical profession, the way in which the medical profession and those of us who are in health education deal with those persons who have a chronic disease, and mistrust of the Federal Government in their efforts, supposedly to protect them against health fraud and to protect them against bad medical care. There is a great distrust—I think we recognize that—and especially a great distrust among those people that turn to these alternative remedies.

The burden against health fraud falls to the private sector. The Government is ineffective, they have no money for enforcement. In the private sector, business has no interest. That leaves it to the

voluntaries to do the job. The job is immense, given the figures that we have seen and the number of people who are involved.

Let me just suggest, in collaboration with others who have spoken today, that we establish a major educational campaign that will enable people to recognize good health decisions that need to be made about their body, regardless of the disease, and especially a way to recognize health fraud and a way that they can debunk the con artist; second, that major funds be given to the regulatory agencies for regulation, not only for investigation of things that are reported to them but in a proactive way to go after people that are hustling this public; and, third, some strong opposition both at the Federal and at the State level against promoters of pet cures that seek to use the law as a protective way to get their particular cure approved by the State and perhaps by the Federal Government when we know, based on all the evidence that we have, that the claimed cure has no possibility of doing that person any good.

We have an ignorant public regarding arthritis. Things can be done to manage the disease and the disability, and only in cooperation with Federal agencies, State agencies, AMA, other medical associations, and the voluntaries like the Arthritis Foundation, Cancer, Diabetes, and others, will we be able to attack this problem.

We cannot tolerate promoters of false hope. We have to support investigators seeking ways to manage these diseases, and I encourage this committee and all of its power to put its efforts behind that in cooperation with the others who are here doing the job that the Federal Government seems unable to do at the present time.

Thank you.

[The prepared statement of Mr. Pennington follows:]

PREPARED STATEMENT OF FLOYD C. PENNINGTON, PH.D., GROUP VICE PRESIDENT FOR EDUCATION, ARTHRITIS FOUNDATION, NATIONAL OFFICE, ATLANTA, GA

My name is Floyd Pennington, Group Vice President for Education, with the National Office of the Arthritis Foundation, the only voluntary health agency concerned with finding the cause, prevention and cure for this nation's number one crippling disease—arthritis. If current estimates regarding the economic impact of arthritis health fraud are correct, for every dollar currently going toward scientific research in arthritis diseases, another \$50 is spent on worthless nostrums and unproven or irrational treatments. Of the estimated annual two billion dollar arthritis health fraud business, it is reasonable to expect that the greatest proportion of that is being spent by this nation's older adults.

Ninety percent of the people with arthritis at some time, and often many times during the course of their disease, will try an unorthodox arthritis treatment. Much of this is a desperate attempt to find something that will stop the excruciating pain associated with arthritis. Placebo peddlers capitalize on this desperation by selling false hope, packaged as quasi medical potions, gadgets, diets or miracle cures.

Despite strict laws against false advertising and misbranding of consumer products, the market for health ripoffs is an immense and many times a life-threatening business. The misery merchants today are clever businessmen capable of bending the laws to their advantage or breaking the law with little fear of retribution.

Even with adequate laws to protect the American public from these fraudulent practices and with major government agencies charged to enforce them, the 36 million Americans with arthritis are still confronted daily with a barrage of ads, direct mail promotions, and media exposure to these swindlers. Why? Quite often because the same laws that grant freedom of speech also give wide latitude to those who mislead and deceive the public.

The government is ineffective in protecting the public against health fraud. Agencies do not have resources to handle cases reported to them, let alone becoming proactive in finding out about the products and ads not reported. The agencies claim

to set investigative priorities for the most hazardous and major economic frauds. Yet little is even done at this level. In the meantime, dollars flow out of the pockets of the person with arthritis into the pocket of the huckster. Those same dollars could have acquired proper medical care to control the painful symptoms of arthritis and reduce the probability of severe crippling and disability resulting from the arthritis.

The burden of the battle against health fraud falls to the private sector, and in that sector business has no interest. Therefore, current initiatives in the battle against health fraud falls primarily to the voluntary health sector and consumer advocate organizations. Scarce resources are even more of a problem in this sector. The result—the bilking of the American public of ten billion dollars a year—two billion of that from persons with arthritis, the majority of whom are aged.

The Arthritis Foundation calls on the federal government to do four things and strongly urges this committee to use its power to accomplish these tasks:

1. Increase funding for arthritis research by establishing a National Arthritis Institute in the National Institutes of Health.

2. Establish a major national Public Education campaign using every available media aimed at teaching people how to recognize health fraud and what legal actions are available to put the quack out of business.

3. A major increase in funds to existing government agencies to support efforts to investigate and prosecute health fraud practitioners.

4. Strong government opposition at both the federal and state levels to promoters of "pet" cures using the law to legitimize unproven unorthodox and potentially dangerous arthritis treatments.

The nation's elderly will be plagued by arthritis until its causes are found and prevented. The nation's elderly will be targets for fraudulent health promoters who peddle false hope, not cures, until cures are found. The nation's elderly are protected from health fraud by intention only—not be action.

We have an ignorant public regarding arthritis. The Arthritis Foundation is working diligently to change this. Distractors abound who are promoting false hope. We must change the capabilities of our population to make good health decisions, including how to recognize and dismiss the health con artist. If not, we will live under the horrendous economic burden of an increasing number of disabled elderly who were misguided, misinformed, and mugged by the larceny of a few greedy health fraud entrepreneurs.

Ms. OAKAR. Thank you very much, Dr. Pennington. Thanks for supplying the committee with some of the quackery devices.

Mr. PENNINGTON. I have plenty more, if you would like some.

Ms. OAKAR. I know.

Our next witness is the distinguished Dr. T. Franklin Williams, who is the Director of the National Institute on Aging, accompanied by Dr. Edward Schneider, who is the Associate Director of the National Institute on Aging for Biomedical Research and Clinical Medicine.

Thank you very much, gentlemen, for coming before the committee.

STATEMENT OF HON. T. FRANKLIN WILLIAMS, M.D.

Dr. WILLIAMS. Thank you, Ms. Oakar, to you and members of the committee. Dr. Schneider and I are very pleased to have a chance to be here.

I have furnished printed testimony and will just summarize it at this time, if that's all right.

Ms. OAKAR. We will submit the entire testimony for the record.

Dr. WILLIAMS. Thank you very much.

I think it's important to keep in mind in thinking of older people, as we do constantly in the National Institute on Aging, that the chronic diseases and disabilities that occur commonly in later years often bring hard choices. Fears and despair may drive people to desperate measures, and all too often older people fall for home

remedies or advertised schemes which hold great promise for benefit or cure.

We have always been a society that looks for fountains of youth, and these are still illusions today, as they have been in the past. Major progress has been made in establishing that many disabilities once thought inevitable may, in fact, be treated successfully, but nevertheless there is decline with age and usually from multiple causes.

We have to keep in mind that there is almost certainly no single total answer to aging or antiaging efforts, and the truth is that progress toward better health will come from progress in segmental or sequential steps over a number of individual fronts.

There have been many good theories advanced about the process of aging and what steps might be taken to minimize or slow down this process, and unfortunately what happens is that faddists or charlatans will pick up some of this information and use it to try to justify an otherwise dubious product.

A good example is cited in your own testimony with superoxide dismutase, or SOD, a naturally occurring enzyme found in all organisms that use oxygen for their metabolism. Its main function is apparently to help avoid some harmful side effects that would occur from oxydized materials inside cells.

This enzyme, as I say, is a naturally occurring substance and does have a role, and in some studies in animals it has been suggested that the more of this enzyme there is present, the longer the lifespan of a given species. Even that evidence needs further examination, but using facts such as this and interesting leads about the process of aging, people have marketed this enzyme as a powder to take orally, on the theory—or on the proposition to the public that it would help prevent aging.

This seems to be totally unlikely, if for no other reason than the enzyme is a protein which is digested when eaten and would never enter the circulation in any active form. This idea is parallel to the idea that some people have had that one could take insulin by mouth, which of course we know is ineffective. I might add that we have no solid evidence that superoxide dismutase would be effective when injected either.

This type of reasoning is also similar to using the knowledge that nerve cells in the brain are involved with intellectual function and, therefore, deciding that it is useful to eat brains to improve intelligence.

Similar claims have been made for a number of other agents—and I cite some others in our summary—as you do in your own report—to indicate how scientific information is picked up and misused in the marketing of a number of substances.

The National Institute on Aging does give considerable attention to efforts to understand the process of normal aging as well as the diseases that afflict older people. I think it's reassuring to find that such age-related changes are, for the most part, gradual in the healthy person and not disruptive, and what we really need to do is to look more and more for the disease conditions that are potentially treatable or manageable.

We receive many calls and letters, just like the other agencies or other people speaking here today, with questions about what might

help in the aging process, and we have an extensive public correspondence.

We publish many Age Pages which deal with these issues. I have several along with me today. A new one is just about to come out on "Can Life Be Extended?"

We try to address these issues in a sound, scientific way, and continually try to help the public make the distinction between what is quackery and what may be useful.

Ms. OAKAR. You know, Doctor—if I could just tell you—my senior citizens in my area love those Age Pages. I think that's one of the nicest things that you put out, and they read them as well. So I hope you continue, and I hope the administration continues to let you do that as well.

Dr. WILLIAMS. Well, we appreciate that and appreciate that compliment, and we certainly find a vast interest in them.

The NIA is concerned about testing legitimate theories and potentially valuable agents. We carry on this research constantly, and we are ready to direct it toward any important questions.

I want to close by saying that there are a lot of reasons to be cautious about turning to any untried measure. Among those that have been mentioned by others testifying today is the clear fact that spending money on questionable items can divert attention from what might be essential efforts toward cure, or hoping for a cure based on a home remedy or some other product may delay timely professional consultation for appropriate therapy.

The public should be suspicious of any product or technique that promises to slow aging or extend life or produce major changes in appearance or vigor.

Ms. Oakar, I'd be very happy to try to answer questions, as would Dr. Schneider.

[The prepared statement of Mr. Williams follows:]

PREPARED STATEMENT BY T. FRANKLIN WILLIAMS, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING, NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICE

Mr. Chairman and Members of the Subcommittee, I am Dr. T. Franklin Williams, Director of the National Institute on Aging. I am very pleased to be here today.

The chronic diseases and disabilities that occur commonly in the later years often bring hard choices to older people. Fears and despair may drive people to desperate measures. Modern medicine seems mysterious to some as well as expensive and all too often older persons fall for "home remedies" or authoritatively endorsed schemes which hold great promise for benefit or cure. Those who would mislead the public have often shown an uncanny ability to use legitimate substances illegitimately and to blur the line between science and anecdotal evidence.

Mankind has always sought the fountain of youth; today it would be billed as an "anti-aging fountain" and it would spout vitamin pills and enzyme potions. It would still be an illusion. Although major progress has been made in establishing that many disabilities once thought inevitable with advanced age are disease processes and not true aging processes, decline still occurs, usually from multiple causes, and eventually death. It is totally understandable that people would want to prolong what they call "youth"; and what I would call "good health." No single significant factor has as much to do with how young one feels as health. The quest is for a simple, single, and total answer. The truth is that progress toward better health and enjoyable aging will come from progress in sequential steps on a number of individual fronts addressing specific diseases in an individual.

Many substances or theories now being seriously studied are taken up by faddists or charlatans to add a scientific gloss to an otherwise dubious commercial project. Consider the promotion as anti-aging or life-extension agents of the following: Levodopa (for increased life span, energy and motivation for exercise), superoxide dismu-

tase (SOD), (to prevent body damage), DHEA, dehydroepiandrosterone (marketed as life extender), Gerovital-H3 (general anti-aging effect), lecithin (memory), choline (memory), BHA, butylated hydroxyanisole (food additive, anti-aging), BHT, butylated hydroxytoluene (food additive, anti-aging), and vasopressin nasal spray (to improve intelligence).

The evidence that any of these are beneficial as claimed is slim and often based upon erroneous interpretation of scientific information. Consider just one of these "miracle" substances, superoxide dismutase (SOD). SOD is a naturally occurring enzyme found in all organisms which use oxygen to obtain energy from food. Its main function, as we know it, is to break down superoxide, toxic substance resulting from the normal process of converting food to energy. One theory of aging postulates that products of this process, "free radicals," are unstable and bounce around inside body cells, often damaging their membranes and the vital proteins, fats, and DNA (deoxyribonucleic acid) within them. SOD is an antioxidant, (others are vitamins A, C and E, and minerals zinc and selenium.) Anti-oxidants can be obtained from food and some are produced by the body. Our NIA animal studies show that longer-lived species possess more of this substance (SOD) in their systems than do animal with shorter lifespans. However this does not imply that taking SOD orally will increase lifespan. In fact this seems very unlikely to be the case as SOD is a protein and taken orally would be digested like any other protein. The logic is flawed. It is similar to using the knowledge that nerve cells in the brain are involved with intellectual function and making a judgment that eating brains would improve intelligence.

Analogous claims have been made for many substances concerning not just anti-aging effects, but also in the treatment of many diseases common in the later years such as arthritis and cancer.

WHAT CAN THE NIA DO?

Much of the research supported by the NIA both in its own laboratories, and extramurally in laboratories across the country is directed at understanding the process of normal aging, as well as the study of the diseases that afflict older people. Some find it reassuring to learn that our longitudinal studies at the NIA's Gerontology Research Center show that age-related changes are for the most part gradual and in a healthy person, not disruptive. We know that the public is seriously concerned about health issues, about the associated costs of illness and about maintaining health and minimizing the effects of chronic diseases and disabilities in the later years. The National Institute on Aging receives many calls and letters each week about memory loss, decline in sexual function, skin problems, nutritional needs—including the use of vitamins in megadoses—and safe exercise. The concerns of the public along with those of the health community and the broader society help us to establish our research priorities.

The NIA is concerned about testing legitimate theories and potentially valuable agents. Such research goes on constantly and can be sensitively redirected to answer important questions.

The NIA is committed to health education and to sharing quickly and efficiently the best state-of-the-art knowledge about aging and the common disorders associated with the later years. We publish a series of lay pamphlets entitled "The Age Pages," and we are involved in an interagency health promotion campaign directed at the elderly. We can offer some hopeful, and safe, advice to the elderly . . . and by implication to all who will someday become older. We suggest that the best chance of having a good life and a long one will improve if you: Don't smoke. Stopping even after years of smoking can help reduce health risks. Use alcohol moderately or not at all. Maintain and/or develop improved exercise patterns. Use seatbelts. Eat a balanced diet, avoiding large amounts of fat, and sugar. Maintain your desirable weight. Have regular health checkups. Follow directions concerning medications. Have your blood pressure checked and obtain therapy if indicated.

BE CAUTIOUS

There are many reasons to exercise caution when you are concerned about aging or suffering from a disease. Medical science is moving quickly; a problem without a solution one day is solved the next. It is an unprecedented time of progress. Many people promise miracle cures and substances that solve many problems at the same time. Researchers look with suspicion on such claims knowing from hard experience that answers are usually specific to a problem and that few miracles exist. There are good reasons to question extravagant claims. Spending money on questionable items can divert precious and often limited funds from more essential nutritional or

medical purchases. Hoping for a cure based on a home remedy or a highly touted product can delay timely consultation with a physician and appropriate therapy. It is best to check with a doctor before buying an over-the-counter preparation or making a substantial dietary change. The public should be suspicious of any product or technique that promises to slow aging, extend life, or produce major changes in appearance or vigor.

Mr. Chairman, this concludes my prepared statement and I will be happy to answer any questions.

Ms. OAKAR. Thank you both very much.

Dr. Schneider, did you have anything you wanted to add?

Dr. SCHNEIDER. Nothing to add.

Ms. OAKAR. Thank you.

Our next witness is Dr. Harrison Rogers, speaker of the House of Delegates of the American Medical Association.

We know you have a very extensive testimony, Doctor. We would love to submit the entire testimony for the record, and you may proceed.

STATEMENT OF HARRISON L. ROGERS, JR., M.D.

Dr. ROGERS. Thank you, Madam Chairman.

We have submitted this for your information.

I am Harrison Rogers. I'm a general surgeon in private practice in Atlanta, GA.

We, first of all, would commend the committee for the investigation and for the report that it has produced. We find both to be very beneficial.

Health fraud, often referred to as medical quackery, continues to thrive and grow, as has been pointed out already today, in this country. In many cases, health fraud results only in the waste of a person's financial resources. This can be serious, since those susceptible often have limited resources, and such expenditures may deprive these people of their daily essentials, such as their food.

However, health fraud can, and frequently does, have direct, significant, adverse health consequences. This is particularly likely when a person turns away from regular medical care and delays receiving proper medical treatment because he or she is relying on false hope by a practitioner, providing a medically unsound practice or a miracle cure.

Unfortunately, by the time many of these people realize that they have been deceived, it may be too late to prevent serious consequences. Patients have aggravated existing conditions or even died unnecessarily because they utilized these systems or treatments.

For example, had some cancer patients sought or followed through with recognized medical care instead of utilizing such methods as coffee enemas or laetrile, a remission or even a cure might be possible in many cases.

We recognize that the subcommittee is particularly concerned about health fraud that affects the elderly. While the elderly do constitute a highly vulnerable group for whom wasted dollars result in a particular economic hardship, they generally fall prey to the same kinds of health fraud that is perpetrated against other age groups as well.

The AMA has had a long-standing interest in the issue of health fraud. Over the years, the AMA has worked vigorously to fight

health fraud, and the association is as committed today as it was in 1947 to the pursuit of medicine based on the best scientific information available.

Our efforts over the years have included the sponsoring of a number of national medical quackery conferences that were designed to draw national attention to the great waste of financial resources and in some cases the waste of human life caused by quackery.

These conferences were a cooperative effort between the FDA, the AMA, and other private organizations.

Currently, the AMA's primary focus in fighting health fraud is through education of physicians and the public. We respond to numerous inquiries from physicians, other health care practitioners, and members of the public concerning questionable medical practices.

Some of the most common inquiries we receive relate to megavitamin therapy, chelation therapy, and laetrile. We provide these persons with information concerning the particular therapy or product in question.

The information comes from varied sources, and we work closely with such groups as the American Cancer Society, the American Lung Association, Multiple Sclerosis Foundation, and the Better Business Bureau.

By making such information available, we try to provide a basis for an individual to make reasoned judgment on what type of therapy to pursue. We believe that informed individuals are the primary defense against the charlatans who perpetrate health fraud.

The AMA provides pamphlets, of which this is an example, on all sorts of health fraud that will help people to identify the problems that are facing them and to seek the proper solution.

Another activity through which the AMA provides valuable information to the medical profession and the public is our diagnostic and therapeutic technology assessment, or DATTA project.

The purpose of the DATTA project is to provide reliable and authoritative information concerning whether a particular drug regimen, medical device, or medical procedure used to diagnose or treat illness is safe and effective. The process is founded on an assessment of opinion and practices of expert physicians across the country.

When a DATTA opinion has been finalized, it is promptly sent to the party who requested it, to each panelist queried in preparation of the opinion, and to each organization that participated in this decision, to all publications, and to the public information resources in the AMA, and to the Journal of the American Medical Association for publication, and its indexing.

The AMA recognizes that some health fraud may be committed by physicians, and we heard one example of that today. While the number of physicians who perpetrate such fraud is miniscule, we acknowledge a duty to the public to police our ranks. Our policy in this regard is to deny membership or to revoke the membership of any physician who is determined to have committed health fraud.

We must also note that the AMA is a private, voluntary membership organization and thus lacks the power independently to in-

investigate and punish purveyors of health fraud who are not AMA members.

However, when an allegation of health fraud is brought to our attention, we make referrals to State boards of medical examiners, local medical societies, postal authorities, the State attorney general, or other appropriate Federal and State authorities.

The AMA believes that the Federal Trade Commission, the Food and Drug Administration, and the U.S. Postal Service should be commended for their efforts in attempting to curb health fraud. We urge the Congress to provide adequate funding to enable these agencies to expand their efforts. We also recommend that Congress carefully review pertinent existing laws which may hinder authorities from more effectively combatting health fraud.

For example, diet fads and certain vitamin regimens have been falsely promoted as being effective in preventing or curing disease. A principal cause of this type of fraud is a gap in the Food and Drug and Cosmetic Act whereby the FDA is currently prohibited from regulating vitamin-mineral supplements as over-the-counter drugs. The result is that the American public spends millions of dollars each year on food supplements whose safety and efficacy have never been demonstrated. We urge you to give the FDA the authority to regulate these products and the money to do it.

Madam Chairman, the AMA commends the subcommittee for conducting an extensive investigation of this sort. We remain staunchly committed to the practice of scientifically based medicine and the elimination of health fraud.

There is no simple solution to this problem, however. The AMA recognizes that patients who are ill, suffering from pain or chronic disease, are particularly susceptible to the appeals of the charlatan and the purveyors of health frauds. Many people continue to search for shortcuts to good health.

What is needed is an intensified, coordinated effort by the medical profession, the appropriate Government agencies, and Congress, as well as other interested voluntary organizations to educate the American people concerning health frauds and to eliminate this practice. We stand ready to help in this effort.

Thank you, Madam Chairman.

[The prepared statement of Dr. Rogers follows:]

STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION, PRESENTED BY HARRISON L. ROGERS, JR., M.D.

Mr. Chairman and Members of the Committee, my name is Harrison L. Rogers, Jr., M.D. I am in the practice of General Surgery in Atlanta, Georgia. I serve as speaker of the AMA's House of Delegates. Accompanying me are Harry N. Peterson, Director of the AMA's Division of Legislative Activities; Betty Jane Anderson, Associate General Counsel of the AMA; and Philip L. White, Sc.D., Director of the AMA's Division of Personal and Public Health Policy. The AMA is pleased to be invited to take part in the Committee's hearings concerning the problem of health fraud.

BACKGROUND

Mr. Chairman, we commend this Committee for addressing the important issue of health fraud. The consequences of health fraud are to be measured not only in lost dollars for useless "cures," but unfortunately also in terms of human pain and suffering for those who are lured away from effective medical care by the false promise of a painless or other quick or easy cure.

Health fraud, often referred to as medical quackery, continues to thrive in this country. In many cases, health fraud results only in the waste of a person's financial resources. This can be serious since those susceptible often have limited resources and such expenditures may deprive these persons of daily essentials such as proper food. However, health fraud can and frequently does have direct significant adverse health consequences. This is particularly likely when a person turns away from regular medical care and delays receiving proper medical attention because he or she is relying on false hope by a practitioner providing a medically unsound practice or "miracle cure." Unfortunately, by the time many of these people realize they have been deceived, it may be too late to prevent serious consequences. Patients have aggravated existing conditions or even died needlessly because they utilized unproven or useless treatments instead of seeking competent medical advice. For example, had some cancer patients sought or followed through with recognized medical care, instead of utilizing such means as coffee enemas or laetrile, a remission or even a cure might have been possible.

We recognize that the Subcommittee is particularly concerned about health fraud that affects the elderly. While the elderly may be a highly vulnerable group for whom wasted dollars result in particular economic hardships, they generally fall prey to the same kinds of health fraud that is perpetrated against other age groups. In light of the extreme adverse consequences of health fraud for the total population, our activities and the comments we make today apply to the problem of health fraud in general.

AMA ACTIVITY

The AMA has a long-standing interest in the issue of health fraud. In fact, when the AMA was founded in 1847 one of its two principal purposes was to combat medical quackery.

In adopting a Code of Medical Ethics, the founders of the Association observed: "Physicians, as conservators of the public health, are bound to bear emphatic testimony against quackery in all its forms; whether it appears with its usual effrontery, or masks itself under the garb of philanthropy and sometimes of religion itself. "By an anomaly in legislation and penal enactments, the laws so stringent for the repression and punishment of fraud in general, and against attempts to sell poisonous substances for food, are silent, and of course inoperative, in the cases of both fraud and poisoning so extensively carried on by the host of quacks who infest the land."

Over the years the AMA has worked vigorously to fight health fraud, and the Association is as committed today as it was in 1847 to the pursuit of medicine based on the best scientific information available.

Our efforts over the years have included the sponsoring of a number of national medical quackery conferences that were designed to draw national attention to the great waste of financial resources and in some cases the waste of human life caused by quackery. These conferences were cooperative efforts between the Food and Drug Administration (FDA), the AMA, and other private health organizations.

Education of the public

Currently, the AMA's primary focus in fighting health fraud is through education of physicians and the public. We respond to numerous inquiries from physicians, other health care practitioners, and members of the public concerning questionable medical practices. Some of the most common inquiries we receive relate to megavitamin therapy, chelation therapy, and laetrile. We provide interested persons with information concerning the particular therapy or product in question.

The information comes from varied sources and often may include recent articles from respected medical journals including the Journal of the American Medical Association and the New England Journal of Medicine. If such information is not readily available, we perform a computerized search of the medical literature and consult with the appropriate professional organizations. In performing this information dissemination function, we work closely with groups such as the American Cancer Society, the American Lung Association, the Multiple Sclerosis Foundation, and the Better Business Bureau. (Attached to our statement are two examples of the kind of information we provide to the public. One packet of information relates to chelation therapy and the other to fresh cell therapy.)

By making such information available, we try to provide a basis for an individual to make a reasoned judgment on what type of therapy to pursue. We believe that informed individuals are the primary defense against the charlatans who perpetrate health fraud.

Another activity through which the AMA provides valuable information to the medical profession and the public is our Diagnostic and Therapeutic Technology Assessment (DATTA) project. The purpose of the DATTA project is to provide reliable and authoritative information concerning whether a particular drug regimen, medical device, or medical procedure used to diagnose or treat illness is safe and effective. This process is founded on an assessment of opinion and practices of expert physicians throughout the country.

A reference panel of more than 600 physicians representing a broad geographic and practice spectrum of major specialties and subspecialties has been appointed for the DATTA project by the AMA's Council on Scientific Affairs. The panel is a dynamic and growing body. Nominees are solicited from all segments of American medicine, including state medical societies, medical specialty societies, the AMA Section on Medical Schools, and other groups represented in the House of Delegates and the Councils of the Association. Panel composition is reviewed annually and additional nominees are sought as specialty or geographic needs arise. Physician panelists are recruited from all areas, *i.e.*, practice of medicine, medical education, and biomedical research.

The DATTA project accepts questions from any source. Questions are then sent to a group of reference panelists who fulfill the following criteria: (1) representatives of major teaching centers in the appropriate specialty who are fully conversant with the state-of-the-art as it may pertain to the question raised; (2) representatives of areas of medical practice that may have occasion to use the device or procedure in their practice; and (3) representatives of primary care specialties where daily decisions are made about referring patients for the type of service in question. In each category an effort is made to reflect a nationally geographic spectrum of diverse practice environments.

DATTA panelists are required to indicate in their responses to questions whether in their experience and professional opinion the procedure or therapy under question may be classified as: established; investigational; unacceptable; or indeterminate, that is, no consensus is apparent to date. Panelists are asked to comment on the risks and benefits associated with use of the technology, treatment, or regimen to assess the value of the technology considering alternative modalities available, and to identify subpopulations of patients and patient selection criteria to distinguish those individuals for whom the general rating assigned may not pertain.

When a DATTA opinion has been finalized it is promptly sent to the party who submitted the question, to each panelist queried in preparation of the opinion, to each individual or organization that has requested inclusion in the DATTA mailing list, to all publications and public information resources in the AMA, and to the Journal of the American Medical Association for publication in the indexed medical literature.

Attached to our statement is a DATTA opinion concerning chelation therapy.

Actions against physicians

The AMA recognizes that some health fraud may be committed by physicians. While the number of physicians who perpetrate such fraud is minuscule, we acknowledge a duty to the public to police our ranks. Our policy in this regard is to deny membership to or revoke the membership of any physician who is determined to have committed health fraud.

It should be noted, however, that we have the authority to discipline only physicians who are direct AMA members. We have no disciplinary authority over physicians who are members of the AMA indirectly through their state or local medical society or who are not AMA members at all. Such cases may be referred to the state or local medical society or to a state board of medical examiners.

We must also note that the AMA is a private, voluntary membership organization and thus lacks the power independently to investigate and punish purveyors of health fraud who are not AMA members. However, when an allegation of health fraud is brought to our attention, we often make referrals to the state board of medical examiners, local medical society, postal authorities, the state Attorney General, or other appropriate federal and state authorities.

SUPPORT OF GOVERNMENT ACTIVITIES

The AMA believes that the Federal Trade Commission, the Food and Drug Administration and the U.S. Postal Service should be commended for their efforts in attempting to curb health fraud. We urge Congress to provide adequate funding to enable these agencies to expand such efforts. We would especially urge Congressional oversight of activities of federal agencies, including the FTC, to review their con-

sumer-protection mandate and activities in this vital area. In the case of the FTC, consideration should be given as to whether resources are adequately directed into activity to protect the public from health fraud.

We also recommend that Congress carefully review pertinent existing laws which may be hindering authorities from more effectively combatting health fraud. For example, diet fads and certain vitamin regimens have been falsely promoted as being effective in preventing or curing disease. A principal cause of this type of fraud is a gap in the Food, Drug and Cosmetic Act. Under the so-called Proxmire amendment, the FDA is currently prohibited from regulating vitamin-mineral supplements as over-the-counter (OTC) drugs. Thus, manufacturers of these supplements are not required to prove their safety and efficacy through controlled scientific studies before they can be marketed. Instead, the burden is on the FDA to show that such products are unsafe. The result is that the American public spends millions of dollars each year on food supplements whose safety and efficacy have never been demonstrated. We urge you to give the FDA the authority to regulate these products as OTC drugs.

CONCLUSION

Mr. Chairman, the AMA commends the Subcommittee for conducting an extensive investigation of the important problem of health fraud and for holding this hearing. We remain staunchly committed to the practice of scientifically-based medicine and the elimination of health fraud. However, no simple solution to the problem exists. The AMA recognizes that patients who are ill, those suffering from pain or a chronic disease, are particularly susceptible to the appeals of charlatans and other purveyors of health fraud. Also, many people continue to search for short-cuts to good health. What is needed is an intensified, coordinated effort by the medical profession, the appropriate government agencies and Congress, as well as other interested voluntary organizations, to educate the American people concerning health frauds and to eliminate such unscientific practices. We stand ready to work with you in this effort.

I will be pleased to answer any questions the Committee may have.

Ms. OAKAR. Thank you very much, Doctor.

Our last witness of this panel is Helen O'Rourke who is with the Council of Better Business Bureaus of Arlington, VA.

Thank you very much for coming, and please proceed.

STATEMENT OF HELEN O'ROURKE

Ms. O'ROURKE. I'm going to deviate from my statement also, since you already have a copy.

My name is Helen O'Rourke, and I'm vice president of the Council of Better Business Bureaus. I'm in charge of the Philanthropic Advisory Service, a division of the Council of Better Business Bureaus.

I'm coming from a little different direction than some of you who are here today, since you are in the medical field. We monitor and report on solicitations groups that raise money for many health and welfare organizations and other 501(c)(3) charitable groups. Unfortunately, not all of them are legal or legitimate.

I will make a few comments here about evaluations of charitable organizations. We believe this is very important since over \$64 billion was given to philanthropic causes last year and 90 percent of that was given by individuals, both living and dead. A lot of people think that all that money comes from foundations and corporations, and it doesn't; it comes from me and thee.

For more than 70 years, the Better Business Bureau system has been reporting on charities as part of its service to business and consumers. Reports on charities were an outgrowth of bureau reporting on businesses and were prompted by the public's need for

more information on charitable solicitations, both local and national.

We are aware of the great need for education in this field. We do a great deal of education in this field through our pamphlets on "Tips on Charitable Giving," and "Standards for Charitable Solicitations."

The Philanthropic Advisory Service—PAS, as we call it—is basically a donor information service. We provide information on charitable organizations to corporations and foundations, local Better Business Bureaus, the media, the general public, and the Government.

We respond to approximately 150,000 inquiries per year and maintain files on over 7,000 organizations. The number does not include the thousands of inquiries that go into the 160 Better Business Bureaus across the country. They report on the local charities as well as disseminate our reports on national charities.

Although we do not seek demographic information from our inquiries, many inquirers volunteer that they are elderly or retired.

Based on our experience, charity seems to be a particular interest to the older consumer. The older consumer believes solicitations are legitimate if they see the appeal on TV, in a magazine, newspaper, or hear it on the radio—and this is not always true. They think that someone has checked out the ads before they are accepted by the media. They are very trusting.

Most people want to give, and it's very disheartening to pick up a letter—and we get many of them—and the letter will say, "I'm a blind widow, 80 years old, on Social Security, but I want to give," and then they'll give you a long list of charities they are giving to, and three-fourths of them don't meet our standards.

Our goal is to have a public that is educated about the charities they give to. People don't know enough to complain about the charities that they are giving to, because they don't see the end result. They don't see what happens to their money when it goes to the Cancer Society or any other charity they are giving to.

I can tell you right now that about 50 percent of our inquiries are from the older people, and about 50 percent of them ask about cancer groups.

The standards cover all of the 501(c)(3) groups. We have a copy of the current standards attached to the written testimony.

We ask for an annual report and completed financial statement. The Council of Better Business Bureaus believes that disclosure of such information will benefit both the public and soliciting organizations.

Among other provisions, the standards address the amount of money a charity spends on its programs, fundraising, and administration. One standard calls for at least 50 percent of a charity's income to be spent on programs. Now that sounds low, and we think it's low too, but that's the minimum we will accept. Anything over that is good and should be there anyway. But of course you have to take into consideration new charities getting started.

Another standard states that more than 35 percent of contributions should be spent on fundraising.

Since the Better Business Bureau is not a Government agency, it has no legal authority to compel organizations to provide information or to meet its standards.

I might add, there is no Government agency that checks on charities either.

Compliance with the standards is purely voluntary. However, most organizations willingly provide us with information, and have no trouble meeting the CBBB standards.

When we determine that an organization does not meet the standards, we write the organization first to inform it of the problems we see and to invite its comments.

When reporting noncompliance findings to inquirers, we also provide the charity's comments, so the inquirer can make an informed decision based on all available information.

We inform the public of the results of our evaluations. We publish individual reports on soliciting organizations which detail the organization's purposes, activities, governing structure, fundraising practices, and finances. The report also explains whether the organization does or does not meet Better Business Bureau standards.

Draft reports are routinely sent to the organization prior to publication to ensure accuracy.

In addition, PAS publishes a bimonthly list of those organizations generating the greatest number of inquiries, which shows whether the organizations meet or do not meet CBBB standards.

The list also indicates which organizations have not provided requested information and which organizations are still being evaluated. A copy of the list called "Give But Give Wisely" is attached to our written testimony.

In view of the time, I will stop here for questions.

[The prepared statement of Ms. O'Rourke follows:]

PREPARED STATEMENT OF HELEN O'ROURKE, VICE PRESIDENT, COUNCIL OF BUSINESS BUREAUS, INC., ARLINGTON, VA

Mr. Pepper, and members of the Subcommittee, my name is Helen O'Rourke and I am a Vice President at the Council of Better Business Bureaus. I am in charge of the Philanthropic Advisory Service, a division of the Council. With me today is Elizabeth M. Doherty, Director of the Philanthropic Advisory Service (and Steve Jones, Vice President for Legal Affairs).

I am pleased to present comments on our evaluations of charitable organizations.

For more than 70 years, the Better Business Bureau system has been reporting on charities as part of its service to business and consumers. Reports on charities were an outgrowth of Bureau reporting on businesses, and were prompted by the public's need for more information on charitable appeals.

The Philanthropic Advisory Service (PAS) is basically a donor information service. We provide information on charitable organizations, including many health and scientific research organizations, to corporations and foundations, local Better Business Bureaus, the media, the general public and the government. We respond to approximately 150,000 inquiries per year, and maintain files on more than 7,000 organizations.

Although we do not seek demographic information from our inquirers, many inquirers volunteer that they are elderly or retired. Based on our experience, charity seems to be of particular interest to the older consumer.

The original BBB Standards for Charitable Solicitations were issued in 1974. Before 1974, local Better Business Bureaus used "Guides for Giving" to evaluate charitable solicitations. One of the major reasons for developing the standards was public demand for guidelines on evaluating charitable appeals. The purpose of the CBBB Standards for Charitable Solicitations is to help ensure an open and ethical marketplace which will inspire public confidence and promote the growth and success of private initiative.

The standards were revised in 1977 and again in 1982. The original standards and the subsequent revisions were promulgated after extensive consultations with representatives of individuals charities, professional fund raisers, the legal and accounting professions, local Better Business Bureaus, government regulatory agencies, corporations and foundations, and the media. The standards apply to all publicly soliciting organizations ruled tax exempt under section 501(c)(3) of the Internal Revenue Code. The standards can also be applied to other types of charitable solicitations, such as those conducted by for-profit entities, or organizations that are not tax exempt.

The current standards focus on disclosure of certain basic information, which donors might reasonably wish to consider in making giving decisions. The Standards are designed to ensure that charities spend contributed funds on the programs for which donors intended them. They also stress that appeals should clearly describe how donated funds will be spent. For example, the standards call for organizations to provide on request an annual report and a complete financial statement. The Council of Better Business Bureaus believes that disclosure of such information will benefit both the public and soliciting organizations.

Among other provisions, the standards address the amount of money a charity spends on its programs, fund raising and administration. One standard calls for at least 50% of a charity's income to be spent on programs. Another states that no more than 35% of contributions should be spent on fund raising.

Since the Better Business Bureau is not a government agency, it has no legal authority to compel organizations to provide information or to meet its standards. Compliance with the standards is purely voluntary. However, most organizations willingly provide us with information and have no trouble meeting the CBBB Standards.

When we determine that an organization does not meet the standards, we write to the organization first to inform it of the problems we see and to invite its comments. When reporting noncompliance findings to inquirers, we also provide the charity's comments, so the inquirer can make an informed decision, based on all available information. We also spend a great deal of time working with individual organizations to help them meet CBBB Standards and improve their overall management.

To inform the public of the results of our evaluations, the Philanthropic Advisory Service publishes individual reports on soliciting organizations which detail the organization's purposes, activities, governing structure, fund raising practices and finances. The reports also explain whether the organization does or does not meet the CBBB Standards. Draft reports are routinely sent to the organization, prior to publication, to ensure their accuracy.

In addition, PAS publishes a bimonthly list of those organizations generating the greatest numbers of inquiries, which shows whether the organizations meet or do not meet CBBB Standards. The list also indicates which organizations have not provided requested information and which organizations are still being evaluated. A copy of the list, called "Give But Give Wisely," is attached to our written testimony.

Finally, I would like to stress that everything done by the Philanthropic Advisory Service is motivated by public interest. We do not seek information about an organization unless it has generated several inquiries to our office. We do not evaluate an organization's practices in relation to the standards unless there is sufficient public interest and we do not prepare detailed reports on organizations unless there is a public demand for them.

I appreciate this opportunity to explain the Philanthropic Advisory Service to you and welcome any questions you might have.

Ms. OAKAR. Thank you very much, Ms. O'Rourke.

Your point is that these tax-exempt charitable organizations are responsible—at least some of them—for disseminating some of this quackery business. Is that the point?

Ms. O'ROURKE. Well, not really. They are going out to raise money in the name of a charity.

Ms. OAKAR. Solicit money as well.

Ms. O'ROURKE. They usually take a cause—like cancer, and use a lot of different names and the general public does not know the difference.

Ms. OAKAR. I see.

Ms. O'ROURKE. And when the general public sees the name "national" or "worldwide" or "American"—anything like that—they just assume that it's legitimate, and sometimes they don't ask questions. A lot of times, they don't ask questions.

Ms. OAKAR. Well, thank you very much.

Let me ask Ms. Brown—you gave some interesting testimony, and I don't want to jump the gun on what we are going to do in the future, but I do want to commend you for your statement.

You indicate that when people hear the word "cancer," their first reaction is they have got to leave that office, and so on. I think we have all had experiences where we have felt that our loved ones were not treated with a lot of patience, and understanding, and explanation by the doctors.

Now, I know that doctors are very busy. My own nephew just graduated from medical school. I don't know how they do it. And doctors—I've seen doctors who work 7 days a week, and they are on call 24 hours a day. So we understand that.

But do you think—you suggested that one reason people turn to this kind of quackery is that they are not dealt with in a very compassionate sense, and they are not given the time. Do you think that's true?

Ms. BROWN. I'm sorry to say, Ms. Oakar, that it's based on fact.

In a recent study of 964 hospital interactions between physicians and patients, the following was found. While the patient was acutely ill in the hospital—the average length of the interactions were 3.5 minutes. There isn't much compassion and information exchange that can take place in 3.5 minutes of physician/patient interaction in a hospital.

Ms. OAKAR. So what you are suggesting, I think, is that if the doctor were in a position—and, again, I realize how difficult it is sometimes for doctors to have all kinds of time. They almost have to be everything at that moment. They have to be psychiatrist, doctor, physician, and, in a sense, friend, and so on and so forth.

But I think what you are suggesting is that when a patient is told that they have a disease, that immediately triggers a fear that their life may be imperiled, and they are not aware of the statistics that you related earlier, that so many of these cancer problems can be cured or at least arrested. The statistics are terrific—and they are getting better all the time—that that experience or lack of experience makes the difference in how they will treat themselves. Is that—

Ms. BROWN. Yes. Most of the patients that I talk to who avail themselves of quack methods of treatment have been to the health care system—to our health care system.

When they talk about alternatives, they are truly talking about alternatives, because we, in a way, let them down. Now this is not the totality of the patients but a great many.

I agree with you. I know how busy physicians are. I work with them all the time. What I am suggesting is that the voluntary agencies and the hospitals themselves aid by offering help to physicians.

Nurses, for instance, can be tremendous change agents. All too many physicians do not use them well to help them with the patient.

The Cancer Society has a marvelous program called Reach to Recovery. Breast cancer patients can visit newly diagnosed patients—those who are going to be operated on or those who have already had surgery, and introduce them to all of the whys and wherefores of recuperating, looking, feeling, and living a long and fruitful life. Too many physicians do not recommend the program.

Ms. OAKAR. And introduce them to the options.

Ms. BROWN. Exactly.

Ms. OAKAR. And that's one of the problems that I think a lot of women face—that they feel they have had unnecessary surgery, and some of the options that are out there that progressive physicians—I'm going to get to you in a minute, doctor; don't worry.

Ms. BROWN. I don't mean this in a condemning fashion. What I'm saying is that—

Ms. OAKAR. No, I'm not either. I think, though, that that is one important issue. You know, we are all so busy as Americans, and I think sometimes if we could discipline ourselves to take more time with individuals, we would see better results in terms of the manner in which they are treated, and we could lay out various programs for the patients—particularly women, I think—so that they know there is not just one way to treat an illness but more than several ways.

I do want to ask you one other question though. You were talking about diet, and so many people mention the quackery related to diet. I don't necessarily want to give any misimpression about that.

Isn't it true that in terms of prevention, that HHS and other agencies—maybe the doctors from the Institute on Aging might want to answer this, or anyone else—that with respect to prevention relative to diseases, like heart diseases, cancer, and so on, diet is very important, and that they can serve, not necessarily as the cure-all, but they can serve even after you have experienced treatment, to complement the treatment?

Ms. BROWN. You are mentioning two different areas.

There is evidence shown from a variety of research studies that lowering the fat intake, increasing the fiber intake, and so forth, may have beneficial effects in the prevention of certain diseases—some cancers, heart disease, and so forth. However, we do not have a diet that we can recommend that will cure cancer.

We do have diets that are beneficial to patients who are under treatment with radiation therapy, with chemotherapy, in regard to supporting their caloric intake and offering them some food that they can digest. There are many different areas of diet that we speak about.

We are discussing diets today that are purported to cure cancer or cure heart disease, and that's an outright fraud until and unless the evidence is presented indicating that this is being accomplished.

Ms. OAKAR. Doctor, did you want to respond to this?

Dr. ROGERS. Yes, Madam Chairman, I had several things I wanted to respond to, if I could, very briefly.

The first was a study that we heard about from Ms. Brown—I really don't know the details of that study—which said that 3 minutes visit with the doctor was the average. That may very well—

Ms. OAKAR. In a hospital, I think she said.

Dr. ROGERS. In a hospital—yes, Ma'am.

That may very well be true, and I just simply can't respond to that. I can say, however, from my own experience, that I visit my patients on a routine basis very quickly and try and answer all their questions, but when an important issue comes up, such as telling someone that they have cancer of whatever organ or wherever it might be located, I try very hard in my own practice—and I know my colleagues do as well—to schedule this time at a time that is convenient for the family to be around, for there to be plenty of time for everyone to sit down and discuss the issue and understand the problem, because acceptably the family and the patient who receives a very tough blow of, "You've got cancer, and that's all there is to it, and we can do nothing else," is going to be very likely to go out to the quack, and I would agree with that.

So I think that physicians, in general, will try hard to do this. They are not perfect, and they don't do a good job.

Second, on Reach to Recovery, Ms. Brown said that we don't—we physicians don't use Reach to Recovery as often as we should, and I would have to say that if we don't use it 100 percent of the time, I think it is bad, because I use it, Ms. Brown. I'm very satisfied with the results that I get. It helps my patients with breast cancer to do better in the future.

So we may not do perfectly, but we are trying to get it very close to 100 percent.

Third, about the nutritional support for cancer patients, I think it is terribly important. Today, we can do things and offer treatments to our patients who have cancer that were unheard of just 10 years ago because of the support that we can give those patients, not only with hyperalimentation by central lines, but we can do all sorts of other supportive methods that were never possible before, enabling us to give that patient the benefit of the extremely beneficial results of treatment.

Thank you.

Ms. OAKAR. Does the AMA have any kind of in-house educational mechanisms so that those physicians who are more likely to deal with more sensitive type illnesses are really trained to deal with the patient's psychology, and, you know, all the other issues that come up when one is told, let's say, that one has cancer?

Dr. ROGERS. Well, the AMA, of course, does not provide directly, education. It does, however, work closely with medical schools, medical societies, specialty societies, and all other organizations that are providing education during the course of medical education and postgraduate as well, in providing that sort of information, and we do feel that is important, and we do participate in that actively all the time.

Ms. OAKAR. Dr. Williams.

Dr. WILLIAMS. Just a brief comment about nutrition and aging. We do need to know a great deal more about what are the very best nutritional approaches for older people. We need a lot more basic research in this.

But certainly, in general, a prudent diet is wise, and there is no evidence yet that any specialized diets or specific diet additives are going to make a difference in the aging process.

Ms. OAKAR. Doctor, you were talking about the aging process and the feeling that most people have that they want to take something fast to get younger or stop the aging process. Isn't it true that the fastest growing population is those who are 85 years and over in our country?

Dr. WILLIAMS. That's quite correct.

Ms. OAKAR. People are living a lot longer, aren't they?

Dr. WILLIAMS. People are living into their later years in much larger numbers. The number of individuals over 85 will double between now and the turn of the century.

Ms. OAKAR. Mr. Borski?

Mr. BORSKI. Yes, thank you, Madam Chair.

Dr. ROGERS, you said during your testimony that the number of physician in the United States that prescribe or recommend the use of nonapproved treatments is miniscule, I believe.

Dr. ROGERS. Yes, sir.

Mr. BORSKI. Could you tell us how a patient would know if a physician was recommending something that was nonapproved? Could they call the AMA?

Dr. ROGERS. Yes, that patient could certainly call the AMA and receive this packet of information that I described, and this is developed by the AMA Library and Research Division and includes all the latest information on all sorts of untried and unproven methods of treatment, and, in addition, the relatively larger number of proven methods.

Mr. BORSKI. Thank you.

Dr. Pennington, I would like to ask kind of pretty much the same thing, I think. How would an arthritis patient determine whether a treatment advertised in a newspaper or magazine is safe and effective? Is there something that the Arthritis Foundation makes available to folks?

Mr. PENNINGTON. Yes, we have a rather large information resource available in the national organization that is distributed through public information memos to the media and to our chapters.

A person reading an ad in a paper, or in a tabloid, or in a magazine, could call the local chapter of the Arthritis Foundation, and either locally they will have the information or nationally we will have the information, and, if not, we will get it. That's how they can find out.

Mr. BORSKI. Thank you.

And Ms. Brown, I guess I know the answer. The phone number that you had given out to us earlier, I assume that folks could just call that and see if anything they saw or read was approved by the American Cancer Society?

Ms. BROWN. Yes; The American Cancer Society has offices throughout the United States. They are all listed in the white pages.

Mr. BORSKI. Thank you, Ma'am.

Ms. OAKAR. Thank you.

Mr. DeWine, let's try to get the questioning in.

Mr. DeWine.

Mr. DEWINE. I'll try to be very brief.

Dr. Rogers, you point out very well, I think, in your testimony that the AMA does not actually license physicians—that you are not involved in that. Could you first tell me what percentage of the physicians in this country belong to the AMA?

Dr. ROGERS. A little over half of the practicing physicians delivering health care in this country belong to the AMA.

Mr. DEWINE. Could you very briefly give us an overview of the licensing procedure in the 50 States? Or actually my question would be more to, if someone has a complaint about a doctor, what is the procedure?

Dr. ROGERS. Well, he can certainly go directly to the local medical society. If the physician is a member of the local medical society, the medical society itself will have jurisdiction as far as membership is concerned.

Mr. DEWINE. But that's only membership.

Dr. ROGERS. Yes, sir. He, however—if that physician is not a member of the local medical society, the local medical society may itself refer the matter to the State board of medical examiners, the licensing board. They are the proper source for full investigation and revocation of license, if necessary.

Mr. DEWINE. You were in the room, I believe, when Dr. Wachsman testified, were you not?

Dr. ROGERS. Yes, sir.

Mr. DEWINE. He was fairly critical of your profession and the ability that you have to police yourself. Would you like to comment on that at all?

Dr. ROGERS. I thank you very much. I certainly would.

Mr. DEWINE. That wasn't meant as a soft pitch. I was trying to get some reaction to that because I think, doctor, actually there is a perception among the public—right or wrong—that doctors do not police themselves very well.

Dr. ROGERS. Well, I would agree that in many cases that may be true. I think, however, that Dr. Wachsman's solution to the problem is a poor one.

I think to suggest that we solve the problem by litigation, of whatever sort, is, in my view, very ineffectual. It seems to me—I believe it was you who pointed out that this would be peaks and valleys across the country. It would, in fact, not solve the problem in Oshkosh but might solve it in Atlanta, GA, if we have a high malpractice rate in Atlanta, GA.

So I don't think that that's an effective way of policing.

Mr. DEWINE. How do we do it then?

Dr. ROGERS. I think that the medical societies across the country must do it themselves. They are in the business of doing this, and they do refer work to the State boards of medical examiners.

I would point out, however, that across the country, State boards of medical examiners are poorly financed. In those States—in my own State of Georgia, for instance, several years ago it became apparent that our State board was so poorly financed as far as its investigation and determination of wrong was concerned that we had to do something about it.

The doctors in the State said, "We will raise our licensing fees to the point where we can furnish enough money to this board," but the money didn't go to the board, the money went to the general

funds, and we had to first extract a promise from our Governor to allocate that money in his budget to the examining board. That was the only way we could get it there, but it was accomplished.

Today we have a far more effective mechanism of doing this.

Mr. DEWINE. Thank you, Doctor.

Ms. OAKAR. Thank you.

Congressman Ridge.

Mr. RIDGE. Thank you, Madam Chairman.

Ms. OAKAR. If I might say, we are speeding this up in questioning a little bit because we do have a vote, and after the Congressman's questions we will take a 10-minute break and begin with the next panel.

So, Mr. Ridge?

Mr. RIDGE. Madam Chairman, if you just will indulge me for a few minutes. Without any questions, what I see is the National Arthritis Foundation, the National Institute on Aging, the American Cancer Society, the Better Business Bureau, and the American Medical Association all working to combat the problem of quackery—national organizations and local organizations.

Your very profound and powerful testimony has suggested to me that Congressmen and Congresswomen—now alerted to the problem because you have educated us in terms of the nature and the degree of the dilemma out there—could try to help and work with you in our own individual districts to harness what appears to be a variety of different available resources.

So I just personally want to express my sincere appreciation for letting us know what you have available for us, to advise and to help our constituents, and I think it will be a project that we will discuss undertaking. I know some of us are talking about it already, and we would like to help.

We want to help, and you have helped us a great deal by your testimony here today, and I thank you very much.

Ms. OAKAR. Thank you very much, Congressman.

I'd like to thank the panel. We are very, very pleased you were here. We are very pleased for your entire statements, and we know we have some other things to do, and we think that the agencies here—at least this Member feels the agencies also have a little more to do, who work for the people. But thank you very much.

We will resume the hearing in about 10 minutes with the next panel.

[Recess.]

Mr. BORSKI [presiding]. The hearing will come back to order.

We would like our third panel to please have a seat.

Dr. Herbert, would you begin your testimony, please?

PANEL THREE, CONSISTING OF VICTOR HERBERT, M.D., J.D., CHIEF OF HEMATOLOGY AND NUTRITION LABORATORY, VA MEDICAL CENTER [BRONXX], PROFESSOR OF MEDICINE, STATE UNIVERSITY OF NEW YORK DOWNSTATE MEDICAL CENTER, AND CHAIRMAN-ELECT OF MEDICINE, HANNEMANN UNIVERSITY; SORELL SCHWARTZ, M.S., DEPARTMENT OF PHARMACOLOGY, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, WASHINGTON, DC; AND CLINTON RAY MILLER, LEGISLATIVE ADVOCATE, NATIONAL HEALTH FEDERATION, ALEXANDRIA, VA

STATEMENT OF VICTOR HERBERT, M.D., J.D.

Dr. HERBERT. Yes, sir.

Mr. Acting Chairman, I'd like to read only the first 2 pages of my 35-page, previously prepared statement but not the 33 pages documenting in detail the national health quackery network and how they can maim and kill, and I'd like to ask that the rest of it be received in the record.

Mr. BORSKI. Without objection, the statement will be received in the record.

Dr. HERBERT. In May 1983, the Senate Select Committee on Aging reported health fraud was No. 1 of the 10 most common frauds against the aging. They noted there were schools for scoundrels organized by cons to teach other cons how to make a sting.

That report barely scratched the surface of the interlocking network of the health quackery mafia ranged against the aging, which rips people off to the tune of \$25 billion a year, of which about \$10 billion is directed against the elderly and may maim or even kill.

The \$25 billion take of the quackery mafia includes their corporations, labs, foundations, hospitals, prevention and holistic clinics, health and wellness centers, publications, fund-raising and other operations, and roughly breaks down as follows: \$6 billion for food supplement, pill, powder, and potion quackery; \$2 billion for antiaging and sexual potency quackery; \$3 billion for arthritis quackery; \$3 billion for cancer quackery; \$3 billion for heart disease quackery; \$2 billion for quack diagnostic tests, such as specious computer questionnaires, hair analysis, cytotoxicity testing, kinesiology, iridology; \$1 billion for Alzheimer's disease and other mental illness quackery; \$2 billion for naturopathic, herbalist, occult faith healing and other cult quackery—see the Dole committee cult hearings for further information—\$2 billion for clinical ecology, hypoglycemia, quackupuncture, unorthodox, holistic, nutritional, nontoxic, metabolic, and natural quackery; \$1 billion for quackery promoting literature; and \$1 billion take by diploma mills in several hundred quackery promoting organizations.

How do we protect the aging against the quackery mafia? One way may be via the following. We have a Federal Organized Crime Task Force to deal with the Cosa Nostra mafia, both those with prior criminal convictions and those with no criminal convictions.

The most potent weapon of this task force is the law which makes it illegal to conspire to engage in a pattern of racketeering.

This morning, Chairman Pepper referred to quackery purveyors as gangsters and racketeers. Quackery is a racket. We need a Fed-

eral Organized Crime Task Force to deal with the quackery mafia, both those with criminal convictions and those without.

I believe a good case can be made that a number of the members of organizations such as the National Health Federation, whose man in Washington, Mr. Clinton Miller, on my left, attacked the committee's report on quackery as "an attempt to throw dust in people's eyes" in this morning's issue of U.S.A. Today, and the American Academy of Medical Preventics are involved in a conspiracy to engage in a pattern of racketeering by misbranding as safe and effective in the treatment of cancer, heart disease, and other illnesses products sold by the same members—and I give the details in my 28 further pages—which in fact are ineffective and unsafe.

We have a Federal court precedent. The U.S. District Court for the Eastern District of Louisiana enjoined Dr. Ray Evers, a former Governor of the National Health Federation and Meadowbrook Hospital, which he owned, from administering chelation to persons referred to the hospital for treatment of atherosclerosis.

The memorandum and order of the court stated that the promotional literature distributed at a National Health Federation convention misbranded chelation therapy as effective and safe in the treatment of heart disease, whereas, in fact, it was neither and was associated with some 14 deaths at the hospital in question. Unfortunately, a similar court in Alabama did not adopt this precedent.

The Louisiana State Board of Medical Examiners denied Evers a permanent license to practice medicine in Louisiana, ruling that his use of chelation therapy constituted incompetency and he "was incompetent to practice medicine in Louisiana" and "deceived and defrauded patients and/or the public."

What we have is a nationwide network of promoters using questionable remedies for heart disease like chelation therapy, which is experimental and can kill—and I give the details further—and questionable remedies for cancer like laetrile, which is experimental, can kill, and gives everybody who takes it cyanide poisoning, which insidiously rots their nerves so they go blind, deaf, and unable to walk, and they and their families think it's the cancer, whereas it is the laetrile.

These promoters belong to a nationwide network of organizations with impressive names created by hucksters to propagandize the Nation with false claims of efficacy and safety of quack remedies.

Not one of the promoters who has been investigated has been found to be making less than \$100,000 a month from their activities. Yet they pass themselves off as just poor citizens trying to protect the public from organized medicine, orthodox medicine, and the establishment, which is exactly what Mr. Miller says in this morning's paper.

The network of quackery-promoting organizations provide an umbrella under which the promoters, in the guise of freedom of speech and giving patients freedom of choice, make the false claims to national audiences for the products they sell, which claims they do not repeat to the patients who flock to them in their offices because to so repeat would be very clearly making the claim to the particular patient, which makes them legally liable for the deception and its harmful consequences.

This month's issue of the National Health Federation News contains at page 4 a statement by the President, "Among our projects this year will be to steal the headlines from Claude Pepper's quackery hearings." Sure enough, this morning Clinton Miller did just that in this morning's U.S.A. Today.

Right now, the National Health Federation is distributing to their 17,000 members form letters asking Senators to enact a bill granting people the right to utilize medications not approved by the FDA. This would legalize the very quack products today's hearings are all about.

I hope this committee will inform their colleagues that this NHF-backed bill is simply disguised legalization of quackery. The NHF can mobilize more letters to Congress than the Vietnam war could, as they showed in prior legislative efforts of theirs.

We need a Federal law requiring all advertisements which state, suggest, imply, or mention any therapy value of products not approved by the FDA to state on the bottle in large block letters, "The FDA has not approved this product as effective or safe in the treatment of any disease."

We also need legislation permitting health insurers to have subrogation rights in their policies so that they can pay the cheated victims who apply for reimbursement for what they thought was real medical care, and the insurers can then go after the doctors who gave the worthless diagnostic tests and worthless therapies and already are home free with the money.

Thank you.

[The prepared statement of Dr. Herbert follows:]

PREPARED STATEMENT OF VICTOR HERBERT, M.D., J.D., CHIEF, HEMATOLOGY AND NUTRITION RESEARCH LABORATORY, BRONX VA MEDICAL CENTER, PROFESSOR OF MEDICINE, SUNY DOWNSTATE MEDICAL CENTER, BROOKLYN, NY, AND CHAIRMAN-ELECT, DEPARTMENT OF MEDICINE, HAHNEMANN UNIVERSITY, PHILADELPHIA, PA

In May, 1983, the Senate Select Committee on Aging reported that health fraud was number one of the ten most common frauds against the aging. They noted there were "schools for scoundrels organized by cons to teach other cons how to make a sting." That report barely scratched the surface of the interlocking network of the health quackery mafia ranged against the aging, which rips them off to the tune of 25 billion dollars a year, and may maim or even kill. The 25 billion dollar "take" of the quackery mafia including their corporations, laboratories, foundations, hospitals, "prevention" and "holistic" clinics, "health and wellness centers," publications, fund-raising, and other operations roughly breaks down as:

"Food supplement" pill, powder and potion quackery: \$6 billion.

Anti-aging and sexual potency quackery: \$2 billion.

Arthritis quackery: \$3 billion.

Cancer quackery: \$3 billion.

Heart disease quackery: \$3 billion.

Quack diagnostic tests (specious computer questionnaires, hair analysis, cytotoxicity testing, kinesiology, iridology, x rays resulting in diagnosis of non-existent subluxations, etc.): \$2 billion.

Alzheimer's disease and other mental illness quackery: \$1 billion.

Naturopathic, herbalist, occult, faith healing, and other cult quackery (see Dole Committee cult hearings): \$2 billion.

"Clinical ecology," "hypoglycemia," "quackupuncture," "alternative," "unorthodox," "holistic," "nutritional," "non-toxic," "metabolic," and "natural" quackery: \$2 billion.

Quackery-promoting literature: \$1 billion.

"Take" by diploma mills and several hundred quackery-promoting organizations: \$1 billion.

The U.S. Attorney General arguably should invoke the federal racketeering conspiracy law which has been used to break Mafia conspiracies to go after the quack-

ery mafia conspirators. Just like the Cosa Nostra Mafia, they consort with each other continuously, even during the probation periods of the convicted criminals among them. Judges, unaware of the existence of the quackery mafia, do not require them as a condition of their probation, to not consort with other quackery promoters. Prosecutors should ask judges to do so.

Promoters of questionable health practices are linked together through several hundred organizations with impressive-sounding names and overlapping memberships, like the National Health Federation (NHF), which was characterized in the book "The Health Robbers" as an organization including "promoters fighting for the right to cheat and victims fighting for the right to be cheated." NHF has its own lobbyist to Congress, Mr. Clinton Miller.

Just as there are writers like Peter Mass who specialize in books exposing the Cosa Nostra, so are there writers who specialize in exposing questionable health practices, like Dr. Stephen Barrett "The Health Robbers," second edition, Stickley Company, Philadelphia, PA, 1980), Dr. William Jarvis (National/California Council Against Health Fraud, Inc., "Newsletter," Loma Linda, CA 92354), Consumers Union "Health Quackery," Consumers Union, Mount Vernon, NY 1980), and myself "Nutrition Cultism: Facts and Fictions" and "Vitamins and Health Foods: The Great American Hustle," written with Dr. Stephen Barrett, both published 1981 by George Stickley Company, Philadelphia, PA).

Unconstrained by any sense of responsibility or ethics, the quackery mafia hard-sells to the aging fake and often dangerous "preventives" and "cures" for aging and all the chronic diseases that afflict the aging, robbing them not only of their money but also of their chances for responsible help and sometimes of their lives. Anecdotes and testimonials are the lifeblood of these hucksters. These tales do not separate fact from fiction, or cause and effect from coincidence or suggestibility or the natural remissions which often occur in chronic diseases.

I recently received a promotional mailing for "Prevention's Lifetime—Health Weekends" at the Tarrytown (NY) Conference Center on May 18–20 and June 22–24, 1984, starring Prevention editor and publisher Bob Rodale, executive editor Mark Bricklin, and five "nutrition doctors": Jonathan Wright and Alan Gaby (both of whom write regularly in Prevention, promoting questionable nutrition practices), Robert Giller, and Warren Levin (who uses a wide range of questionable diagnostic tests and therapies, including chelation, in his New York City practice), and Michael Schachter. Dr. Schachter gave Joey Hofbauer laetrile instead of proper treatment for Joey's Hodgkin's Disease, which was Stage I and curable in 95% of cases with proper treatment. Joey subsequently died with lungs full of Hodgkin's Disease (for a full account, see the book "Nutrition Cultism," pages 60–63). Dr. Schachter was one of the 8 promoters of questionable practices in the treatment of cancer who constituted the original scientific advisors to the American Institute of Cancer Research (AICR), a 3-million dollar-a-year "Breast Cancer Survey" fund solicitation exposed by Allan Parachini and Betty Cuniberti in the Los Angeles Times for April 20 and 24, 1984.

Prevention's "People's Medical Society" is working to de-license physicians, thereby destroying the public's protection against quacks diagnosing and treating disease. Similarly, promoters of quackery have prevented the licensing of responsibly trained nutrition professionals such as R.D.s (registered dietitians) in many states, because licensing responsible professionals would prevent the quacks from operating. Last week, I was informed that lawyers for Shaklee and Amway appeared at the Delaware legislature and lobbied against the proposed licensing of only responsibly trained nutrition professionals as nutritionists in that state, convincing the chairman of the pertinent committee to allow supplement sellers to "tell customers what the products can do" (i.e., to deceive and mislead?), just as lawyers for chiropractors had done earlier when R.D.S attempted to secure licensing of responsibly trained nutrition professionals in New York State.

When responsible health professionals speak out against the quackery mafia, they are harassed by threats of legal action. Those who speak out for responsible medical treatment risk being sued on frivolous grounds.

A few years ago, the Coalition for Alternative Therapies and the National Health Federation (NHF) published in their monthly magazine an interview by Maureen Salaman with "nutrition doctor" Robert Atkins stating that I "house an evil spirit that needs to be exorcised," which was followed shortly by several anonymous death threats by mail and phone to me. In March, 1984, the magazine Health Foods Business carried an exhortation to join the NNFA for an "aggressive offense" against me. The very next month, a law firm employed by the NNFA, without identifying themselves as employed by NNFA, made a "Freedom of Information Act" (FOIA) demand in the law firm's name (no client identified) to the Veterans Administration

for all my "records, including but not limited to, notes, memoranda, reports and correspondence which pertain to (my) activities as they relate to human nutrition." My records run to over a million pages. Of course, they knew when they made that demand that they are not entitled under FOIA to what they demand, but they also know or should know that responding to their harassment would waste a substantial amount of my time and that of my superiors. If they thought defending against this harassment would so tie me up that I couldn't testify at hearings such as these, they were wrong.

I hope the FBI "Dipscam" operation (Time magazine, April 2, 1984, page 90) is looking into Donsbach University. It is a Huntington Beach, California mail-order diploma mill run by chiropractor Kurt Donsbach, convicted of quackery (i.e., practicing medicine without a license) (Judge Fenton E. Jones, West Orange County Municipal Court, Westminster, CA, docket #37778, trial date 4/9/71, guilty plea, 2 years summary probation plus \$600 fines plus \$2000 restitution to the State of California department of Public Health, Bureau of Food and Drug Inspections, Sacramento, which as a full record of the investigation). Donsbach University allegedly sold more Ph.D.s in nutrition through the mails (at about \$300 each; Visa and Mastercard accepted) in 1983 than were issued by all the reputable universities accredited by the American Council on Education. It is pertinent to note that in 1982, a New Jersey Court (Ref: In the Matter of Tugender 541 A 2d 1328, N.J. Superior Court, App. Div., September 28, 1982) ruled that a psychologist whose "doctorate" was obtained from an unaccredited institution cannot use the title "doctor" and the designation "Ph.D."

As the California Council Against Health Fraud (CCAHF) states in their September/October 1983 Newsletter: "Graduates of nutrition diploma mills advertise themselves as nutrition consultants with academic credentials when they are nothing more than salespeople armed with nutrition misinformation preying on an unsuspecting public."

Many individual promoters of quackery subscribe to a legal protection plan which brings attorneys to their immediate defense, with a large travelling circus of quackery-promoting "expert" witnesses.

New York State requires prosecuting attorneys to provide defense attorneys with any potentially exculpatory information ("Brady material") of which they are aware. We need a federal law to require defense attorneys to provide prosecuting attorneys (and attorneys for victimized consumers) with any incriminating information of which they are aware.

One does not have to go far from Washington to see the interlocking relationships of the promoters. The International Foundation for Preventive Medicine (IFPM) in Annandale, Virginia, sells tickets throughout the Washington area for its annual "Reversing the Aging Process" seminars (the very title of which arguably constitutes misbranding of the products promoted) at the Lisner Auditorium of George Washington University, hosted by IFPM medical advisor George H. Mitchell, M.D., who runs a Washington, D.C. alleged "preventive medical center." In New York, IFPM uses the Felt Forum at Madison Square Garden. IFPM seminars in the San Francisco Bay Area are hosted at the Berkeley Community Theater of Berkeley High School by chelation therapist Ross Gordon, M.D., President of the American Academy of Medical Preventives. In Chicago, the IFPM seminars are hosted at Medinah Temple by local chelation therapist William J. Mauer, D.O. At these seminars, a gamut of questionable practices is promoted by Robert Atkins, Jeffrey Bland, Elmer Cranton, Garry and Ross Gordon, Saul Kent, Warren Levin, Richard Passwater, and Michael Schachter. Dr. Atkins, Ph.D. Bland and Mr. Passwater are on the IFPM Board of Directors; Dr. Cranton is Director of Research.

With respect to sales of literature promoting health quackery, the California Council Against Health Fraud (CCAHF) in its July/August 1983 CCAHF Newsletter noted that Clinton Miller, lobbyist for NHF, wrote that "The hard facts are that the entire 'health food movement' is built upon just such sales of millions of health books, magazines and other publications to promote the sale of some other product as part of a commercial scheme." Miller was exhorting the promoters in their successful fight against H.R. 1342 (and S. 450), a postal bill aimed at the heart of quackery because it would enable the Postal Service to prosecute the purveyors of false and misleading hidden advertising that is spread through books, magazines and other literature under the guise of ordinary editorial comment. As CCAHF noted, Miller was making a direct admission that so-called "health" publications are intended as sales instruments. This identifies them as dealing in commercial language undeserving of protection as free speech in the same way advertising is not protected under the Constitution. CCAHF noted that "H.R. 1342 and S. 450 deserve the support of everyone who believes the public has a right to be protected against the ex-

plotation and deception inherent in books and magazines which masquerade as purveyors of health information." the quackery mafia successfully lobbied away that bill by misrepresenting it as an attack on freedom of speech.

Emory University Professor of History James Harvey Young has distilled from his decades of study a ten-point profile of health quackery:

- (1) Exploitation of fear.
- (2) Promise of painless treatment and good results.
- (3) Claims of a miraculous scientific breakthrough.
- (4) Simpleton science: Disease has but one cause, and one treatment is all that is needed to fight it. Bad nutrition causes all disease; good nutrition cures it.
- (5) The Galileo ploy: Like Galileo, we cult gurus are misunderstood by blind scientists, but are destined to be heroes to future generations.
- (6) The conspiracy theory, also known as "The establishment is out to get us."
- (7) The moving target: Shifts in theory to adjust to circumstances. Laetrile went from drug to "vitamin," from cure to palliative to preventive, from low to high dosages, from working alone to never working alone, from one chemical formula to another, and so forth. "B₁₅" ("pangamate") is any chemical or combination of chemicals the seller chooses to put in the bottle.
- (8) Reliance on anecdotes and testimonials. They don't separate fact from fiction or cause and effect from coincidence.
- (9) Distortion of the idea of "freedom." By distorting "freedom of informed choice" to "freedom of choice," snake-oil salesmen acquire freedom to defraud, and their victims can lose their money, their health and their lives.
- (10) Large sums of money are involved.

To understand why quackery flourishes, *cherchez le dollar*. It is necessary to recognize that quackery is big business, based on exploitation, deception, misrepresentation, anecdote and testimonial. Responsible physicians should be aware that fundamental to the success of this business is the group defamation of responsible physicians and other health scientists by categorizing them as "establishment" and "orthodox" and, therefore, untrustworthy. By destroying their credibility, the snake-oil purveyor can then say, "You can't trust the establishment; trust me!" It is also fundamental to the success of quackery that the public accept as valid the reversal of the two basic health canons that no therapy is safe until proved safer than doing nothing, or effective until proved more effective than doing nothing. The reversals read, "safe until proved unsafe, and effective until proved ineffective."

It is necessary to remind the public and the executive, legislative and judicial branches of our government that anecdotes and testimonials are worthless as evidence of cures or effects of treatment, whether described by laymen or by professionals and that the only reliable evidence about the usefulness of any proposed remedy is that obtained from well-planned and carefully conducted randomized and, where possible, double-blind clinical trials. Uncontrolled studies can suggest a direction, but they are not evidence. Every claim of "nutritional cure" of cancer, arthritis, heart disease, etc., with laetrile or green-lipped mussels or EDTA or nutritionally destructive regimens represented as "nutrition" by defrocked physicians and dentists and various health cult groups have never been objectively demonstrated to cure a single case. Every claimed such cure which has been fully investigated has fallen in one of the following categories: (1) Never had the disease (the diagnosis having been made without proof the disease existed); (2) the disease was cured by proper therapy but misperceived or misrepresented as cured by a questionable remedy concurrently or subsequently given; (3) the disease is progressing, but a symptomatic, and the patient erroneously believes a cure has been achieved; (4) the patient is dead, but is represented as cured.

Examples of each of these four categories are given in our 1984 article "Faddism and Quackery in Cancer Nutrition" in the scientific journal *Nutrition and Cancer*.

We must constantly remind the public that it is legal to lie about health products provided one does not do so on the label of the product. Thus, one can arguably sell books, magazines and other literature claiming quack remedies are safe and prevent and cure everything under the sun, so long as the bottles of products are on a different shelf from the literature, and the labeling on the bottles does not make the claim. If the literature is sold with the product, it is labeling, and the seller can be convicted of misbranding.

When hucksters tell us pills, powders, and potions will prevent or cure this or that, we must say, "Write the claim down, sign your name to it and then scotch-tape it to the bottle." They won't do it, because lying on the label is a crime.

What are some of the major quackeries against the aging?

(1) *Anti-aging and sex-rejuvenation quackery*

Gerovital.—The main ingredient in Gerovital is procaine, a local anesthetic which can cause convulsions and other serious side effects if rapidly absorbed. PABA is a breakdown product in the urine of people taking procaine, so some American quacks sell PABA as "anti-aging procaine tablets." Since PABA blocks sulfa drug action, a person taking a sulfa drug for an infection who also takes PABA will be protecting the infecting bug against the sulfa, and could die. PABA is a B-vitamin for bacteria; the quackery mafia falsely claims it is a B-vitamin for humans. PABA is a good sun-blocker, but it is unsafe to drink your sun-tan lotion.

Vitamin E megadoses, fraudulently promoted as rejuvenating, can produce a wide variety of serious harms. An article published in the Proceedings of the National Academy of Sciences in 1982 reported that elderly people in California who took megadoses of vitamin E got sicker sooner and died sooner than those not taking vitamin E supplements. According to the article, Prevention magazine sponsored the questionnaire which produced the data. I do not recall seeing Prevention ever informing its readers of this result. A wide variety of harms from megadoses of vitamin E (and megadoses of other vitamins and minerals) are reported in "Vitamins and Minerals: Help or Harm?" by Charles W. Marshall, Ph.D., Stickley Company, Philadelphia, PA, 1983. I do not recall Prevention ever publishing these harms or favorably citing Dr. Marshall's book.

Selenium supplements are falsely represented as anti-aging and anti-cancer, but have never been shown to protect a single human being against cancer or aging. The National Academy of Sciences 1982 "Diet, Nutrition and Cancer" report recommends against them, and against supplements of other vitamins and minerals as protection against cancer. "Superpotent" selenium is highly toxic. A 57-year-old lady who started taking selenium pills against aging had her hair fall out, her fingernail beds developed discharges of pus, and she got episodic nausea and vomiting, a sour-milk breath odor, and increasing fatigue. Her case was reported by the Center for Disease Control (CDC) in their Morbidity Mortality Weekly Reports for March 30, 1984. Her selenium pills were accidentally "superpotent" (a euphemism for "supertoxic"). She could have died, but the dangerous megadose of vitamin C she was also taking daily probably saved her by converting most of the selenium she ate to an unabsorbable form. Endemic selenium intoxication has been reported in a number of villages in China (Amer. J. Clin. Nutr. 37:872-881, 1983).

"Life Extension Formula".—These quick nostrums have never been demonstrated to extend a single human life, and the recommended drugs and high doses of vitamins and minerals can produce a wide variety of harms. The basic false claim is that since trace quantities of diluted antioxidants preserve foods, huge quantities concentrated as "supplements" will preserve you. Quacks tell the aging to take 2 grams daily of concentrated BHT and BHA and sell the stuff for \$15 for a one and two-thirds ounce bottle. One gram daily of BHT or BHA can be fatal for rabbits (Western J. Med. 139:229-230, 1983) but since quacks never report the harm they do, we don't know yet if humans have been killed by life extension formulas.

Perhaps in a decade, we will have a report on the harms done by "life extension" formulas. For more than a decade, toxic megadoses of vitamin B₆ were being given to autistic children, schizophrenic adults, women with premenstrual tension, and people with carpal tunnel syndrome, but the promoters never reported a single case of all the harm they did. Finally, on August 25, 1983, responsible neurologists reported in the New England Journal of Medicine 309:445-448, that such doses produced severe sensory nerve damage in 7 people, and caused an eighth, a schizophrenic patient, to commit suicide.

Zinc only has value in treating zinc deficiency, which is uncommon in the aging. Excesses of zinc can produce anemia and may also promote heart attacks and strokes. Non-existent zinc deficiency is often diagnosed by quacks using hair analysis.

Bee pollen is promoted by quacks as "anti-aging." They claim President Reagan takes it. It is not only essentially worthless, since it adds insignificant amounts of a variety of nutrients to the diet, but can be very dangerous because it really is pollen, one of the most allergenic substances known. If you have rose fever, hay fever, or dandelion fever, and you eat a bee pollen capsule with one of those pollens in it, you may wind up in your local hospital emergency room in anaphylactic shock or dead, as pointed out in the Journal of Allergy and Clinical Immunology.

RNA pills.—Fraudulently represented as anti-aging, the RNA in these pills is digested by our intestine enzymes, and what is absorbed is only simple building blocks, some of which can precipitate gout in people so predisposed. Since RNA is a specific blueprint and can only reproduce itself, and what is sold is yeast RNA and sardine RNA, if we actually did absorb it and could use it, we would turn into young

yeasts or young sardines. This was brought out during cross-examination of defense "expert" witness Robert Atkins, M.D., during a Postal Service hearing against RNA seller Great Life Laboratories (Postal Service docket No. 8/82, G.C. 52-80-F, February 5, 1981). It was also brought out that Dr. Atkins failed that part of his Boards in Internal Medicine which required drawing correct conclusions from observation and examination of patients. This has not prevented him from making millions annually promoting questionable health practices, networking with convicted (New York City Municipal Court, 1945) quack Carlton Fredericks, who calls himself "doctor" on the strength of a night-school Ph.D. from New York University in the field of radio communications.

(2) Cancer quackery

Laetrile.—Laetrile is 6% cyanide by weight. Those who take it get slowly progressive cyanide poisoning and gradually rot away, becoming unable to walk, see, and hear, and thinking all the while it is the cancer rather than the laetrile which is killing them. Taking in over \$1 billion a year for product alone, the merchants of death in this arm of the quackery industry luckily are as venal as heroin dealers, and cut their product so that it ranges from 0% to 80% of the amount stated on the label. This is why acute deaths from cyanide poisoning from laetrile do not number in the thousands. (For details, see the book "Nutrition Cultism: Facts and Fictions" by Victor Herbert. Stickley Company, Philadelphia, 1980-81.)

Coffee enemas.—This 100-year-old quack remedy is worthless against cancer but has killed people by producing acute cardiac arrhythmias (see Journal of the American Medical Association, October 3, 1980). Steve McQueen was getting such coffee enemas. He died of an acute cardiac arrhythmia. Whether the two were connected, we will never know. He had been in the care of William Donald Kelley, who, according to Charles Petit in the San Fro Chronicle of October 16, 1980 (page 2) is an orthodontist whom Texas authorities accused of practicing medicine without a license and whose Texas dental license was suspended for "offering cancer treatment along with orthodontics." Kelley runs the "International Health Institute" whose "nutrition counselors," called "certified metabolic technicians," promise a "complete progressive health care and metabolic lifestyle program" and have full-page ads in Prevention magazine giving an 800 number to call for the nearest "certified metabolic technician." Membership in his International Health Institute is open to any individual who pays \$10 and signs an application asserting he is not a government agent, will never aid a government agency that brings any action against the institute, and that neither he nor his heirs will ever sue or bring a criminal charge against the Institute, and that he will never divulge any information about the Institute to any investigator. (For further details, see Herbert and Barrett, "Vitamins and Health Foods: The Great American Hustle." Stickley Company, Philadelphia, 1981).

Macrobiotic diets.—These nutritionally marginal regimens can rob cancer patients of their ability to fight cancer by draining them of adequate nutrition (see pages 93 to 106 of "Nutrition Cultism"). Anthony Sattilaro, a physician whose prostate cancer was put in remission by proper treatment (castration and female hormone therapy) is fraudulently represented by the lucrative macrobiotic industry as having been cured with a macrobiotic diet. His book "Recalled to Life" is misleadingly advertised to support such claims, but he sent a letter to the American Cancer Society's Committee on Unproven Methods denying that he ever claimed that his macrobiotic diet brought about his improvement. He has continued on a macrobiotic diet, and it has been indicated to me that he may now be in relapse.

Other "alternative therapies" for cancer.—"Alternative therapy" is often a euphemism for quackery. When responsible health professionals speak of "alternative therapies," they mean alternatives like whether to use aspirin or acetaminophen. The quacks mean alternatives to what works (i.e., they mean therapies that don't work) rather than alternatives between two things which work. They are telling you that you have the following alternative: believe responsible health professionals who will tell you the truth, or believe them. They will sell you false hope, rip you off, and may send you to an early grave. In their chapter "The Cruellest Killers" (in Stephen Barrett's book "The Health Robbers"), Congdon Wood and Birdie Presley of the American Cancer Society wrote "Cancer quackery is big business, with an estimated yearly income in the billions. It is also cruel business, for its customers come in deadly fear. Those customers who come while also undergoing good medical care will buy only empty promises. But those . . . who delay or abandon medicine's best, will purchase death" (like Joey Hofbauer and countless other victims of the cancer quackery industry).

(3) Arthritis quackery

The Arthritis Foundation (Atlanta, GA) regularly informs the public that arthritis has nothing to do with nutrition, except that, if you are overweight, you should lose the overweight since it's tough on your joints, and if you have gout, you should reduce the intake of certain foods. According to Diana Benzaia in her chapter on arthritis quackery (in Barrett's "The Health Robbers"), "for every dollar spent on arthritis research, twenty-five dollars are spent on arthritides quackery."

DMSO, a quack arthritis remedy, when taken with Clinoril, a standard anti-arthritis drug, can produce severe and permanent nerve damage. DMSO was reported in *Science* in January, 1983 to be mutagenic, and therefore may promote the development of cancer. Green-lipped New Zealand mussel extract, the latest quack arthritis cure, can produce severe allergic reactions.

(4) Heart disease quackery

Chelation therapy ("chemical endarterectomy").—This treatment, which rips its willing victims off for \$3000 to \$5000 for a few weeks of injections of EDTA, can kill when injudiciously used. It is based on the deception that the problem in coronary arteries is narrowing by calcium, whereas in fact the problem is narrowing by fat, cholesterol, and fibrous tissue. The Diagnostic and Therapeutic Technology Assessment (DATTA) of "chelation therapy" on page 672 of the August, 1983 *Journal of the American Medical Association* (JAMA) (Vol. 250) stated:

"The original thesis that repeated intravenous infusions of the chelating agent, edetate disodium, was of benefit to patients with coronary artery disease, as manifested by the anginal syndrome, has *not* been established in any well-designed, controlled trial. Although some uncontrolled studies claim benefits, others have shown no substantial effects from such therapy. There is no supporting evidence that it has any substantial effect on the atherosclerotic plaque. Furthermore, the safety of using edetic acid, especially in patients with coronary artery disease, is questionable. Chelation of plasma calcium will decrease the levels of ionized calcium and result in tetany, cardiac arrhythmias, convulsions, and respiratory arrest. It can cause renal tubular necrosis and renal failure, permanent renal damage, bone marrow depression, and prolongation of the prothrombin time.

"The majority of respondents believed that this treatment was unacceptable or indeterminate therapy for atherosclerotic vascular disease. About half as many felt that it could still be considered investigational, i.e., worthy of a controlled trial under protocol.

The Department of Health and Human Services released a report entitled "EDTA Chelation Therapy for Atherosclerosis" in 1981 (HRST Assessment Report Series, volume 1, No. 18). It is noted that chelation for this indication is controversial, that there is no accepted rationale for its effectiveness, and that its safety is questioned. "The Medical Letter," in 1982, reviewed the experience of over 20 years and concluded that "there is no acceptable evidence that chelation therapy with EDTA is effective in the treatment of atherosclerosis and the adverse effects of the drugs can be lethal." The American Heart Association has also reviewed the data and found no scientific evidence to support the claims of benefit in patients with atherosclerosis. This opinion is shared by the American College of Physicians, the American Academy of Family Physicians, the American Society for Clinical Pharmacology and Therapeutics, the American College of Cardiology, and the American Osteopathic Association.

"In summary, there is general agreement that chelation therapy has not been established as an acceptable treatment for coronary or other arterial atherosclerosis."

Additionally, according to FDA Consumer magazine (volume 16, pages 28 and 29, 1982), "In at least one reported case, a patient under chelation therapy died when a calcium embolus, or clot, freed from a large arterial plaque, lodged in his brain." In view of the DATTA report in the widely-read JAMA, it is arguable that any physician representing that chelation therapy is effective and/or safe, and using it on patients, should have his license lifted for incompetence by his state's authorities.

The promoters have their own "American Board of Chelation Therapy" and advertise "a physician who is board certified is recognized as an expert in chelation therapy . . . Endorsed by American Academy of Medical Preventives, American Holistic Medical Association (and) (by application) American Board of Medical Specialists." The final phrase is misleading, because the American Board of Medical Specialists does not recognize chelation as either effective or safe. The American Academy of Medical Preventives (AAMP), a group of 390 "chelation doctors," (executive committee: Ross Gordon, M.D., who runs a "preventive medicine and chelation therapy" clinic in Albany, California; James Frakelton, M.D.; Charles Rudolf, D.O., Ph.D.; William J. Mauer, D.O., a Chicago "specialist in chelation therapy"; Warren

M. Levin, M.D. of New York City, Elmer Cranton, M.D. of Virginia; and Murray Susser, M.D.) puts out a slick-paper Quarterly and sponsors chelation-promoting television interviews on the national "Viewpoint on Nutrition" show hosted by chiropractor Arnold Pike from California. Arguably, the AAMP may be considered a conspiracy to misbrand as effective and safe in the treatment of atherosclerosis the chelation AAMP members use in their individual practices. The U.S. Attorney General arguably should determine whether this is prosecutable under the federal law against conspiracy to engage in racketeering. The January-February 1984 Quarterly has full-page ads for convicted criminal (for conspiracy to smuggle laetrile, and for smuggling it; 76-0448, U.S. Dist. Ct., S. Dist. Calif., filed May 16, 1977) Robert Bradford's "Chelation Therapy and the Killer Diseases" filmstrips, and "chelation doctor" Garry Gordon's MinerLab "proven chelation efficiency and potential life extension" pills. According to American Medical News for October 27, 1975, the Sacramento, California, County Medical Society Professional Conduct and Ethics Committee found Garry Gordon's methods unscientific and without justification.

H. Ray Evers, M.D., a former National Health Federation governor and godfather of chelation for heart disease, claims to treat a thousand patients a year, which, at \$3,000 each, would give him an income of \$3 million a year from this alone. If, from among the membership of the AAMP, NHF, the IFPM, the American Holistic Medical Association, the Association for Chelation Therapy, and the many other groups networking with these, they do only 350 times as much chelation as Evers alone, they would be taking in a billion dollars a year. It is more likely they do a thousand times as much, and that would be \$3 billion a year for this form of heart disease quackery alone.

The Louisiana State Board of Medical Examiners denied Evers a permanent license to practice medicine in Louisiana in 1974. Judge Melvin Duran, Civil District Court Judge in New Orleans, ruled that his use of EDTA was "a drug which violated a recommendation of the U.S. Food and Drug Administration" and concluded that Evers "was incompetent to practice medicine in Louisiana" and "deceived and defrauded his patients and/or the public" (New Orleans Times-Picayune, February 4, 1976). Although a physician can use any drug he or she wishes, the drug cannot be illegally labeled (i.e., misbranded). In the case of prescription drugs, like EDTA, the term "labeling" includes advertising. That is why the Louisiana Civil District Court (Civil Action No. 75-1790, September 28, 1976 at New Orleans) enjoined Dr. Evers and Meadowbrook Hospital (which he owned) from administering chelation to persons referred to the hospital for treatment of atherosclerosis. According to the Memorandum and Order of District Judge J. Gordon, Evers and promotional literature distributed at an NHF convention misbranded EDTA, to wit:

"Testimony at the injunction hearing established that Dr. Evers has held a press conference and distributed promotional literature advocating EDTA therapy for cardiovascular disease, and that promotional literature of the same sort was distributed at a convention of the National Health Federation. It is shown that Dr. Evers continued to distribute chelation therapy advertising to prospective patients and both he and Meadowbrook Hospital enjoy a national reputation as employing EDTA in the treatment of arteriosclerosis.

"Accordingly, it is this Court's conclusion that the intended use of EDTA at Meadowbrook Hospital is in the treatment of arteriosclerosis and that the failure of the drug's label to comply with 21 C.F.R. <200.100 causes it to be misbranded within the meaning of 21 U.S.C. <352f(1)."

The program for the chelation therapy weekend seminar given at the Omega Institute for Holistic Studies in Rhinebeck, NY, on June 25-26, 1983, by Drs. Levin and Schachter states, "EDTA chelation therapy, a highly effective treatment for atherosclerotic diseases . . . Michael Schachter, M.D., and Warren Levin, M.D., estimate that they have supervised over 12,000 intravenous chelation infusions between them over a ten year period in their two practices." Is this misbranding?

Promoters of questionable practices appear to exculpate themselves by requiring their patients to sign statements such as the following used by Dr. Evers' clinic:

"I understand that the type of therapy given at the RA-MAR CLINIC may not be in perfect agreement with the so-called orthodox methods of treatment as approved by the AMA, FDA or HEW. I understand that the . . . therapy given here is the type that the Physician and I both agree is the correct future of medicine. (By the use of nutrition, enzymes, physical therapy, magnetic medicine, use of pyramids, etc., or any other modalities that may be used to benefit mankind) . . . I willingly request this type of therapy and will abide by the results."

Others, like Dr. Warren Levin of the World Health Medical Group in New York City give their patients a 4-page come-on entitled "Holistic Medicine: A Statement of Principles, Benefits, and Practices" which slips in on page 2 an arguably exculpa-

tory statement which insurers can use to refuse reimbursement for what Dr. Levin does, since most insurers only reimburse for "diagnostic and therapy practices generally recognized as reasonable and necessary throughout the medical profession." It can also be arguably used by State authorities to challenge the competence of Dr. Levin in diagnosis and therapy. The page 2 statement is:

"We must inform you from the onset that the testing procedures and therapies we employ differ considerably from those used by most of organized medicine. Many health professionals consider our approach to health care experimental and look with skepticism at these concepts. Therefore, you must understand that there will be strong criticism by members of the medical establishment toward physicians who practice in the new fields of Preventive Medicine, Nutrition, and Chelation Therapy. You must, however, keep in mind that medicine has always progressed slowly and that it is reluctant to accept any new concept. Even penicillin was considered highly experimental and controversial for many years, as was the use of Vitamin C in scurvy and the use of iodine in goiter."

"If psychologically you cannot accept or financially you cannot afford the concepts of Preventive Medicine and Nutrition, we recommend that you bring these matters up during your first consultation, or whenever they arise. We can then attempt to clear up any possible misunderstanding from the onset. By your freely expressing any doubts or fears that you may have regarding any aspect of the recommended therapies or tests, we may either be able to allay your anxiety through suggesting alternative approaches, or we may recommend more orthodox medical care for your consideration."

Evers is now running a lucrative clinic in Alabama, just across the border from Mississippi, protected by an Alabama judge's decision opposite to that of Louisiana Judge Melvin Duran's order, which was "Dr. H. Ray Evers is not to practice medicine anywhere within the State of Louisiana."

AAMP states that HCFA has determined that the use of EDTA for impaired circulation is experimental, so AAMP has not been able to get third-party payment from federal or insurance sources, and is trying to force such payment through political pressure by their new lay organization, the Health Association of the United States (HAUS).

(5) Diagnostic tests the charging for which usually identifies promoters of quackery

Hair analysis purports to tell you your vitamin and mineral deficiencies and mineral imbalances. There are no vitamins in hair clippings, and mineral levels in hair have no reliable relation to mineral levels in living tissue except as a late (because hair only grows two-fifts of an inch per month) measure of heavy metal poisoning. Early measures of poisoning are in the blood. Hair analysis diagnoses non-existent lead poisoning in people using Grecian Formula 9, and non-existent selenium poisoning in people using Selsun Blue. Diagnosing vitamin and mineral deficiencies or mineral imbalances or the basis of hair analysis is fraud, as is the prescribing of vitamins, minerals, and other "nutritional supplements" on the basis of a hair analysis. See the article by Professor K. Michael Hambridge exposing the hair analysis fraud in the American Journal for Clinical Nutrition 36:943-949, 1982 (November) and the article "Hair Analysis? May as well be bald" in the FDA Consumer, April, 1983, pages 16 and 17.

Cytotoxicity testing.—Advertised in New York and other magazines and newspapers across the country, this promotion rips off the aging for \$300 to \$500 a test for a sample of their blood, which is dropped into a series of wells to which a series of foods are added. Many liquids and foods destroy white blood cells to varying degrees in the test tube; this has no diagnostic meaning. The patient is told that because tap water or a variety of foods destroy their white blood cells in a test tube, they have a wide variety of allergies which they don't have. They are then given a wide variety of pills, powders, and potions at high cost to "cure" the nonexistent allergies. A series of studies published in the Journal of Allergy and Clinical Immunology show cytotoxicity testing to have no relation to whether or not a person is allergic to a particular food. This is to be expected, because none of the foods we eat or liquids we drink reach our white cells unaltered, as they do when fed to white cells in the test tube. What passes into the blood stream across the filter of the small intestine after being digested in the stomach and small intestine is completely different from what went in the mouth. "Clinical ecology" promotion leans heavily on highly questionable allergy tests like cytotoxicity testing. The facts about the clinical ecology rip-off are revealed by Dr. Charles May in his article in the March 1984 issue of Nutrition Reviews.

Nutrient deficiency computerized questionnaires.—Put out by Donsbach, Kelley, and other promoters, these questionnaires purport to diagnose nutrient deficiencies.

In fact, the questions they ask are largely unrelated to nutrition. They are of the quality of "are you tired after a hard day's work?" For example, the Donsbach computer is programmed to spit out that you need an extra 50 mg of vitamin C for each cigarette you smoke. In fact, smokers usually have normal vitamin C levels. A study in the *Annals of Internal Medicine* suggests that smokers who take megadoses of vitamin C will actually get lung cancer and other cigarette-smoke-associated ills faster, because mega-C drives nicotinic acid out in the urine, causing you to reach for that next cigarette that much faster.

Kinesiology.—In this fraud, the quack has you hold out your arm, presses down on your wrist and tells you that you will be unable to resist that pressure if you have a lump of sugar in your hand. He then puts a lump of sugar in your hand, and sure enough, you don't resist as well. This is suggestion and not cause and effect, but you don't realize that.

The health frauds are almost beyond counting, and new ones appear daily. Until we recognize that we are dealing with a highly organized quackery industry, and organize a federal task force against it like the one against organized crime, we will continue to be ripped off for 25 billion dollars a year, and untold costs in suffering and premature death. The federal law against criminal conspiracies allows the government to force the conspirator to disgorge all their profits. Until we use this conspiracy law against the promoters of quackery, to hit them where it hurts—their pockets—they will happily march on to ever increasing wealth as they impoverish and slowly destroy their victims.

Quackery promotion is on the march. Frank Salaman has a criminal conviction for conspiracy with Roberet W. Bradford to smuggle laetrile; conviction upheld October 20, 1978, U.S. Court of Appeals for the Ninth Circuit. Maureen Salaman, President of the laetrile-promoting National Health Federation, writing on page 4 of the May, 1984 Health Freedom News of the NHF states: "We have made tireless attempts this year to build bridges to other organizations with whom we have mutual interests. I am assured by Rosemarie West, President of the National Nutritional Foods Association, that we can expect a letter from the NNFA which will show a distinct change in attitude on their part in our cooperative efforts. The American Academy of Medical Preventives' leadership is pleased with the bridge between the two organizations and I have once again been asked to address their membership in May . . . During the past year, I have been invited to speak in 28 states to thousands of people . . . The NHF, standing alone, stopped the ominous Post Office Bill . . . Among our projects this year will be to steal the headlines from Claude Pepper's "Quackery Hearings." We will introduce a "Free Choice" amendment which will allow individual patients to choose exemption from FDA protection."

In their March/April 1984 Newsletter, CCAHF notes:

"The National Health Federation (NHF) is distributing a form letter to their members asking Senators to introduce, cosponsor and work for enactment of a bill granting people the right to utilize medications which have not been approved by the FDA. This approach to attempting to legalize quackery is typical of the NHF's distortion of reality in freedom of choice matters. In fact, the law does not restrict people from using unproven methods but prevents promoters from selling them. The ploy is a diversion from the sellers to the desperate or deceived disease sufferers with whom we all sympathize. Of course, patients cannot be free to buy unproven remedies unless someone can sell them, which means the next move would likely be to permit misguided maverick doctors and nonscientific practitioners to sell these after having patients sign a waiver. Since there is no way to control the deceptive tactics such purveyors of quackery would use, this would simply provide a hunting license for the untrustworthy to use on vulnerable people. Hopefully, this 1984 strategy will not get very far, but we cannot be certain that the same misguided politicians that supported legalizing laetrile won't make a thrust toward a "free choice amendment." This tactic may represent an attempt to counter Representative Claude Pepper's anti-quackery efforts scheduled for this year."

The two 1984 associated editors of Health Freedom News are the above Mrs. Salaman and the ubiquitous Kurt W. Donsbach. Kurt Donsbach has 2 convictions in connection with his activities in the field of health, each resulting in two years summary probation and one subsequent conviction for probation violation (see details in the book "Vitamins and Health Foods"). He is the creator of the Donsbach University Ph.D. nutrition diploma mill, and of the International Academy of Nutrition Consultants credential mill, which for \$50 sold my cat Charlie a professional membership. He is also 1984 Chairman of the Board of the American Association of Nutritional Consultants credential mill which for \$50 sold my dog Sassafra professional membership. These two organizations, with their approximately 12,000 members, have just combined into one. Their monthly magazine *The Nutritional Consultant*

and Health Express, March 1984 issue, has separate full page ads promoting "the tools and treatments for rejuvenation and health promotion . . . including the only "fresh" live cell therapy in the Americas . . . a total package of life extending, health-promoting approaches," chelation therapy, Donsbach lectures all over the U.S. \$125 admission fee), professional memberships in the American Association of Nutrition Consultants (AANC) for \$50, hair analysis, cytotoxicity testing, Donsbach University degrees, and laetrile. One of the full-page ads for cytotoxicity testing is from convicted criminal (for conspiracy; details in the book "Nutrition Cultism") Robert Bradford's American Biologics. The same issue has a 3-page article by the same Mr. Bradford (representing him as "Dr." and "Ph.D.") promoting cytotoxicity testing.

The New York Times reported on Sunday, May 27, 1984, that when Dr. Carl Bodenstien testified before Congress on infant deaths from an intravenous vitamin E preparation, he stated that when he and his associates told the distributor of deaths possibly linked to their product, they were told that the substance had been proved safe, and were threatened with libel or slander charges if they said otherwise. Quackery promoters are likewise highly litigious and constantly intimidate responsible health professionals and layment with threats of libel suits. Dr. McMahon of Tulane was actually sued by a chelation promoter (see "The Perils of Identifying Quacks" in the New England Journal of Medicine 302:870, 1980). NNFA (represented by attorney Robert Ullman) was thrown out of court when they sued Drs. Fredrick Stare and Elizabeth Whelan for daring to speak the truth as they saw it about health food rip-offs (78 Civ 6276 (ADS), U.S. District Court, Southern District of New York; opinion dated June 21, 1980). Defending against such harassment is costly in time and money. In that case, Judge Sofaer opined that any further suit by NNFA against critics of the health food industry should be scrutinized carefully to determine whether it was brought in bad faith, with an eye to requiring the plaintiffs to pay the defendants' counsel fees. To that one might add that the defendant should consider a countersuit for malicious harassment and abuse of process as well as barratry, after winning judgment. In a recent frivolous suit, the judge ordered the plaintiffs and their lawyer to pay \$10,000 each (Business Week May 28, 1984, page 67).

The basic protection for the consumer is the FDA requirement for clinical trials to demonstrate that a product is (1) effective and (2) safe. None of the quack remedies have been demonstrated to be either (1) more effective than doing nothing or (2) as safe as doing nothing.

Promoters of quackery almost never file an Investigational New Drug (IND) application with the FDA, a procedure that would allow them to conduct the clinical trials they always claim they want. If you ask them, "Did you file an IND?" and the answer is "No," you can be pretty sure it is a quack remedy.

A decade ago, when the FDA proposed a rule to protect the public against toxic megadoses of nutrients for forbidding over-the-counter sales of nutrients containing more than 150% of the RDA (recommended daily allowance) of any nutrient, promoters got Congress to pass a law forbidding the FDA from requiring vitamin and mineral sellers to prove safety, and instead requiring the FDA to prove toxicity. Since toxic doses of nutrients are used almost exclusively by promoters of quackery, and they rarely report to the FDA the harms they produce, this law effectively castrated the FDA in this area and set up the consumer as a pigeon for nutrition quackery.

Another consumer protection would be a law forbidding holders of diploma mill Ph.D. degrees to call themselves "doctor" or "Ph.D.," since to do so is a consumer deception. Such is now the law in New Jersey, as noted earlier in this testimony.

The quackery mafia promotes diagnosing disorders using tests which don't diagnose, and treating with treatments that don't work. They promote a questionable brand of medicine, defined as not successfully answering the three basic questions with regard to all therapy, to wit:

1. Is the proposed therapy more effective than doing nothing?
2. Is the proposed therapy as safe as doing nothing?
3. If the proposed therapy is not as safe as doing nothing, is the potential for benefit greater than the potential for harm?

By definition, no treatment works until it has been demonstrated to work, in a matter satisfactory enough that the demonstration is accepted for publication in the peer-reviewed scientific literature, and is satisfactorily reproducible subsequently by others. None of the remedies discussed in this presentation have passed that test, and all have had plenty of time to do so. That is why they are quack remedies.

Just as the Costa Nostra Mafia says, "Why go after us—go after the shoplifters—they are the real crooks!" so the quackery mafia say, "Why go after us—go after the

doctors who do unnecessary surgery—they are the real quacks.” This obvious diversionary tactic involves their typical creation of their own private meaning for words, which has no relation to the dictionary meaning. Unnecessary surgery is abusive use of what works, and is entirely different from quackery, which is the use of what does not work. Another big difference is that quackery is organized. There is no national organization of “Surgeons Dedicated to Unnecessary Surgery,” but there are national organizations dedicated to quackery.

Promoters of cancer and arthritis quackery frequently tell anecdotes about patients getting pain relief from the quack remedies they promote, and they have the patients state how wonderful is the pain relief they got. These promoters know, but never tell, that if you believe something will give you pain relief, it will, even when it's a complete fake. They know about, but never mention, the studies by Professor Beecher, Chairman of the Department of Anesthesiology at Harvard, in World War II and the Korean War. Professor Beecher filled half the morphine syrettes with saline, and corpsmen went out on the battlefield and half of the GIs with chest wounds, belly wounds, and head wounds, got saline instead of morphine. They got two-thirds as much relief as those who got morphine. The 10 percent who were most suggestible got complete relief; the 10 percent who were not suggestible at all got no relief. This was a dramatic illustration of the power of the placebo, i.e., the power to make you feel better of the belief that something will make you feel better.

Of course, the promoters of quackery usually take no chances, and when they invite someone to observe how their patients have been relieved of pain, they often slip the patients something that really will relieve pain, unbeknownst to the patients, such as various pain-killers, and, in the case of laetrile, the laetrile itself, which gradually destroys the nervous system with cyanide poisoning, and while the nervous system is rotting away, there is less pain because the nerves are dying, along with the nerves that allow us to see and hear and walk, so the patients gradually become unable to see, hear or walk, go blind and deaf, and become confined to wheelchairs, rotting slowly to death from progressive cyanide poisoning. The patients think this is because of the cancer, but in fact it is the 6 percent cyanide in the laetrile. Similarly, promoters of arthritis quackery often give the patients steroids in irresponsible doses which make them feel better but produce bleeding stomach ulcers and severe hormonal imbalances, sometimes causing psychotic episodes in which patients have thrown themselves out windows to their deaths.

The fact is that if you believe something will make you feel better, you will feel better even if it is killing you and is a deadly poison which is slowing and insiduously rotting you to death from cyanide poisoning, as laetrile does, or killing you acutely, as laetrile has also done, as we document in the chapter “Laetrile: The Cult of Cyanide—Promoting Poison for Profit” in our book “Nutrition Cultism: Facts and Fictions”.

We must not be sucked into the “It's us versus the health monopoly” baloney of the quackery promoter. The fact is that the majority of the leading promoters of health quackery who are M.D.s and have gotten rich in such promotions are members of the A.M.A. Although they don't mention their membership to their audiences when they promote “alternative medicine” (i.e., alternatives to what works), these members are part of organized medicine—they are the disreputable part. When they appear in court cases, they use their A.M.A. membership as “proof” that they are reputable.

When the promoters of quackery scream for “health freedom” they are screaming for freedom to cheat and freedom for victims to be cheated. They want to destroy health freedom, which is freedom to be healthy, by deceiving the public into buying the health-harming products they promote.

The tight coordination among the various separate operations of organized quackery is seen most clearly through the involvement of the same individuals in different operations. For example, organized quackery is working to prevent the states from passing legislation to license competent nutrition professionals. Such legislation would make illegal the dangerous and unsound (but lucrative) “professional” advice promoting quackery given by nutrition amateurs. The campaign is orchestrated by the same Clinton Miller who works closely with Kurt Donsbach and is not only paid lobbyist for NHF but also lobbyist for AANC (Kurt Donsbach is a power in both). On page 41 of the May 1984 issue of Nutritional Consultant (official publication of the American Association of Nutritional Consultants [AANC], Mr. Miller, listing himself as “Legislative Advocate, AANC and NHF,” delineates how to convince the public the attack on licensing is a freedom of speech issue instead of the consumer protection issue it in fact is. Mr. Miller urges readers to copy page 43 and mail it to their state legislators and “be sure your Health Food Store, Chiropractor and others have copies for their other customers.”

Attached is the page 43 they ask readers to copy and send to state legislators. Note that paragraph 4 identifies AANC, NNFA, and NHF as behind the opposition to legislation to protect the public against amateurs promoting nutrition quackery. Typical such amateurs are most of the Nutritional Consultants of the AANC, who promote every form of nutrition quackery their leaders (like contributing editor Kurt Donsbach, advertised on page 26, 28, 50, and 59) indicate to them is effective and safe, from cyanide-containing laetrile (advertised on page 26) for cancer through sometimes lethal chelation therapy for heart disease to toxic megadoses of vitamins and minerals for all the ills of humankind.

Note also the false and paranoid (pandering to paranoia is one of the characteristics of health quackery) representation in paragraphs one and two that the American Dietetic Association (ADA) seeks laws giving themselves the exclusive right to use the word nutritionist. The proposed laws state "RDs", not "members of the ADA." One does not have to be a member of the ADA to be an RD. To be an RD, one must be a nutrition professional with specialized nutrition knowledge gained in long and intensive academic preparation.

How does an incompetent rank amateur get to deceive the public into believing they are a professional? by paying \$50 to AANC. Attached is the advertisement on page 45 of the same May 1984 Nutritional Consultant, two pages after the petition against licensing of nutrition professionals, to join the thousands of "professional" Nutritional Consultants promoting lucrative nutrition quackery in the guise of "professional advice." Note you are asked to join "if you are employed where you offer nutritional advice" (i.e., health food store, etc.) and "if you sell, manufacture or recommend food supplements" (i.e., members of NNFA). Note also that there are not requirements for competence in nutrition to be an AANC "professional nutritional consultant" and to display their certificate and thereby deceive the public that you are professionally competent. State licensing laws for nutrition professionals would prohibit it; this is why promoters of quackery oppose such laws. The only requirements for the AANC certificate are that you have a name, an address, and the application must be accompanied by \$50. Attached is a photo of my dog Sassafras with his credential as a professional nutrition consultant. Sassafras met all three requirements for membership: she has a name, an address, and \$50 accompanied her application. There are many thousands of people across the USA, who met the same non-existent competency requirements as Sassafras, promoting health quackery for personal financial gain.

Organized quackery has its own jargon. They speak of "professional" members (i.e., ones who have a name, address and \$50). This is typical consumer deception by misuse of words. The use of the word professional by organized quackery has no relation to the dictionary definition, on which the public relies, which is (Webster's Seventh Collegiate): "professional: engaged in one of the learned professions; profession: a calling requiring specialized knowledge and often long and intensive academic preparation."

Organized quackery is big business—about \$25 billion a year, of which about \$10 billion is ripped off from the aging. Our country needs a federal organized quackery strike force to protect our population from it.

DON'T LET DIETICIANS OUTLAW NUTRITIONISTS

The Honorable _____

19 _____

Capitol Building _____

(State) _____

(City) _____

(State) _____

(Zip) _____

Dear Senator, Representative, Assemblyman, or Delegate _____

There is an improper attempt underway by the American Dietetic Association (ADA) to outlaw and make criminals of all nutritionists in the USA who do not pay dues to, or who do not teach the dietary dogma of the ADA.

The ADA seeks monopoly laws in all 50 states giving themselves the exclusive right to use the title of "nutritionist" alone or in combination with words like "educator, teacher, consultant, reporter, investigator," etc.

I am strongly opposed to any law which will restrict my freedom to choose my own nutritionist. I have no objection to a state law which will license dieticians. Dieticians want exclusive use of the title of "registered dietician" as they have for decades, it is OK by me, provided that the law stops there.

However, I strongly support The American Association of Nutritional Consultants (AANC), and the National Nutritional Foods Association (NNFA), and the National Health Federation (NHF) in their objection to the relentless attempts by ADA members to expand and misuse licensing or title laws to enable them to act as America's unelected Diet Dictators.

ADA members represent only one single (and not very popular) school of nutritional thought in the USA. They are best known for their preparation of the monotonous (and not very nutritious) menus in hospitals and prisons for which they have been subjected to increasing and well-deserved criticism. There is far more justification to break up the ADA's present monopoly control of hospital and prison diets than to expand that monopoly to include those of us fortunate to be out of their control.

There are as many vastly different beliefs about nutrition as there are about religion. In fact, many nutritional theories and practices are tightly intertwined with widely opposing religious doctrines and traditions. Orthodox Jews, Moslems, Seventh Day Adventists, and many other religions follow strict nutritional laws set down by their prophets.

Please be on the alert for the ADA legislation and vote against any proposal that goes beyond licensing or titling ADA members as "registered dieticians."

Thank you in advance for protecting my health freedom.

Sincerely,

Print Name: _____

Signature: _____

Address: _____

City: _____

State: _____

Zip Code: _____



This Certificate Belongs on Your Wall or Desk

IF: you offer nutrition or dietary counselling in your profession.

IF: you are employed where you offer nutritional advice.

IF: you sell, manufacture, or recommend food supplements.

Join Today

Where would physicians or today without a strong association like the AANA fighting for their causes in the courts and legislatures? Like physicians, if Nutritional and Dietary Consultants are to ever achieve the professional recognition they so justly deserve, they, too, must fight for it, and fight for it with the power of numbers through a strong, professionally organized association. The American Association of Nutritional Consultants is that association—fighting public ignorance, fighting adverse legislation, and working constantly to enhance the prestige and professional status of its members. The Association provides a forum for the open and free exchange of information through its monthly Journal.

Besides the above benefits—and those listed below—the AANC offers a daily consultation, FREE, to all its professional members regarding not only technical aspects of nutrition but the day-to-day business problems involved in the operation of a profitable nutritional consulting practice. And for future professionals (such as students), who may join as Associate Members, we provide a list of AANC approved schools.

MEMBERS INCLUDE

Alphabetically: Acupuncturists • Agronomists • Athletic Directors • Biochemists • Chiropractors • Dentists • Dietitians • Health Food Stores • Health Spas • Medical Assistants • Manufacturers of Health Products • Nurses • Physicians • Schools of Nutrition • Students Majoring in Nutrition (associate membership only) • Wholistic Centers and Clinics.

MEMBERSHIP BENEFITS BY CATEGORY

PROFESSIONAL MEMBERSHIP

- Subscription to the *Journal of Nutrition and Dietary Consulting*.
- Listing in the Official Directory of Nutrition and Dietary Consultants (if desired).
- Free Classified Ads in "Position Wanted" section of the AANC Journal.
- Free professional referral service.
- 15% discount on Academy books and tapes.
- Eligible for participation in insurance program.
- Beautiful certificate for your wall or desk.

SUSTAINING MEMBERSHIP

- All the above benefits of professional membership plus:
- Monthly listing in the front of *The Journal of Nutrition and Dietary Consulting* as a Sustaining Member.
- 50% discount on display advertising in *The Journal*.

ASSOCIATE MEMBERSHIP

- Subscription to *The Journal*.
- 15% Discount on Association books and tapes.
- Beautiful certificate for your desk or wall.

MEMBERSHIP APPLICATION

YES: I wish to become a member of The American Association of Nutritional Consultants. I understand that my category of membership will appear prominently on my membership certificate. I have enclosed payment in full and know that \$12.00 of which is for a one-year (12 issues) subscription to THE NUTRITIONAL CONSULTANT & Health Express Magazine.

- Professional Member \$ 50.00
 Associate Member \$ 30.00
 Sustaining Member \$100.00
 Magazine Subscription To Non Members ... \$12.00

Make checks payable to AANC (in U.S. Funds)

Print Carefully.
Include your
degree initials
if any.

My Name _____

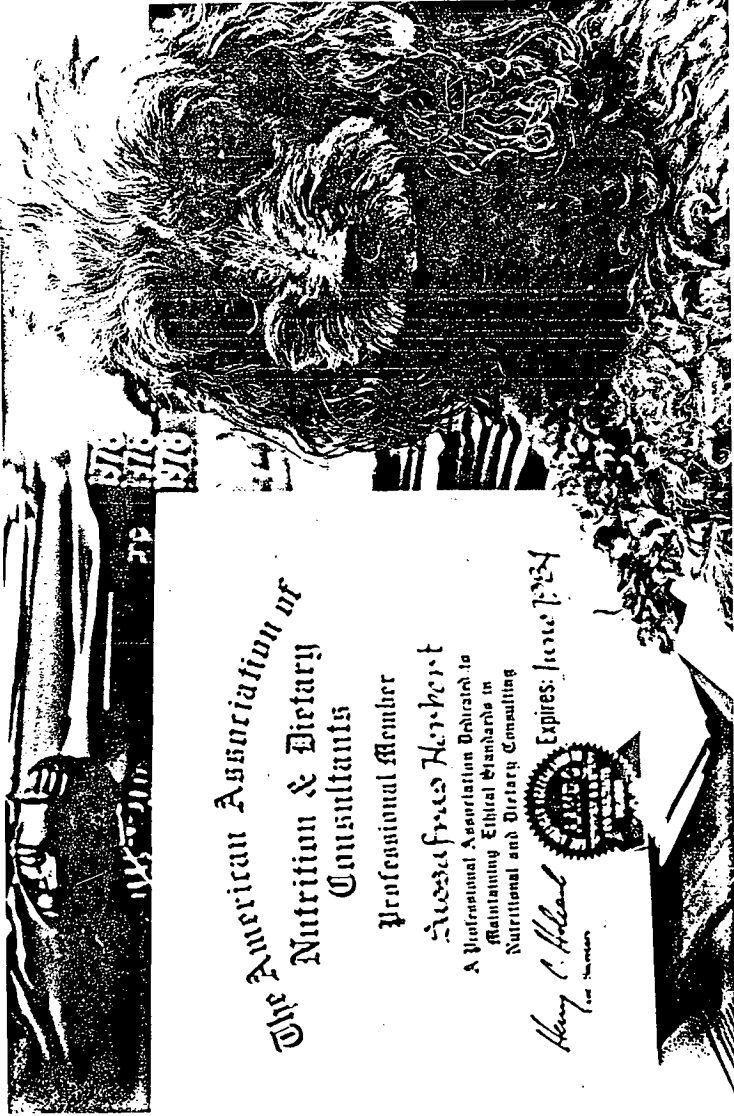
City _____

State _____

Zip _____

The American Association of
Nutritional Consultants

P.O. Box 10987, Beverly Hills, CA 90213



The American Association of
Nutrition & Dietary
Consultants

Professional Member

Frances Herbert

A Professional Association Dedicated to
Maintaining Ethical Standards in
Nutritional and Dietary Consulting

Expires: June 1954



Henry C. Hildner
President

Mr. BORSKI. Thank you very much, Dr. Herbert.
Dr. Schwartz, may we have your testimony, please?

STATEMENT OF SORELL SCHWARTZ

Mr. SCHWARTZ. Yes, sir, Mr. Chairman.

There are a couple of items. First, I have submitted to staff a lengthy written statement, which I wish submitted to the record.

Mr. BORSKI. It shall be so submitted.

Mr. SCHWARTZ. Secondly, I see the C-Span cameras here, and I would like to make two points. No. 1, there are other people in the room besides me; and, secondly, I am not the person to the left of Dr. Herbert to whom he was referring, just in case, when his hand went out, I got into the picture.

Mr. Chairman, ladies and gentlemen, my name is Sorell Schwartz, and I am currently professor of pharmacology at the Georgetown University School of Medicine in Washington.

Beginning in the late 1970's, I consulted for the U.S. Postal Service on matters concerning the advertisement and sale of remedies through the mails.

In most of the cases on which I was asked to render an opinion, it was my judgment that the advertisement for the remedy was false and misleading. This was probably because I was seeing the result of a preliminary screening by the Postal inspectors. That is, they did not submit something for my review unless they suspected something was wrong.

The aged are obvious targets of worthless remedies because of the accumulation of the chronic conditions of aging. The physician says, "There is not much we can do; you have got to learn to live with it." The advertisement says, "We have got something new." And the object of the advertising, the person to whom it is aimed, wants more than to believe. And as we have heard this morning, "They wouldn't be allowed to say it if it wasn't true."

The problem is a lot more insidious than some of the horror show type of things we have seen this morning. I don't mean to, in any way, lessen the importance of these and to what Dr. Herbert is referring. Many of the elderly are already on half a dozen or more medications prescribed by their physicians. We call it polypharmacy.

There is already a problem of compliance with the physician's directions: What are they to take? When are they to take it? How much are they to take? Many of the problems we have with legitimate drug therapy in aged people is getting them or their families to keep track of their medication.

There is also the problem of adverse reactions. The aged are more susceptible to adverse reactions to individual drugs; the interaction of the multiple drugs they are taking compound the problem. The addition of any new worthless dosage regimen compounds this problem. Irrespective of the so-called harmlessness of the added regimen, it compounds the problem of managing medication in the elderly.

In some cases, such as the marketing of phenylpropanolamine, PPA, as an appetite suppressant, a stimulant, a means of increasing sexual function in the aged, the primary biological effect is to

contribute to problems associated with preexisting cardiovascular disease, diabetes, thyroid disease, as well as the interactions with the legitimate medication.

The marketing of therapeutically useless remedies to the elderly cannot be considered a problem just associated with reducing the size of the retirement check. Nor is *caveat emptor* an appropriate response. The sophisticated marketer is now using MD's Ph.D's and other scientifically sophisticated individuals to help write advertising.

I have seen some of these same people in court testifying to the most absurd scientific hyperbole during hearings and trials. I have seen advertisements passing as scientific articles that have been written by professionals in such a way that preliminary research on vitamins and elements is inappropriately extrapolated to clinical efficacy for antiaging and anticancer activity.

An example is selenium. There is research suggesting that selenium may have some effect in scavenging for free radicals, the so-called natural carcinogens. But, as the analogy of eating brain to gain intelligence, that analogy suffices for taking selenium at this time to protect yourself against cancer.

But some of these advertisements—these so-called articles—are written with such sophistication that they would fool a physician who is not familiar with current studies in the area.

Under existing FDA regulations, scientific data presented by the drug company in its advertising literature for prescription drugs is considered part of the label and must meet certain FDA review requirements. I submit that when advertising for over-the-counter remedies purports to present supporting scientific data on a similar system, a regulatory scientific review should be imposed.

I would like to end with one particular example. For many years there has been published a book called the Physician's Desk Reference. The Physician's Desk Reference up to about 20 or so years ago was nothing more than a compilation of the advertisements for prescription drugs that the drug companies paid to have put in the book. Then regulations were imposed which obligated the material in the Physician's Desk Reference to be considered labeling and therefore subject to review by the Food and Drug Administration. Consequently, the Physician's Desk Reference now contains information provided by the drug company but which has a legitimate scientific basis.

In 1980, the same company that publishes the Physician's Desk Reference came out with a book called, "The Physician's Desk Reference for Non-Prescription Drugs." The physician has learned to use the original PDR, as he calls it, as a quick guide on drug toxicity, drug efficacy, and research with the expectation that the Food and Drug Administration has reviewed the information. But he does not know that no such qualification holds for the Physician's Desk Reference for Non-Prescription Drugs.

Any company can pay to have their materials put in this book, which many physicians would consider—and I did when I first opened it up—to be an authoritative reference. I have a 1980 edition here. I don't know if the same entry is in the 1984 edition—but there is a point to be made about the book. On page 592, they refer to Fluidex Plus tablets, containing 25 milligrams of phenyl-

propranolamine, 55 milligrams of powdered extract of buchu, 650 milligrams of couch grass, 32½ milligrams of powdered extract of corn silk, and 32½ milligrams of powdered extract of hydrangea. It is described as an appetite suppressant, in conjunction with a diet plan, combined with a mild natural diuretic as an aid in the elimination of body fluids. It goes on and discusses the actions and clinical studies as if all of these had the same legitimacy as the PDR for prescription drugs has. The preparation is relatively useless.

I suggest that one possible solution is that when remedies are advertised in magazines containing alleged scientific articles about those remedies, the articles should be considered labeling and they should come under the same scrutiny as any other labeling regulations.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Schwartz follows:]

PREPARED STATEMENT OF SORELL L. SCHWARTZ, PH.D., PROFESSOR OF PHARMACOLOGY, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, WASHINGTON, DC

Mr. Chairman, Ladies, and Gentleman, my name is Sorell L. Schwartz. I am Professor of Pharmacology at Georgetown University Medical Center, Washington, D.C. In the late 1970's I began working with the U.S. Postal Service in connection with mail-order remedies. This work involved the preparation of medical opinions and testimony at Postal Service Administrative law Hearings and in U.S. District Court. My experience involves not only contact with the advertisements and the products but with some of the so-called medical experts relied on by the distributors involved.

Most of the advertising for remedies is directed at the general public. Some is specifically directed at the elderly. Even that which is not specifically directed at the elderly often finds a much greater audience among the elderly than among the young. I have classified the mail-order remedies into five general and, perhaps, somewhat arbitrary groups.

1. Remedies that have therapeutic or supplemental activity and for which the advertisements are within some reasonably broad definition of veracity. In this group, I include those instances where the advertisements may be considered by some to border on being misleading but not out-and-out false. An example is the advertisement for vitamins which describes superior "naturalness" or superior "purity" but not associated with exaggerated claims for therapeutic efficacy such that the use of the vitamins is keyed to the prevention, mitigation, or cure of specific disease. Another example in this category is an advertisement for one of the "most effective arthritis drugs available" which, of course, turns out to be aspirin, or a derivative, at an exorbitant price. The marketing of caffeine preparations to overcome mid-day fatigue is another example falling into this category.

2. Remedies for which there is demonstrable therapeutic or supplemental activity but for which the advertisements are false and misleading. In this group are generally the same drugs or remedies described above but that cannot be considered to deliver the effects promised. The use of vitamins for the promised or guaranteed prevention, cure, or mitigation of specific diseases is a widely represented example. The marketing of aspirin as a guaranteed cure for arthritis or caffeine as providing lost energy and rejuvenation to the body would also be examples. With respect to the elderly, in particular, combinations of vitamins and caffeine have been advertised for renewed sexual function and correction of impotence.

3. Remedies which contain ingredients with no demonstrable therapeutic activity but for which claims of prevention, cure, or mitigation of diseases are made. Preparations with small amounts of plant extracts or animal glandular extracts are example of this category. In many cases, if the therapeutic effects claimed were true—e.g., hormonal effects from animal glandular extracts—these preparations would probably require further testing under Food and Drug regulations for adverse reactions.

4. Remedies which contain pharmacologically active substances for which the advertised therapeutic claims are in question and for which there is concern about toxicity. The most notorious examples of this category are those preparations containing phenylpropranolamine (PPA). This drug is the common ingredient of over-the-counter appetite suppressant drugs. As I have testified before this Committee on a previous occasion, I strongly doubt the therapeutic efficacy of this substance. Of

greater concern, however, is the potential toxicity of this material in individuals with such conditions as cardiovascular disease, diabetes, and certain types of thyroid dysfunction. This makes the elderly a special target of such a substance. PPA has been vigorously advertised through the mails such that claims of therapeutic efficacy and safety are false and misleading. The drug has also been incorporated into preparations which are claimed to provide renewed sexual drive and function to the elderly and has been advertised for preparations which increase alertness and overcome fatigue. All such uses are clearly contraindicated for this drug and, in my opinion, especially dangerous to the elderly.

5. Remedies for which experimental data exists suggesting potential but unproven therapeutic usefulness and for which advertisements claim such therapeutic efficacy. In this category are those substances which are the subject of current research in the area of certain highly reactive natural metabolic products of the body referred to as "free radicals." There is current data which suggest that free radicals are important in the progression of the aging process and in the process of carcinogenesis. There are compounds which are known to inactivate free radicals. Among these are vitamin E and compounds containing the metal selenium. These materials have been suggested as potential anticarcinogens and by some of be potentially beneficial in slowing the aging process. This is, at the moment, speculative and hypothetical. However, there is an extra-ordinary amount of advertising through the mails which makes such a broad jump from the laboratory and speculation on the part of the scientists to actual clinical efficacy that the advertisements are clearly misleading. For example, even if it were established beyond a reasonable doubt that these compounds can have some beneficial anticarcinogenic and anti-aging effect, it is unclear when they would have to be started, how long they would have to be used, and in what dose.

The first category is by definition within the framework of propriety. The second and third categories are "buyer beware" categories which can be dealt with by an alert and questioning public, i.e., consumer awareness. It is the latter two categories which should be of special concern.

Polypharmacy, the use of a number of different drugs, is a common fact of life for many of the elderly. Such patients are commonly on five or six or seven drugs prescribed by their doctors. They are required to keep matters straight; take the right drug at the right time in the right dosage. This is confusing under the best of circumstances and, in the case of the elderly, often results in irregular therapeutic compliance. The elderly are also subject to exaggerated and unusual drug responses, a situation exaggerated by the use of multiple drugs. The use of a drug with recognizable adverse effects by the elderly is of special concern because of the greater likelihood of an adverse reaction. Added to an already existing multidrug therapeutic regimen, the difficulty is significantly compounded.

One of the major concerns that I have is that in the case of the 5th category—the marketing of drugs with potential but not proven therapeutic use—the marketers and distributors are being aided by individuals with some medical and scientific credentials. I have read articles purporting a scientific basis for the use of such materials as selenium and Vitamin E for the prevention of cancer in aging which used existing experimental data and imaginative extrapolation to support efficacy. Some of the articles written by M.D.'s and Ph.D.'s draw a second look from many of us who are familiar with the research involved. A careful reading of these articles generally reflects the ultimately specious reasoning which leads to the conclusion of efficacy. However, the speciousness is not always so obvious and is often buried in a "mechanism" which the cognizant scientist recognizes as speculative. On the other hand, physicians who may not be keeping up with the scientific literature in this area could, themselves, very well be misled into thinking there is something to the discussion. As a consequence, the physician may be less likely to be able to provide advice to a patient inquiring about the article than would be under more obvious situations involving frank quackery. My concern is that there are situations in the latter two categories described above which cannot ordinarily be evaluated under the rubric of consumer awareness. In some cases both the patient and the patient's physician may be misled by "articles" supporting efficacy of an anticarcinogenic or anti-aging material. I consider this analogous to a drug company providing a physician with misleading data on a prescription drug. In that case the patient is defenseless and must rely on the physician's insight and judgment.

In summary, it must be recognized that even the marketing of pharmacologically inactive materials may impose upon an elderly person's ability to manage medication schedules. There are also materials marketed which are pharmacologically active and have potential adverse effects either alone or in combination with the individual's other medication. The fact that some of the advertising is "scientifically

sophisticated" precludes the assumption that the problem can be managed by ordinary means of precautions against gullibility on the part of the elderly or their families.

Mr. BORSKI. Thank you very much, Doctor.

We will now hear from Mr. Clinton Miller, legislative representative from the National Health Federation.

STATEMENT OF CLINTON RAY MILLER

Mr. MILLER. Thank you, Mr. Chairman.

Mr. Chairman and distinguished members of the subcommittee, the National Health Federation very much appreciates the opportunity to testify in your 1984 hearings on quackery. My name is Clinton Ray Miller. I am the man to the left of Dr. Herbert that he was referring to.

I have represented the National Health Federation since 1962 as its Health Freedom Legislative Advocate. During these 22 years, NHF has had a long-running and sometimes bitter battle with the American Medical Association, the U.S. Postal Service, the Food and Drug Administration, and the Federal Trade Commission, until FTC repented, over the related issues of medical quackery, health monopoly, and health freedom. Please note our exhibit No. 1 and No. 2, which shows the Washington Post and Press International coverage of our battle with the AMA and FDA over the second and third Congresses on medical quackery, which were held in 1963 and 1965.

Now, you will note, Mr. Chairman, we put the term "medical quackery" in quotes and small type, because what the AMA calls medical quackery, and what most U.S. citizens think of as medical quackery—and I have those two words in caps in my written testimony—are worlds apart.

Mr. Chairman, the National Health Federation and our thousands of members are just as interested in identifying and controlling medical quackery, as any person on this committee. But we can recognize the difference between using quackery as a pejorative term, as Dr. Herbert uses it quite frequently. He has a special definition that fits him alone—anybody that has gone to his school is not a quack; all other people are. Anyone who believes what he believes is not a quack; all other people are.

Mr. Chairman, the American people just don't buy that kind of a definition of quackery. One witness earlier today said that quackery is an exact legal term and that it requires intent. That was false testimony. It does not. And this is the reason that we are so outraged at these quackery hearings.

Quackery is a pejorative term pure and simple by which people who have bigoted ideas about health come down on other people in an intolerant way in order to try to get unfair laws enacted to enforce their own ideas about what are good or bad about health practices upon the majority of other people. We, the people will not buy health bigotry.

Chairman Pepper himself cosponsored and backed our vitamin bill, against which Mr. Horowitz, a previous witness was so strongly opposed. Chairman Claude Pepper—in fact, we called it the Pickle-Pepper-Proxmire bill—was the one who was able to finally get the bill through Congressman in 1976 over the opposition of

Congressmen that the AMA had bought—or thought they had bought—with more political money than these Congressmen ever could use in their campaigns.

Now, most of us consider that unnecessary surgery—now let's talk about real quackery. Most of us in America consider the unnecessary surgery performed on elderly people and paid for with tax money, as real medical quackery. When these helpless elderly people die on the operating table as a result of these unneeded operations, then, to use the chairman of this subcommittee's phrase in the Congressional Record last November, "To my mind that is murder".

Perhaps we have overlooked it, because I went through the report so quickly but we do not find in this 250 page report that the committee's staff has spent 4 long years preparing while looking for quackery in America—a single mention—not a single word about unnecessary surgery in the quackery report. Is the staff blind to what all Americans see as true quackery in this country? This report was prepared over 4 years with the Postal Service Investigators working with your staff. They could not recognize that the major quackery in this country is unnecessary surgery. That is causing more deaths than moon dust by 10,000-fold. This is what most people are worried about when we talk about medical fraud.

Mr. Chairman, the biggest and the most costly and the most dangerous quackery rampant in the United States today is the medical quackery inside organized medicine as represented by the American Medical Association, and every last American knows it. Topping the list are unproven surgical procedures. Close behind these are millions—and I am talking about millions—of prescriptions, as did Ralph Nader's report on ineffective drugs and dangerous laboratory tests. Again, Mr. Chairman, not once in this 4-year report did the committee find one single drug prescribed by a medical doctor as medical quackery.

Now, thank goodness Sidney Wolff and the Health Research Group, as founded by Ralph Nader, were able to find out and report that today in America there are millions of prescriptions given by members of the American Medical Association that are being prescribed each year to their patient which result in harmful side-effects. And the Food and Drug Administration has already determined that these drugs are either noneffective or less than effective.

Now, Mr. Chairman, overprescribed drug are second only to unnecessary surgery in the number of deaths that are being caused in this country by true medical quackery, prescribed by medical doctors who are members in good standing of the American Medical Association.

Topping the list are unproven surgical procedures. Close behind these are millions of prescriptions for ineffective drugs and dangerous laboratories.

In his best-selling book, "Male Practice," Dr. Robert Mendelson reports, on page 82, "The evidence is clear; we have too many surgeons who are being paid to do too many operations that their patients don't need. A variation of Parkinson's law, as it were, the number of needless operations performed increases to fill the time of those who are paid to do them.

"In 1976, a congressional committee concerned about the soaring costs of medical care studied the problem of the unnecessary surgery in the United States. It reported that in 1974, doctors performed nearly 2.4 million unnecessary operations." That was 10 years ago. It is way up over that now. That is 2.4 million unnecessary operations.

Neither the minority nor the majority staff could find any quackery in that. "Think of it, Dr. Mendelson said, "This is equivalent to placing every resident of Kansas, Colorado, Mississippi, or South Carolina on the operating table for surgery that they don't need."

Now, that is quackery; it is fraud. And, in my opinion, when those people needlessly die, their doctors should be tried for murder. If you really want to strengthen the laws in this country to help protect the people and the aged, every surgeon who gives unneeded surgery; and their patient dies on the operating table should by law be tried for murder.

Dr. Mendelsohn reported: The committee estimated the cost of this worthless surgery at nearly \$4 billion. Undoubtedly, it wiped out the life savings of many families, forcing some into bankruptcy or overwhelming debt. Yet, those who paid only with their money were the lucky victims. About 12,000 persons paid with their lives.

"To put this tragedy of useless surgery in perspective, consider this: In 1974, knives were the instrument of 15,000 absolutely senseless deaths in the United States; 3,000 of them were used by murderers. In the other 12,000 cases a surgeon held the knife."

In his runaway best-seller, "Pills That Don't Work," Sidney Wolf, MD, states—it is in this book here—"Many doctors are unaware that the FDA has found more than 1,000 drugs were less than effective and are continuing to prescribe them." These drugs are prescribed by MD's. And when I heard the AMA witness today say that, "well, we do have one or two quacks in the AMA, but it is minuscule—"Minuscule? Horseradish. It is rampant.

"What is even worse is that since all drugs involve some risk, those which lack any evidence of effectiveness expose patients to dangers without any compensating benefits, and some have serious side-effects."

Elderly patients buying these prescriptions are not told by their AMA physician that the FDA has found these Rx drugs ineffective, so that they, the patients, can exercise an informed choice in case they wish to follow or ignore FDA's evaluation.

Now, Dr. Herbert made a negative reference to a bill that we hope to have introduced. We hope, Mr. Chairman, you will introduce the bill because I think it will solve a lot of these problems. It is a bill which would allow people to have any drug they want in this country or any other country once they are an adult, once they have been fully informed about whether the Food and Drug Administration has cleared it for safety or not. This bill will do for health what the first amendment did for religion.

What is wrong with letting an adult make a bad choice? It happens to be the price of freedom. In a free country, it was not the intent of the people when they vote you into your office to have you pass laws making health decisions for them. They want to make their own health decisions. But they want to be fully informed of the side-effects of drugs. FDA can do nothing more im-

portant than just report the side-effects of all drugs and then let people make their informed choice, we in the National Health Federation believe adult Americans should be able to make that choice. And that is what health freedom is all about.

That is why, when Mr. Herbert pointed out, when this got down to a tough 14-year battle between the AMA and the National Health Federation—the National Health Federation with 17,000 members, and the AMA with over 700,000, and billions of dollars behind them—that we, the National Health Federation, had millions of people on our side who said, look—to Congress—let us have freedom to buy vitamins and minerals in any potency or combination we want just like we can buy potatoes. And Congress, under the leadership of Chairmen Pepper and Representative Pickle and Senator Proxmire, passed the bill unanimously; not one opposing vote.

The list of 600 prescription drugs prepared by Dr. Wolff and the health research group founded by Ralph Nader is found in exhibits 3 and 4 attached to my testimony. You will note it includes millions of prescriptions filled every year costing hundreds of millions of dollars. They cost about \$1 billion a year.

Mr. BORSKI. Mr. Miller, this Aging Committee has had a hearing on pills that don't work. Today, we would like to hear about quackery. I would appreciate it if you would respond to some of the testimony we had this morning or finish with your prepared statement. We have had a hearing; I wanted to make that clear for the record. There has been a hearing.

You stated earlier, and a lot of your testimony I think is dealing with pills that don't work. This committee has had a hearing on that.

Mr. MILLER. So that is checked off. It doesn't appear in any reports.

Mr. BORSKI. That is not in this report, sir.

Mr. MILLER. Obviously, it is not. I think it is a gross omission. If you had a hearing, what would have been wrong to referring to the hearing you had and make reference to it? I frankly think it is a gross omission. And I will say nothing more about pills that don't work.

Mr. BORSKI. Thank you.

Mr. MILLER. Mr. Chairman, I would like to draw your attention to my two letters in my testimony asking for more information about these hearings and the quackery investigation being conducted by members of your subcommittee staff. And I might like to state here that this is not in any way, I hope, unfairly critical of the staff. I cannot express how fairly and how patiently and how cooperative both the minority and the majority staff have been. They have been excellent.

I am just very upset about the way that this report was brought out. The refusal of the committee, or of the chairman to answer our letters upsets us. We addressed these letters to the chairman—two of them—way back in November 1983, asking some very simple questions about your quackery investigation and report. You will remember, way back last November 13, 1983, Donald Rubinson wrote an article in the Parade magazine section that appeared in major newspapers across the country. In this article, he

referred to the quackery investigation that was taking place by your staff and U.S. postal inspectors. We had just taken on the Postal Inspection Branch of the U.S. Postal Service, and had won a major victory over their attempt to be able to get legislation enacted to allow the USPS investigators to invade every home and business in this country without a search warrant. NHF had successfully persuaded Congress to drop that civil investigative demand section from the bill that has been referred to today as the subpoena section. So we were very touchy about the way the U.S. Postal Service carried on their so-called quackery investigations. We were very angry about the fact that the Postal Service had just banned a health book. We had a list of over 20 health books that the Postal Service had banned. And the reason for them banning the book, Mr. Chairman, was—get this—that the statements in the book did not conform to the consensus of medical opinion. Now, this book was banned from the mails—not in Russia, but here in the United States, February 11, 1982.

So when we found U.S. postal inspectors were working together with your staff, to investigate quackery, we asked some logical questions. The first question, which I am sure that you would ask if you were in my position, is: Is the National Health Federation one of the quack organizations? I would like to ask you that now, Mr. Chairman. Are we?

Mr. BORSKI. This is role reversal. But I am not here to answer your questions. I was hopeful to be able to ask you some. If you have testimony you would like to give, we are most happy to receive it.

Mr. MILLER. We were told that the answers to these two letters would be forthcoming when the report would be published. To date, none of the questions in the letters have been answered by your staff.

Mr. BORSKI. Mr. Miller, the report is as complete as it can get. I think that is the only answer you are going to get.

If I may, let me go to some questions now. Do you have anything else you wanted to add, briefly? We are running a little bit behind.

Mr. MILLER. You are the chairman, Mr. Chairman.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF CLINTON RAY MILLER, LEGISLATIVE ADVOCATE OF THE
NATIONAL HEALTH FEDERATION

Mr. Chairman and distinguished members of the Subcommittee, the National Health Federation very much appreciates the opportunity to testify at your 1984 hearings on "Quackery."

My name is Clinton Ray Miller. I have represented the National Health Federation (NHF) since 1962 as its Health Freedom Legislative Advocate. During these 22 years, NHF has had a running battle with the American Medical Association (AMA), the U.S. Postal Service (USPS), and the Food and Drug Administration (FDA), over the related issues of "medical quackery," health monopoly, and health freedom. (See Exhibits 1 and 2.)

We have put the term "medical quackery" in quotes and small types because what the AMA calls "medical quackery" and what most U.S. citizens think of as medical quackery are worlds apart.

Most of us consider the unnecessary surgery performed annually on elderly people and paid for with tax money as MEDICAL QUACKERY in capital letters. When these helpless elderly lie on the operating table as a result of these unneeded operations, then, to use your phrase, Mr. Chairman, "To my mind, that's murder."

Perhaps we have overlooked it, but we do not find a single mention of unnecessary surgery in the Quackery Report prepared and distributed by your Committee staff members this morning. Mr. Chairman, the biggest, most costly, and most dangerous quackery rampant in the United States today is the quackery inside organized medicine.

Topping the list are unproven surgical procedures. Close behind are the millions of prescriptions for ineffective drugs and dangerous laboratory tests.

In his best selling book, "Male Practice," Dr. Robert Mendelsohn reports on p. 82:

"The evidence is clear: We have too many surgeons who are being paid to do too many operations that their patients don't need. A variation of Parkinson's Law is at work: The number of needless operations performed increases to fill the time of those who are paid to do them.

"In 1976, a congressional committee concerned about the soaring costs of medical care studied the problem of unnecessary surgery in the United States. It reported that in 1974, doctors performed nearly 2.4 million unnecessary operations. Think of it! This is about equivalent to placing every resident of Kansas, Colorado, Mississippi, or South Carolina on the operating table for surgery they don't need.

"The committee estimated the cost of this worthless surgery at nearly \$4 billion. Undoubtedly, it wiped out the life savings of many families, forcing some into bankruptcy or overwhelming debt. Yet those who paid only with money were the "lucky" victims. About 12,000 patients paid with their lives.

"To put the tragedy of this useless surgery in perspective, consider this: In 1974, knives were the instrument of 15,000 absolutely senseless deaths in the United States. Three thousand of them were used by murderers. In the other 12,000 cases a surgeon held the knife!"

In his runaway national bestseller, "Pills That Don't Work," Sidney M. Wolfe, M.D. states:

"Many doctors are unaware that the FDA has found more than 1,000 drugs were less than effective and are continuing to prescribe them. What is even worse is that since all drugs involve some risks, those which lack any evidence of effectiveness expose patients to dangers without any compensating benefits—and some have serious side effects."

Elderly patients buying these prescriptions are not told by their AMA physicians that the FDA has found these Rx drugs ineffective so they can exercise an informed choice, in case they wish to follow or ignore FDA's evaluation.

The list of 600 prescription drugs prepared by Dr. Wolfe and the Health Research Group founded by Ralph Nader is found in exhibits #3 and #4. You will note that it includes millions of prescriptions filled every year costing hundreds of millions of dollars.

Mr. Chairman, I draw your attention to my two letters to you of November 28, 1983, asking for information about these hearings and the quackery investigation being conducted by members of your subcommittee staff. See Exhibits #5 and #6.

We were told the answers to these letters would be forthcoming when the report was published. To date none of the questions in these letters have been answered by your staff. We would appreciate a response now that the report has been published.

Mr. Chairman, I appreciate the opportunity to testify in behalf of the National Health Federation before this Subcommittee. We will be glad to answer any questions or work with your committee staff in any way we can to help protect senior citizens from medical quackery within organized medicine and non-medical quackery without.

Washington Post

Times Herald

SUNDAY, OCTOBER 20, 1963

Opposing Groups to Meet on Health

United Press International
The National Health Federation is hoping to re-enact the battle of David and Goliath this week when the Second National Congress on Medical Quackery gets underway here.

The Congress will be co-sponsored by the American Medical Association and the Food and Drug Administration Friday and Saturday in an effort to make the public less gullible to what they consider quackery.

The NHF hopes to challenge the two giants of the health field by staging simultaneously the first National Congress on Health Monopoly.

At the First National Congress on Medical Quackery in 1961, the AMA and FDA aroused the ire of the NHF by attacking so-called health foods. The NHF believes a person should have the freedom to choose any type of food he wants to eat and if he wants to pay \$20 for a bottle of seawater in hopes of improving his health, that is his business.

In the Second Congress on Quackery, the FDA said, "the program primarily will explore why people are vulnerable to medical quackery and how the public can be made less gullible."

Conference speakers will include Anthony J. Celebrezze, Secretary of Health, Education and Welfare; AMA President Edward R. Annis, Deputy Postmaster General Sidney W. Bishop, and Paul Rand Dixon, chairman of the Federal Trade Commission.

The chairman of the rival conference will be Dr. Miles H. Robinson, a Doctor of Medicine from Potomac, Md.

"The Congress will explore charges that an unholy alli-

ance exists between the AMA and the FDA," Dr. Robinson said.

Long Island Press

LONG ISLAND PRESS, MONDAY, APRIL 5, 1965

2 Giants in Field of Health Square Off Over Quackery

Two heavyweights in the field of health square off in Manhattan this week for a battle royal.

The big issue: Quackery. In one corner will be the National Health Federation. In the other, the New York State Medical Society.

The NHF will strike the first blow as it opens a two-day Congress on Health Monopoly tomorrow at the New York Hilton Hotel.

One block away, at the Americana Hotel, the medical society will launch its

all-day Congress on Health Quackery.

IT WON'T be the first time the two giants squared off against each other. In October, 1963 the two organizations held simultaneous conferences on the same subjects in Washington, D.C.

And this week, as in 1963, the NHF has intentionally planned its meeting to provide direct competition to the medical society.

Dr. James Stephenson of New York, a physician and chairman of the Health Monopoly Congress, said the

two-day meeting will "emphasize the teaching of therapeutic freedoms in our schools."

He pointed out that although he is an M.D., he believes Americans should be able to choose from "many therapies and specialties."

THE ONEDAY conference on quackery will be attended by more than 2,000 educators, professional people, civic and church leaders, legislators and law enforcement officers.

Its purpose, according to

Dr. Waring Willis, president of the state medical society, is to "focus public attention on the increasingly dangerous and costly program of medical quackery."

Speakers will include Dr. Hollis S. Ingraham, state health commissioner; Dr. Sol R. Baker, president of the California division of the American Cancer Society, and noted authorities on arthritis, drugs and nutrition.

THE CONFERENCE is aimed at educating the public, Dr. Willis said. And he added:

"The medical profession believes that education and exposure are the best ways of combatting quackery. We hope that by presenting this conference, which will feature nationally known authorities on health quackery, we will make the people aware of the extreme danger and the terrible waste involved in quackery."

4

Exhibit #3, "Pills That Don't Work," by Sidney M. Wolfe, M.D., and the Health Research Group founded by Ralph Nader, Appendix A; and Exhibit #4, Appendix B of the same book, have been retained in Committee files in compliance with current copyrights laws, and may be reviewed upon request.

HAND DELIVERED, NOVEMBER 28, 1983 (EXHIBIT #5)



**NATIONAL
HEALTH
FEDERATION**

CLINTON RAY MILLER
LEGISLATIVE ADVOCATE
5001 Seminary Road, Suite 1330
Alexandria, Virginia 22311
(703-379-0589)

November 28, 1983

INFORMATION INQUIRY LETTER #1

The Honorable Claude Pepper
Chairman,
House Subcommittee on Health
and Long Term Care
Room 715
House Office Building Annex #1
Washington, D.C. 20515

Dear Congressman Pepper:

In the November 13, 1983 Parade Section of the Washington Post a feature article by Donald Robinson reported that you were holding hearings about medical quacks in January, 1984.

The article said that your subcommittee investigators worked as a team with U.S. Postal Service Inspectors to prepare testimony for your January hearings.

The article also said that these investigators "attended dozens of meetings sponsored by quack organizations" in preparing to testify at your January hearings.

I respectfully request a list of all the quack organizations your investigators visited.

I respectfully request a list of all the "dozens of meetings," dates and places, they attended.

Because we need this information today to prepare our testimony for your January hearings about medical quacks, this letter will be hand delivered to your staff today, Monday, November 28, 1983.

Thank you for this information.

Sincerely,

Clinton Ray Miller
Clinton Ray Miller

CRM/bm

cc All interested parties



(EXHIBIT #6)

CLINTON RAY MILLER
 LEGISLATIVE ADVOCATE
 5001 Seminary Road, Suite 1336
 Alexandria, Virginia 22311
 (703-379-0589)

November 28, 1983

INFORMATION INQUIRY LETTER #2

The Honorable Claude Pepper
 Chairman,
 House Subcommittee on Health
 and Long Term Care
 Room 715
 House Office Building Annex #1,
 Washington, D.C. 20515

Dear Congressman Pepper:

In my inquiry letter #1, of November 28, 1983, I requested a list of all the meetings of quack organizations your subcommittee investigators attended to prepare for your January hearings on medical quacks.

To prepare our testimony we will need some additional information about your investigation.

- (1) How did the members of your house subcommittee decide which organizations in the United States are quack organizations?
- (2) What standards were used?
- (3) What is your subcommittee's definition of a quack organization?
- (4) Approximately how many quack organizations are there in the United States?
- (5) Is there a list or directory of all quack organizations compiled by your subcommittee investigators?
- (6) Approximately how many U.S. citizens belong to these quack organizations?
- (7) Do these quack organizations meet secretly or do they have public meetings open to the press and the public?
- (8) When your subcommittee investigators "attended dozens of meetings" sponsored by quack organizations did they announce to those in charge of the meetings that they were there officially conducting an investigation for your House subcommittee, or were the investigations secret?

- (9) Did your subcommittee investigators secretly tape record any sessions of these quack organizations?
- (10) Do you have any tape recordings of any talks given at the meetings of these quack organizations?
- (11) How many members of your subcommittee took part directly or indirectly in this investigation?
- (12) What are their salaries?
- (13) How much money has been appropriated by Congress to conduct this investigation of quack organizations?
- (14) How much has been spent to date?
- (15) How much travel has been authorized or paid to date for all investigators taking part in this action?
- (16) How long do you estimate the investigation will continue?
- (17) In conducting this investigation did your subcommittee investigators secretly tap any telephones or authorize the tapping of any telephones or have knowledge of the tapping of any telephones of any officer or any members of these quack organizations?
- (18) Same question as #17 for U.S. Postal inspectors.
- (19) In conducting this investigation was a mail cover placed on the mail of any officer or member of any of these quack organizations?
- (20) Has any kind of mail surveillance of any member or officer of any of these quack organizations been made in preparation for these hearings?
- (21) Is all the information collected by your congressional subcommittee investigators open to the press and the public, or is part or all of it secret?
- (22) Were any private homes visited by U.S. Postal investigators or congressional subcommittee investigators in conducting this investigation?
- (23) Were membership or mailing lists of any quack organizations obtained or used in any way in preparation for this investigation?
- (24) Were any meetings in any churches attended by subcommittee or USPS investigators in preparation for these hearings?

- (25) Are there any federal or state laws outlawing quackery?
- (26) Is there a federal or state statutory definition of medical quackery?
- (27) Is there a definition of medical quackery used by your subcommittee and the USPS in conducting this investigation?
- (28) Is the American Medical Association a quack organization?
- (29) Are any officers or any members of the American Medical Association medical quacks?
- (30) Can a physician be a member of the American Medical Association in good standing and a medical quack at the same time?
- (31) Does the AMA deny membership to all medical quacks?
- (32) How many medical doctors have been ousted from the AMA for being a medical quack?
- (33) Did the investigators of your staff consult with any officials or members of the AMA in preparing a list of quack organizations or medical quacks to be investigated?
- (34) Specifically, have any of the investigators of your staff or any of the U.S. Postal investigators consulted with Dr. Victor Herbert in any way in conducting this investigation?
- (35) Same question as #34 for Dr. Stephen Barrett.
- (36) Same question as #34 for Dr. William Jarvis.
- (37) Are any chiropractic organizations considered quack organizations by you, any of your subcommittee investigators, or any of the consultants used by subcommittee or USPS investigators in preparation for these hearings?
- (38) Is Dr. Linus Pauling, or any other Nobel Prize winner or University professor, considered a medical quack by you, any subcommittee or USPS investigator or any of the consultants used in preparation for these hearings?
- (39) Do you or your subcommittee investigators consider it medical quackery for medical doctors to give the drug Oralflex to treat arthritis?
- (40) Did your subcommittee investigate Oralflex deaths?
- (41) Do your subcommittee investigators intend to investigate the Oralflex matter in any way for your January hearings?

- (42) If not, why not?
- (43) Will your hearings investigate unnecessary surgery of the aged as a quackery procedure?
- (44) Is the National Nutritional Foods Association considered a quack organization by you, any of your subcommittee or USPS investigators?
- (45) Did the subcommittee or USPS investigators attend any regional or national meetings of NNFA in preparation for these hearings?
- (46) Do you or any of your subcommittee or USPS investigators consider Amway, Shaklee, or any other direct sales company which markets nutritional or herbal products a quack company or organization?
- (47) Were any homes or sales meetings of any salespersons of any of these direct sales companies visited by your subcommittee or USPS investigators in preparation for these hearings?
- (48) How many medical quacks have ever been prosecuted by the USPS for practicing medical quackery via the mails?
- (49) Does the USPS have statutory authority or a Congressional mandate to investigate and prosecute medical quacks for the practice of medical quackery?

Because we need this information today to prepare our testimony for your January hearings about medical quacks, this letter will be hand delivered to your staff today, Monday, November 28, 1983.

Thank you for this information.

Sincerely,



Clinton Ray Miller

CRM/bm

cc All interested parties

INVESTIGATE USPS "INVESTIGATORS"

The Honorable _____ 19_____
U.S. House Office Building
Washington, D.C. 20515

Dear Representative _____:

I am intrigued to learn Congress is planning to hold hearings on "Medical Quackery" and "Quack Organizations" in 1984.

However, I have very serious reservations about Congress relying on secret United States Postal Service "investigators" for its information on "medical quacks" and "quack organizations."

The USPS has a long and sordid history of book banning. It has banned 20 books in 20 years! Therefore, it would be far wiser for Congress to investigate the USPS "investigators" than to let the USPS continue its 20 year vendetta against health books, nutritional therapies, and health clubs under the pretense that it is investigating quackery.

The announcement of the forthcoming quackery hearings was made in a 3 page feature article by Donald Robinson in the November 13, 1983 *Parade* Sunday supplement of the *Washington Post*.

The hearings will be held by the House Subcommittee on Health and Long-Term Care which is chaired by Representative Claude Pepper (D-Fla.).

Pepper had the *Parade* article inserted in the Congressional Record, November 16, 1983, pp. 10014-10015.

Robinson's article revealed that a very unusual coalition of federal "investigators" are conducting a massive, ongoing investigation of "Quack Organizations" and "Medical Quackery."

One group of these "investigators" is provided by Pepper's Health Subcommittee. The other is what Robinson calls "A task force of U.S. Postal Inspectors." He says Congressional and USPS investigators work together "as a team."

The enormous scope of the "team's" clandestine investigation can be envisioned by Robinson's description:

"Preparing to testify about their findings in such (medical quackery) cases... They answered advertisements for products of dubious medical value in 114 publications. They subsequently had items they purchased analyzed by recognized medical authorities. The investigators visited *hundreds* of questionable *clinics, hospitals, institutes and foundations* in the United States and *Mexico*, attended *dozens* of meetings *sponsored by quack organizations*, met with quack doctors and interviewed their patients."
(emphasis is ours)

From the above it appears Congressional and USPS "investigators" have already compiled a secret list of "Quack Organizations," "Medical Quacks," and their patients.



This raises many very serious national and international questions:

- (1) Who conducted the investigations in Mexico?
- (2) Were they conducted with the knowledge and consent of the Department of State?
- (3) Were they authorized by President Reagan?
- (4) Are the files of the Mexican investigation open to members of Congress? The press? The public? If not, why not?
- (5) Was the Mexican investigation conducted with the knowledge and approval of Mexican authorities?
- (6) Were they secret investigations?
- (7) How did the USPS determine which organizations in the United States are quack organizations?
- (8) What is the USPS or statutory definition of quack organization?
- (9) Approximately how many quack organizations are there in the United States?
- (10) Is the USPS list of all quack organizations open to members of Congress? If not, why not?
- (11) Approximately how many U.S. citizens belong to these quack organizations?
- (12) Do these quack organizations meet secretly or do they have public meetings open to the press and the public?

I respectfully request your help to get the names of the "quack organizations" already investigated by the USPS. To date, the National Health Federation has made repeated requests for answers to the above questions. All requests have been denied by USPS and congressional investigators.

One obvious way for Congress to help us protect ourselves from Medical Quacks is to make public a list of the hundreds of hospitals, clinics, institutes, foundations, quack organizations and quack doctors already investigated by the USPS.

Please investigate the USPS "Investigators."

Sincerely,

Signature _____ Print Name _____
 Address _____ City _____
 State _____ Zip Code _____

This form letter was prepared for my convenience by Clinton Ray Miller, Health Freedom Legislative Advocate of the National Health Federation, 5001 Seminary Rd., #1330, Alexandria, VA 22311. Phone: (703) 279-0589. Additional copies: \$5.00/50; \$9.00/100 at NHF, Box 688, Monrovia, CA 91016.

SECRET INVESTIGATIONS BY SECRET POLICE ARE INTOLERABLE IN A FREE COUNTRY.

The WASHINGTON Report



USPS "INVESTIGATORS"

By Clinton Ray Miller

SHOWDOWN BREWING IN CONGRESS OVER "MEDICAL QUACKERY"

In 1984 a major health freedom battle will be fought in Congress to determine who are—and who are not—America's "Medical Quacks."

On one side will be the National Health Federation, alternative health practitioners, herbalists, nutritionists, health food stores, chiropractors, hands-on therapists, fitness enthusiasts, and millions of our friends.

On the other side will be the American Medical Association, the American Cancer Society, the Arthritis Foundation, the U.S. Postal Service, Dr. Victor Herbert and others of that ilk.

As we wage this battle, Health/Aging Subcommittee Chairman Claude Pepper (D-Fla.) is about to become one of the greatest lawmakers of all time—or one of the worst. At 83, he is already the oldest person in Congress and one of the most active.

The battle will be fought before Representative Pepper's Subcommittee on Health and Long-Term Care in the House of Representatives. Pepper, as chairman, and his staff can determine who testifies and who doesn't. The 25 other U.S. Representatives who are members of Pepper's Subcommittee have the opportunity to be statesmen or demagogues. Everyone has the op-

portunity to get into the act, especially YOU.

On November 13, 1983, 24 million families learned about only one side of the quackery dispute from a 3 page feature article in the Sunday supplement *Parade* magazine section of their morning newspaper. The title of the biased article was "Medical Advice You Should Avoid." The author was Donald Robinson.

It was a deadly serious article which revealed that a massive undercover federal investigation of "Medical Quacks" has been ongoing for the past 5 years or more.

The article told of a very unusual coalition of "investigators." One group of these investigators came from Pepper's Subcommittee; the other was a special "task force of U.S. Postal Service Inspectors." The two groups work together as a "team."

The enormous scope of this team's investigation can be envisioned by Robinson's description:

"Preparing to testify about their findings in such (medical quackery) cases... They answered advertisements for products of dubious medical value in 114 publications. They subsequently had items they purchased analyzed by recognized medical authorities. The investigators visited hundreds of questionable clinics, hospitals, institutes, and foundations in the United States and Mexico, attended dozens of meetings sponsored by quack organizations, met with

quack doctors and interviewed their patients." (Emphasis, mine.)

NHF INVESTIGATES THE "INVESTIGATORS"

The *Parade* article contained so many outrageous exaggerations, distortions and falsehoods that we felt we should conduct our own investigation of the investigators and Donald Robinson to see if any or all of them were lying or were just badly informed.

November 14, 1983, we wrote a letter to Chairman Pepper asking to be scheduled as a witness to testify at his January 1984 "Quackery Hearings."

Because the NHF Annual Convention is held in California in January every year, we asked Pepper to notify us "as soon as possible when the hearings will be held so I can arrange my schedule."

When we received no reply by November 25, we wrote a follow-up letter and asked the first of 50 questions I now have submitted to Pepper's investigators—so we can have the facts to prepare our testimony.

Our first request was for "full documentation for the statement in the *Parade* article of November 13, 1983, which said:

"Investigators note that though the controversial cancer drug laetrile has steadily declined in status, its promoters are netting (emphasis is mine) about \$1 billion annually."

Continued on page 44

The University of Chicago burn clinic produced a paper, based on an investigation of this healing process, and found that the application of aloe gel did in fact heal second degree burns more rapidly, with little infection (much less than other jellies), and no scarring—better results, it was determined, than when presently available burn petroleum jellies were used.

In recent years, the development of the juice of the aloe leaf, the controlled laboratory conversion of the thick gel, has allowed consumption of aloe juice much the same as fruit and vegetable juices. Perhaps the prominent reason for this development was the realization that if external tissue healing potential is maximized by the presence in the wound area of the mucilaginous aloe gel, that some healing potentiation would benefit internal tissues. This is exactly what did occur and the results of healing have been the same internally, namely, multiple and varied.

Many documented testimonials credit aloe vera juice with healing in cases of hyperacidity, ulcers, and other internal systemic diseases. I have spoken personally with a man, improved greatly from a debilitating arthritis condition, whose change was brought about by the only identifiable difference in his life style—drinking four 4-ounce units of aloe vera juice each day for six months.

In another case, I spoke with a middle aged woman treated for years with

cortisone for a progressive lung disease, diagnosed as sarcoidosis, who was relieved of all symptoms; X-rays showed healing resolution of all lung tissue. Again the one change in life style was the drinking of four 4-ounce units of aloe vera juice daily for eight months.

There is no question that controlled studies are needed before aloe can be credited with the capacity to aid in healing internal systemic afflictions. There is also no question that for some fortunate individuals aloe does have internal healing potential. At this point in research, still illusive and most frustrating is the fact that the cause and effect of aloe induced healing remains unknown.

Two questions come to mind at this point: What can be done to assure that during processing all the natural herbal healing potential of this marvel of nature is preserved? And what is in fact the chemico-physiology of the aloe healing mechanism?

As to the first question, that of processing the aloe leaf, there are facilities which have demonstrated significantly high performance in their product quality. These manufacturers of aloe gel tend to base their production processes as close to natural procedures as possible throughout their technique. Sterile conditions and processing without heat is essential to assure maximum nutrient content. The use of preservatives is controlled,

natural when possible, and specific to need to assure total long-term product preservation control.

The question of the healing process and the mechanism of the beneficial effect of the aloe gel is complex. It can be seen from the normal structure and function of skin, and the problems which develop with the aging process,

The Food and Drug Administration calls the claims being made for aloe "exaggerated and unsubstantiated." It also worries that people who should be getting medical treatment for serious ailments are instead just swigging aloe or smearing it on their sores; however, the FDA can't order products off the market unless it can prove they are harmful or "misbranded."

why the aloe gel would be eminently effective in aiding the healing process. If one took the time to view the total reaction occurring when an aloe leaf is cut from the plant, the similarity to the human healing process of skin would be striking.

The opened leaf end reveals a thick gel which quickly develops a sealing film as a temporary closure to seal out invaders and prevent water loss; next, the mucopolysaccharide rich gel supplies new elements to close the wound and reorganize function; finally, the leaf end is closed tight as though there were never the slightest trauma and normal function ensues.

One other amazing point—the "healing" process occurs on both open ends of the leaf; one, part of the plant; the other, part of the separated leaf.

Analysis demonstrates that the basic gelatinous substance of aloe gel is primarily mucopolysaccharide protein, the same elemental substance comprising the basal dermal layer of skin. Further, there are vitamins present in aloe

Continued on page 25

Belief in the restorative powers of aloe vera isn't new. The clear gel inside the plant's long, spikey leaves has been regarded as a potent elixir for centuries.

According to legend, Nefertiti and Cleopatra used it to enhance their beauty, and Alexander the Great conquered Socotra because he wanted the island's aloe to heal his troops' wounds. Marco Polo reported that the Chinese used aloe to treat stomach ailments, rashes and other disorders.

as "quacks" then Pepper's hearings are far more than a name-calling session.

MONSTERS IN THE ALFALFA PATCH

Some of the murdering quacks—as seen by Pepper and his two teams of highly paid investigators—are engaged in selling or advocating the use of "vitamin C," "alfalfa," "secret herbs," and "odd diets...consisting almost exclusively of whole cereal grains, some vegetables, a few beans and a little soup" (as reported in the *Parade* article).

This issue contains a form letter and a list of the 60 other members of the Full House Select Committee on Aging. Those names marked with an asterisk (*) are members of Pepper's Health Subcommittee.

If you agree with the form letter, please copy, sign and mail it to your U.S. Representative and as many members of the Full Committee and Subcommittee as you can. Get as many friends as possible to do the same. We need your help.

HFN

My letter to Pepper continued:

"Either you or I have been grossly misinformed about the amount of laetrile traffic.

"I respectfully request the names of the 'investigators' who gave this information to you and your staff, and to Donald Robinson, author of the *Parade* article.

"My estimates come from the very persons or companies who sell most of the laetrile sold in the United States and the world.

"My sources tell me the \$1 billion figure is an outrageous exaggeration.

"Perhaps there was a misprint in the article.

"Should the figure have been \$1 million instead of \$1 billion?

"If so, I believe a correction should be printed in both *Parade* magazine and the Congressional Record."

Pepper had inserted the *Parade* article in the Congressional Record on November 16, 1983, pp 10014-10015.

On December 12, 1983, having received no answer from Pepper, I sent a similar request to Donald Robinson, *Parade* magazine, and the *Washington Post*.

Actually, the gross (not net) sales of all laetrile in the entire world is far less than \$5 million annually and the net on all worldwide sales is far less than \$1 million.

PEPPER EQUATES MEDICAL QUACKERY WITH MURDER

In the *Parade* article Robinson quoted Pepper as saying:

"Last year alone, medical quacks robbed senior citizens and other unsuspecting Americans of more than \$50 billion," says Rep. Claude D. Pepper (D-Fla).

"And that was only a small part of the crimes these quacks committed. They fatally poisoned *scores* of people. Furthermore, they were responsible for *thousands* of sick people dying who could have been saved by the right treatment. To my mind that's murder." (Emphasis is mine.)

If the USPS investigators are preparing to criminally prosecute those herbalists, nutritionists, and alternative physicians they have classified



**FOR
IMMEDIATE
RELEASE**

CONTACT: CLINTON RAY MILLER
(703) 379-0589

FOR RELEASE: MAY 31, 1984

The National Health Federation today told Senator Claude Pepper and members of his House Subcommittee on Health and Long-Term Care that "the biggest, most costly and most dangerous, quackery rampant in the U.S. today is the quackery inside organized medicine."

Clinton Ray Miller, Health Freedom Legislative Advocate of the National Health Federation (NHF) leveled the charges against the American Medical Association at Pepper's Hearings on quackery and its impact on senior citizens.

Mr. Miller said that "...topping the list of life-threatening medical quackery in the U.S. are unproven surgical procedures. Close behind are the millions of costly prescriptions for ineffective drugs and dangerous laboratory tests."

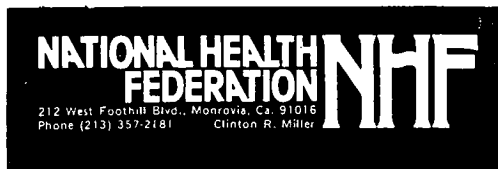
Mr. Miller gave figures compiled by Dr. Robert Mendelsohn, immediate past president of the NHF who warned:

"In 1974, knives were the instrument of 15,000 absolutely senseless deaths in the United States. Three thousand of them were used by murderers. In the other 12,000 cases a surgeon held the knife!"

"The evidence is clear: We have too many surgeons who are being paid to do too many operations that their patients don't need. A variation of Parkinson's Law is at work: The number of needless operations performed increases to fill the time of those who are paid to do them.

"In 1976, a congressional committee concerned about the soaring costs of medical care studied the problem of unnecessary surgery in the United States. It reported that in 1974, doctors performed nearly 2.4 million unnecessary operations. Think of it! This is about equivalent to placing every resident of Kansas, Colorado, Mississippi, or South Carolina on the operating table for surgery they don't need.

"The committee estimated the cost of this worthless surgery at nearly \$4 billion. Undoubtedly, it wiped out the life savings of many families, forcing some into bankruptcy or overwhelming debt. Yet those who paid only with money were the "lucky" victims. About 12,000 patients paid with their lives."



**FOR
IMMEDIATE
RELEASE**

CONTACT: CLINTON RAY MILLER
(703) 379-0589

FOR RELEASE: MAY 31, 1984

DR. MENDELSON CHALLENGES DR. HERBERT TO QUACKERY DEBATES

The National Health Federation today issued a public challenge to Dr. Victor Herbert to a "Public and Continuing Debate" over the extent of medical quackery within organized medicine.

Clinton Ray Miller, spokesperson for the National Health Federation testified before Representative Pepper's Subcommittee on Health & Long Term Care that:

... "The biggest, most costly, and dangerous quackery rampant in the U.S. today is the Medical Quackery inside organized medicine."

Dr. Victor Herbert, who was also a witness at the Hearing takes the opposite view. "He can see no quackery when a fellow M.D. kills a patient with unnecessary surgery but is outraged when a chiropractor, a health food store owner, or Prevention Magazine suggests taking alfalfa tablets or cod liver oil to help prevent arthritis," said Mr. Miller.

"Let's find out who the majority of U.S. citizens consider are the most dangerous quacks," said Mr. Miller. Let's have a continuing and public debate followed by a vote of those listening."

Mr. Miller suggested that the topic be - -

RESOLVED: THAT THERE IS FAR MORE/LESS DANGEROUS QUACKERY
INSIDE ORGANIZED MEDICINE THAN WITHOUT.

Miller said Dr. Herbert could phrase the topic so he could take the affirmative or negative side. He said the National Health Federation would be represented by its past president, Dr. Robert Mendelsohn, author of Confessions Of A Medical Heretic, Medical Male Practice, and How To Raise A Healthy Child In Spite Of Your Doctor.

Dr. Victor Herbert is author of Vitamins and "Health Foods: The Great American Hustle, and Nutrition Cultism, Facts and Fictions. In his book, Herbert castigates two-time Nobel Prize winner Linus Pauling, Dr. Benjamin Feingold, Adelle Davis, Dr. Lendon Smith, Bob Rodale, Dr. Carlton Fredericks, U.S. Senator Steven Symms (R-Idaho), Dr. Michael Jacobson, Dr. Robert Mendelsohn, and Dr. Emanuel Cheraskin—along with Anway, Shaklee, Neo Life, Chiropractors, NNFA and NHF—as charlatans or promoters of nutritional quackery.

Mr. Miller invited Dr. Herbert to debate the quackery issue at the National Health Federation's Midwest Regional Convention, Aug. 25, 26, 1984, at the Holiday Inn O'Hare Kennedy, and at NHF's Southeast Regional Convention, November 17-18 at the Sheraton Twin Towers, Orlando, Florida.

Miller said Dr. Mendelsohn would also be glad to debate the quackery issue with Dr. Herbert before any group of senior citizens acceptable to Dr. Herbert.

Mr. BORSKI. Thank you very much.

I have a few questions I would like to ask. Perhaps it may be easier and more interesting to ask Dr. Herbert if he would like to comment on anything that Mr. Miller has stated today.

Dr. HERBERT. Mr. Miller, as is typical for his organization, defends the promotion of quackery by saying that there are things which physicians do, and his outfit often refers to me as the spokesman for the AMA, which is sort of silly since I am not a member of the AMA; never have been—but that is another story—and because I am partially in academic medicine—I teach patient care, do patient care and research.

What he does is he says don't worry about the murders committed by promoters of quackery, cyanide poisoning from laetrile, promoted by National Health Federation, deaths with chelation therapy, promoted by the National Health Federation. Don't worry about any of that stuff; worry about unnecessary surgery. Unnecessary surgery is a separate subject. It is a real problem. It is a separate problem.

But surgeons don't place national ads. They don't have a National Health Federation promoting "Go to doctor for this." The National Health Federation says, "Go to X and Y," in their ads. They tell you to go down to Tijuana for laetrile. Frank Salaman, who I believe is the husband of the President of the National Health Federation has a criminal conviction for conspiracy to smuggle laetrile into the United States.

We are talking about national promotions in newspapers and magazines of quackery. And, as I say, surgeons—some surgeons do unnecessary surgery, and they should be stopped, those who do. But even those who do don't take out national ads, and they don't have a national organization promoting going to them.

Mr. BORSKI. I would like to add, I guess, once more for the record, that this committee has had extensive hearings in the past on unnecessary surgery.

Dr. Herbert, there was one other question that I had for you: How large a problem is what one witness this morning called quacketeering, or organized quackery? And what can be done to control it?

Dr. HERBERT. I think it adds up to about \$25 billion a year. And I think the only way to control it is to have a branch of the Federal Organized Crime Task Force deal with it under the act which allows jailing of promoters who engage in conspiracies to promote racketeering and quackery. As Chairman Pepper noted this morning, he said, "These people are gangsters."

Mr. BORSKI. Thank you, doctor.

Dr. Schwartz, would you like to comment on anything?

Mr. SCHWARTZ. I would like to answer Mr. Miller's question about whether I think the Federation is quackery. The Federation is not involved in any surgery, as far as I know. And his definition of "quackery" is surgeons who do unnecessary surgery. If he would like to expand that definition to deal with the promotion of worthless remedies, I would be more than happy to respond affirmatively to the fact that, yes, I think it is a quackery organization.

Mr. BORSKI. Thank you very much.

Mr. Miller, if I could ask you to briefly respond to anything that these gentlemen have said. Would you care to do so?

Mr. MILLER. Well, let's take the size of quackery. I have four figures here that I have heard. Mr. Herbert just said—

Dr. HERBERT. Excuse me. If you would refer to me as "Doctor." You are "Mister." I am "Doctor."

Mr. MILLER. Excuse me, Victor. I am sorry.

Mr. SCHWARTZ. And I am "Professor."

Mr. MILLER. OK.

Victor referred to \$25 billion as his estimate of the amount of quackery there is in the U.S. Mr. Horowitz this morning said there is \$100 billion. He said it was 10 times higher than the \$10 billion figure. Mr. Pepper has given us two figures—\$50 billion, in November of 1983, in the Congressional Record; and \$10 billion on this report.

Mr. Chairman, figures have a wonderful way of being exact. You can measure the extent of the problem we are dealing with. Maybe these people see quackery that we don't see. I would like to see in the committee report a documentation of the \$10 billion. I did appreciate Victor's attempt this morning to outline so many billion dollars for each of the quackeries that he saw. But I would like to know why quackery from Mr. Pepper dropped from \$50 billion to \$10 billion in 6 months. At that rate, in 6 more months we won't have any problem.

I would like to see, No. 1, the amount of quackery, the amount of dollars spent on moon dust in the U.S. Incidentally, I was improperly quoted in USA Today. What I did say in that I thought the purpose of this hearing was to blow moon dust in people's eyes and draw them away from the real problem—unnecessary surgery and unneeded drugs.

Now, people who deal with figures are upset with this flippant way in which the committee throws billions of dollars around—is it \$100 billion? Is it \$50 billion? Is it \$25 billion? Is it \$10 billion? The only way to solve that is to have some documentation. How much quackery is there from eating raw human glands, for example?

As far as the defense of laetrile, I proudly stand on my record with laetrile. It is true that laetrile is legal in this country today, and any person in the country can get laetrile at this moment is in no small part due to the efforts that I and NHF have exerted to keep it legal. I hope it will be legal as long as I live.

Now, let's go into laetrile. Mr. Chairman, do you know that only two legislators in all this debate—and this debate has been raging now for the 22 years I have been in Washington—only two legislators in the whole United States ever had what I call the health statesmanship. When they heard of this controversy, they said, "let's go look." These two State legislators called me when I was in our main headquarters—in Monrovia, CA. They said, "You have a bill coming up in Nevada now to legalize laetrile in Nevada. Could you help us visit one of the clinics and their patients down in Mexico?"

Well, I had never been through these clinics. I had been defending them for 15 years without ever having been through a clinic. I said I would be glad to; I would like to see the clinic myself.

Two Nevada State Senators of opposite political parties flew down to San Diego after their work day. I took them over to the clinic, Clinico Del Mar—no, it was the Clinica Cydel—

Mr. BORSKI. Mr. Miller, for the sake of time, could I ask you to wrap up your statement? Anything you would like to submit for the record would be appreciated. We are running pretty much behind.

Mr. MILLER. May I finish this story?

One Senator said, "I only want to ask these people three questions." In the Clinica Cydel, the cancer patient is allowed to go in and live in an apartment with their family. It is not like in a U.S. hospital where they pay \$600 a day for a single room. Only \$30 a day is what they paid for their apartment, and the family was allowed to stay with them.

The Senator from Nevada said to the patient in the first room when he went in, "Have you taken laetrile?" In every case, the answer was affirmative. The second question was, "Were you in pain when you came into the clinic?" In every single case, the answer was affirmative. The third question was, "Are you in less pain, or are you taking less pain killers than when you came in?" And eight out of the first ten people he talked to said they were in less pain or out of pain because they had taken laetrile.

This Senator, at the end of 10 patients, said, "I have heard enough. I will stake my political career that laetrile is effective in the treatment of pain in cancer patients."

Now, what people like Victor Herbert do is to set up straw men about laetrile. Then they knock them down. Laetrile has never been promoted as a cancer cure, to my knowledge. But it has been promoted as a help and an aid in the treatment and prevention of cancer. And in pain of cancer.

Mr. BORSKI. Thank you very much.

Dr. HERBERT. Mr. Miller grossly misrepresents reality. Laetrile is 6 percent cyanide, by the way. The first thing it does is destroy the nervous system by knocking out cytochrome oxidase. Patients feel less pain because their nerves have been destroyed by this poison, which gradually makes them blind and deaf and kills them. And murders from laetrile are recorded with the coroners' reports in my book, "Nutrition Cultism," which I am sure Mr. Miller has read in depth; and also my book "Vitamins and Health Foods," which Mr. Miller reminded me refers to him in person.

Mr. MILLER. I carry them wherever I go.

Dr. HERBERT. I thought you would.

Mr. BORSKI. Thank you very much.

Thank you, gentlemen, for your testimony.

We would appreciate our fourth panel, State and Federal enforcement officials.

Mr. MILLER. Mr. Chairman, could I have one more second?

We have here a challenge to Dr. Herbert to debate Dr. Mendelson publicly in a continuing debate which we would like to offer him at this time.

Mr. BORSKI. This is not the time or the place for that.

Thank you all for your testimony. It is very much appreciated.

Mr. BORSKI. Our fourth panel, please.

Mr. Charles Nelson, Assistant Chief Postal Inspector, Criminal Investigations, U.S. Postal Service; Mr. Glen Braswell, Federal Corrections Institute, Lexington, KY; Dr. Stuart L. Nightingale, Associate Commissioner for Health Affairs, Food and Drug Administration; Ms. Carol Crawford, Director, Bureau of Consumer Protection, Federal Trade Commission, and the Honorable James McKenna, Assistant Attorney General, Augusta, ME.

Mr. BORSKI. We will ask Mr. Charles Nelson if he is prepared to start his testimony.

PANEL FOUR, CONSISTING OF CHARLES NELSON, ASSISTANT CHIEF POSTAL INSPECTOR FOR CRIMINAL INVESTIGATIONS, U.S. POSTAL SERVICE; GLEN BRASWELL, FEDERAL CORRECTIONS INSTITUTE, LEXINGTON, KY; DR. STUART L. NIGHTINGALE, ASSOCIATE COMMISSIONER FOR HEALTH AFFAIRS, FOOD AND DRUG ADMINISTRATION; CAROL T. CRAWFORD, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION; AND HON. JAMES A. MCKENNA, ASSISTANT ATTORNEY GENERAL, CONSUMER AND ANTITRUST DIVISION, AUGUSTA, ME, ON BEHALF OF JAMES E. TIERING, ATTORNEY GENERAL, STATE OF MAINE

STATEMENT OF CHARLES NELSON

Mr. NELSON. Mr. Chairman, we have submitted a rather lengthy testimony for the record. With your permission I will just go through a brief that I have.

Mr. BORSKI. I would appreciate you doing that.

Mr. NELSON. On my right is George Davies, Assistant General Counsel, Consumer Protection Division.

We appreciate the opportunity to be here today to discuss the Postal Service's efforts to combat unlawful use of the mails to market false or fraudulently advertised medical products or devices.

The Nation's mail system has been a favorite marketing medium for the sale of worthless or grossly exaggerated pills, potions, and devices for well over a century. The advertising pitches for these products are all too familiar. The common message running through advertisements for these and similar schemes is one of hope. The consumer is told that the product offered for sale is the result of research conducted by those who have been able to tap a source of truth that has eluded the medical and the scientific community.

Unfortunately, many of these so-called cures and treatments advertised by unscrupulous operators are dangerous in and of themselves, and by encouraging consumers to rely on mail order "remedies," advertisers often discourage the afflicted from seeking competent medical treatment until their condition has further deteriorated. Again and again the disappointed victims of these schemes tell us that the Government has failed to protect them. As the committee has found, medical quackery schemes are often targeted at the Nation's 26 million elderly citizens. Since 1979 Postal inspectors have assisted the staff in its investigation of swindlers who use the mail to prey upon older Americans. A joint effort between your

staff members and an inspector led to the referral of several possible false representation cases to fraud inspectors.

With Congress' assistance, the Postal Service is working hard to minimize the adverse effects of medical schemes on mail order consumers, particularly the elderly. The statutory weapons available to the Postal Service include the Criminal Mail Fraud Statute, 18 United States Code, section 1341, the Administrative Postal False Representation Statute, 39 United States Code, section 3005 and a supporting injunctive statute, 39 United States Code section 3007.

The criminal statute provides for a fine of \$1,000 and imprisonment of up to 5 years for the intentional use of mails in furtherance of a fraudulent scheme. While its deterrent power lies mainly in the possibility of a jail sentence, we have often found that courts are reluctant to incarcerate so-called white-collar criminals, particularly for first offenses.

Inasmuch as targets of criminal mail fraud investigations and prosecutions may continue in business during the course of these proceedings, we rely on the false representation statute to more promptly protect the public from being victimized by schemes to obtain money or property by mail. The mandate of this statute is simple, namely, that persons offering goods or services for sale through the mail refrain from misrepresenting their products.

The mail order consumer protection amendments of 1983 enacted last November have enhanced the effectiveness of the false representation statute. This new law authorizes us to purchase and receive in person upon payment of the advertised price products or services sold through the mail.

Because our regulations implementing this authority just became effective on March 29, 1984, we have not had extensive experience in the new procedure. Our experience to date, however, would seem to support our expectation that this new authority will eliminate delays of a month or more in obtaining advertised products for testing.

The 1983 amendments also provided that false representation order may include a cease and desist order. Previously the statute only authorized the issuance of a mail stop order. Promoters subject to mail stop orders could circumvent their effect by changing their address and/or name and continue to operate the scheme without risk of penalty. By authorizing U.S. district courts to impose a civil penalty of up to \$10,000 per day against anyone who continues or resumes a scheme which he or she has been ordered to cease operating, the new legislation should deter this practice. Since our implementation of the cease and desist authority in December 1983, 48 such orders have been issued. To date we have not identified any violation of the cease and desist order.

We believe this new law constitutes a major step toward making the statute a more effective tool with which to combat mail order misrepresentation schemes, and would like to commend the subcommittee and the principal sponsors of this important legislation for working for its enactment. We are confident that we will maintain and improve what we consider to be a pretty good track record in this area.

In closing, we want to emphasize that the key ingredient in any effort to curb the abuses of mail order swindlers is an increased

public awareness of the problem. We strongly believe that the hearings your committee has held in the past, as well as today's session, have helped to increase public awareness and we commend you for bringing national exposure to this problem.

Again, we would like to thank you for inviting the Postal Service to be here to testify today, and we will be happy to answer questions later.

[The prepared statement of Mr. Nelson follows:]

PREPARED STATEMENT OF CHARLES P. NELSON, ASSISTANT CHIEF POSTAL INSPECTOR

Mr. Chairman, my name is Charles P. Nelson, Assistant Chief Postal Inspector for Criminal Investigations. I appreciate the opportunity to be here today to discuss the Postal Inspection Service's efforts to combat the unlawful use of the mails to market false or fraudulently advertised medical products and devices.

The nation's mail system has been a favorite marketing medium for the sale of worthless or grossly exaggerated pills, potions, and devices for well over a century. The advertising pitches for these products are all too familiar. If one lacks the will-power to control eating, a variety of pills are offered to make the task effortless. If one's genetic code preordains small breasts or baldness, a cream or lotion can be ordered which overrides biology. Loss of memory or declining sexual performance need no longer concern the elderly thanks to the promoter's latest combination of vitamins and minerals.

The common message running through advertisements for these and similar schemes is one of hope. The consumer is told that the product offered for sale is the result of research conducted by those who have been able to tap a source of truth that has eluded the medical and scientific community. Members of the public who are frustrated by medical science's inability to provide a complete, inexpensive solution to their particular problem are often too willing to believe advertisements which promise successful results.

Unfortunately, many of the so-called cures and treatments advertised by unscrupulous operators are dangerous in and of themselves. And by encouraging consumers to rely on mail-order "remedies," advertisers often discourage the afflicted from seeking competent medical treatment until their condition has further deteriorated. Again and again the disappointed victims of these schemes tell us that the Government has failed to protect them by properly fulfilling what they perceive is its obligation to make sure that everything sold by mail will perform as advertised.

With Congress' assistance, the Postal Service is working hard to minimize the adverse affects of medical schemes on mail-order consumers, particularly the elderly. The statutory weapons available to the Postal Service include the criminal mail fraud statute, 18 U.S.C. § 1341, the administrative postal false representation statute, 39 U.S.C. § 3005, and a supporting injunctive statute located at 39 U.S.C. § 3007.

The criminal statute provides for a fine of \$1,000 and imprisonment of up to five years for the intentional use of the mails in furtherance of a fraudulent scheme. While its deterrent power lies mainly in the possibility of a jail sentence, we have often found that courts are reluctant to incarcerate so-called "white collar criminals," particularly for first offenses. The \$1,000 fine would seem to have little deterrent effect for persons who believe their promotion will reap much more substantial returns.

Inasmuch as targets of criminal mail fraud investigations and prosecutions may continue in business during the course of these proceedings, we rely on the false representation statute to more promptly protect the public from being victimized by schemes to obtain money or property by mail through false representations. The mandate of this statute is simple: namely, that persons offering goods or services for sale through the mail refrain from misrepresenting their products in any material respect.

False representations proceedings are conducted pursuant to the Administrative Procedure Act (5 U.S.C., Chapters 5 and 7) and are initiated by the filing of a formal complaint with the Postal Service's Judicial Officer. A copy of the complaint, notice of hearing, and our Rules of Practice are served upon the promoter. The complaint is assigned to an impartial administrative law judge, who presides over a formal evidentiary hearing where the respondent may be represented by counsel, present testimony, and cross-examine witnesses. After the hearing, the administrative law judge renders an initial decision either recommending or not recommending that a false representation order be issued.

The entire record, including the transcript of the hearing, is then reviewed by the Judicial Officer. If the Judicial Officer concludes that the Postal Service has proven by a preponderance of evidence that the statute is being violated, he will then issue a false representation order. A respondent may seek judicial review of an adverse decision in a Federal District Court. While the false representation case is pending, 39 U.S.C. § 3007 allows the Federal courts to order the Postal Service to detain the promoter's incoming mail where we can show probable cause to believe we will prevail in the administrative case.

The Mail Order Consumer Protection Amendments of 1983, enacted last November, have enhanced the effectiveness of the false representation statute. This new law authorizes postal officials to purchase and receive in person, upon payment of the advertised price, products or services sold through the mail. Because our regulations implementing this authority just became effective on March 29, 1984, we have not had extensive experience with the new procedure. Our experience to date, however, would seem to support our expectation that this new authority will eliminate delays of a month or more in obtaining advertised products for testing.

The 1983 amendments also provided that the false representation order may include a cease and desist order. Previously, the statute only authorized the issuance of a mail-stop order which directed a postmaster to return to senders mail responding to the particular name and address used in the false representation or lottery scheme. Promoters subject to mail-stop orders could circumvent their effect by changing their address and/or name and continue to operate the scheme without risk of penalty. By authorizing U.S. District Courts to impose a civil penalty of up to \$10,000 per day against anyone who continues or resumes a scheme which he or she has been ordered to cease operating, the new legislation should deter this practice. Since our implementation of the cease and desist authority on December 9, 1983, 48 orders have been issued. To date, we have not identified any violation of a cease and desist order. Accordingly, no penalty cases have been initiated.

We believe this new law constitutes a major step towards making the statute a more effective tool with which to combat mail-order misrepresentation schemes, and would like to commend you, Mr. Chairman, and the other principal sponsors of this important legislation for working for its enactment. We are confident that we will be able to maintain and perhaps improve what we consider to be a pretty good track record in this area. For notwithstanding the loopholes in section 3005, we brought approximately 607 administrative cases against medical and cosmetic promotions during the period covered from Fiscal Year 1977 to March 31, 1984.

Over the years, we have brought to the Subcommittee's attention many examples of cases which demonstrate the callous nature of unscrupulous promoters and the dangers which are sometimes involved in using their products. I would like to review with you some of the more significant of these cases.

In a California cancer cure scheme, the operator provided, for a fee of \$700, a treatment which consisted in part of injections represented as 100 per cent pure organic extractions from kelp and seaweed. In fact, the injections were contaminated with bacteria which could cause serious illness or death. The promoter of this scheme pled guilty to four counts of mail fraud. He was fined \$1,000 and sentenced to six months probation.

Another case involved an eye exercise program which for \$9.95 plus shipping charges would allegedly cure nearsightedness, farsightedness, astigmatism, and middle age sight problems. The program directed users to ignore standard medical advice and medication and stare directly into the sun. A false representation case against this promoter resulted in a mail-stop order.

A chiropractor from Buffalo, New York marketed a \$25.00 computerized nutrient deficiency test which medical experts found to be worthless in determining a person's nutritional status. The patient was instructed on the virtues of wheat fiber tablets to cure a non-existent condition described as "Black Intestinal Plaque." On December 19, 1983, the promoter pled guilty to related charges and was sentenced to six months probation with the condition that he not pose as an expert in nutrition or give nutritional advice through broadcast media without first obtaining a graduate degree in nutrition from an accredited college or university. He was also directed not to promote or offer for sale any food or drug product for a therapeutic purpose which does not appear in its labeling.

One hundred thirty-eight false representation complaints were filed against 50 different medical-cosmetic products marketed by Braswell, Inc. through a multitude of addresses in Atlanta, GA and Ft. Lauderdale, FL. These cases were concluded through 32 false representation orders and 15 consent agreements. Among the products sold by Braswell were anti-aging preparation and baldness cures. Evidence in one case revealed that Braswell received over \$2 million for a worthless baldness

cure in one six-month period. Mr. Braswell pled guilty to mail fraud charges involving the faking of before and after advertising photographs purportedly revealing the results of bust developer, hair growth and cosmetic products, and was sentenced to five years probation. He was also sentenced to a three-year prison term of Federal income tax evasion and perjury charges developed during our mail fraud investigation.

Herbal Education Center of Burlington, VT, mailed over 800,000 catalogs advertising herbal cures for cancer, arthritis, varicose veins, and other serious illnesses. More than 30,000 persons responded to these mailings and collectively invested an estimated \$750,000. A false representations complaint against this promotion resulted in a consent agreement. In addition, the promoter was indicted for mail fraud, convicted, and sentence to serve a two-year prison term.

The Mark Eden Company was indicted for mail fraud arising from alleged false and fraudulent advertising claims for devices known as the Mark Eden Bust Developer, the Sauna Belt Waist Line Reducer, the three reducing garments known as Slim Skins, Vaccu-Pants, and Vacuum Pants. Since 1979, millions of individuals across the United States paid an average of \$10 each for these worthless products. Had the defendant been tried and convicted on each of the 13 counts in the indictment, the maximum fine under the Mail Fraud Statute would have been \$13,000. But through and innovative Civil settlement negotiated by the United States Attorney in San Francisco, the criminal indictment was dismissed in return for a somewhat more realistic civil fine of \$1.1 million coupled with the defendants' agreement to cease further sale of the products.

Many of our investigations have involved diet plans, pills and gadgets which allegedly cause weight loss. These schemes are aimed at all age groups, including senior citizens. One of these involved advertisement promoting the "Cambridge Diet" as a rapid reducing formula which would cause weight loss of six pounds in 48 hours and 46 pounds in six weeks. It was claimed that the diet "actually reduces fat as fast as complete starvation, yet eliminates hunger" and was completely safe to use as it "provided all the body's recommended needs of vitamins and minerals." The diet, allegedly was endorsed by the medical community and backed by hundreds of scientific and clinical studies. For an average cost of \$9.95 plus \$2.50 for handling and shipping, respondents received a ten meal supply of protein powder to be used as a total food substitute. The operation, based in Monterey, CA, and related to the Mark Eden promoters, was receiving up to 5,000 orders a day.

We engaged the services of a professional survey research firm to ask physicians to assess the safety of this diet. A questionnaire was mailed to approximately 1,900 physicians randomly selected from an American Medical Association mailing list. Approximately 80 percent opposed use of the diet and considered it unsafe. Some described it as a "severely restricted caloric intake diet" similar to a "starvation" diet which was reported to have caused at least 17 deaths. A severely restricted caloric intake diet is one involving less than 800 calories a day. Under the Cambridge Diet, an individual would receive only 330 calories a day. Physicians responding to the survey stated that no one should use the Cambridge Diet without careful monitoring by a physician and warned that certain individuals such as children, pregnant women, and the elderly should not use it at all.

Based upon our investigation, we filed an administrative complaint under the false representation statute against the diet's promoters. In a subsequent consent agreement they agreed future advertising would warn users to consult their doctors before starting the diet and emphasize that certain individuals should not use the diet under any circumstances. We estimate that prior to the consent agreement 125,000 people across the country had collectively paid well in excess of \$1 million for this diet.

As this committee has found, these and other medical quackery schemes are often targeted at the nation's 26 million elderly citizens. Concern for these elderly victims prompted us in 1980 to designate the investigation of postal crimes against the elderly as one of our top priorities. Since 1979, postal inspectors have assisted your staff in its investigations of the swindlers who use the mails to prey upon older Americans. A joint effort between your staff members and an inspector assigned to work with them on a full-time basis in 1981 led to the referral of several possible false representation cases to fraud inspectors. We have also appeared before congressional committees on several occasions such as this to highlight the problems mail fraud poses for the elderly and to support legislative initiatives designed to extend further protections to the elderly against deceptive mail order schemes.

In closing, let me emphasize that the key ingredient in any effort to curb the abuses of mail-order swindlers is an increased public awareness of the problem. I strongly believe that the hearings your committee has held in the past, as well as

today's session, have helped to increase public awareness and we commend you for bringing national exposure to this problem.

Again, I would like to thank you for inviting me to be here today. I will be happy to answer any questions you may have.

Mr. BORSKI. Thank you very much, Mr. Nelson.

Our next testimony will come from Mr. Glen Braswell.

STATEMENT OF GLEN BRASWELL

Mr. BRASWELL. My name is Glen Braswell. I was asked to come and testify as a public service by the committee.

I am now serving a 3-year sentence at FCI, Lexington, with 5 years probation to follow.

I was a businessman that believed in the product he sold and was doing fine 6 years ago when the postal authorities broadened the scope of their investigation and invited other Government agencies in on their war against me.

At the time I was doing business that employed over a hundred people and sales were more than \$1 million per month.

I thought this was not bad for a man who 7 or 8 years prior had nothing, had started my business from scratch with no outside investment. I was proud to be an American because this is one of the few places in the world that something like this could be done.

My main interest was in health. I read everything that had to be done with nutrition and preventing the corrective problems. My particular interest at the time was with hair. In my readings, I became certain that nutrition had to be reflected in one's hair. From this I had a vitamin pill and a vitamin-fortified shampoo made. It took years before I became successful.

No one was hurt, while dangerous products still are not stopped. Customers of mine were aware and needed no protection from the postal authorities. My customers consisted of over 3,000 doctors, Senator Strom Thurmond, Pat Boone, and John Wayne. Do these people need to be protected when buying cosmetics?

Should they not have the freedom to buy on their own? Plus, there was a money-back guarantee.

General Motors, Procter & Gamble, GE, none of these companies give a money-back guarantee.

The products were all formulated by doctors, manufactured in licensed laboratories, all 100 percent safe. Never was one person hurt by any of these products. I believed in these products and I thought they were the best. It seems a shame that the vast amounts of taxpayers' moneys were paid to protect them from something they needed no protection from.

Then they are not protected from dangerous clinics that claim cures for cancers, that keep people from seeking the proper medical care that could possibly help.

Companies that prey on people that have dire medical needs and fill them with false hopes in order to make profits are in my opinion the very ones the postal authorities should be after.

It seems to me they should take a look at their priorities and protect the people from what they need to be protected from.

Other examples are amphetamine diets, PPA; they have warnings printed on them and for good reason. They are dangerous.

My employees were advised by counsel not to give medical advice on any problem; directed them to require proper medical care.

We only sold vitamins and cosmetics.

The Post Office picked the wrong target. It seems if the Post Office will pick out one target, it overdoes the particular target and is almost blind to others, even when they are pointed out.

If they do the overkill on one case to be a deterrent on the other, it appears to be not working. I know of two companies in the same business I was in and have had discussions on the fact they avoid me because they are aware that the postal authorities have singled me out and, of course, they do not want to be connected.

They can run their business virtually without fear of postal regulations because they know the Post Office is spending all its budget on an overkill on a few.

So, in fact, in my opinion it works the opposite of a deterrent. Other companies can make claims I would never have used. These claims are made with the postal authorities' knowledge. I hope now that I have no company and am broke, and in jail, they are still not wasting their money on me.

Please put the companies out of business that are costing lives.

A lot of money was spent on me. I feel that my situation could be used in order to see if there was excessive Government intervention in business in the wrong place. Stop and think. Would I be the only person in prison in the country if we were all put under a microscope by an investigation that took 5 years, 15 FBI agents, three U.S. attorneys, numerous postal inspectors, the FTC, FDA, DEA, IRS, State and local enforcement agencies?

FBI claims to have a 1,000-page report. My home, my person, were searched without warrants, guns were pulled on me on two occasions. Rest assured there was more that I don't know about.

I am lucky not to have gotten life in prison or be shot by some overzealous agent.

This is an investigation that only Public Enemy No. 1 should have gotten, or maybe a person selling a false cancer cure. Maybe the reason they were so difficult to indict me was that there was no reason to start with.

But surely an investigation that has this type of money spent on it requires an indictment of some kind. It would be considered a waste of money if something was not found wrong at the end.

The investigation played a heavy toll on me. I lost my business, I lost my health, both physical and mental, all my worldly goods, and most important, my freedom. This is because of my cosmetics which harm no one.

What about the false medical cures of diseases that cause people to lose their lives? Isn't this different?

I hope that my input will help direct towards the real problem and stop these problems so people don't lose lives over false hopes.

Thank you very much.

Mr. BORSKI. Thank you very much, Mr. Braswell.

Mr. Braswell, would you tell us how much money you made?

Mr. BRASWELL. Personally or—

Mr. BORSKI. Yes.

Mr. BRASWELL. Well, I don't really know.

Mr. BORSKI. Is there a guess?

Mr. BRASWELL. I never really took a salary. I let the accountants take that. I would guess that the corporations probably grossed close to \$75 million in 12 years.

Mr. BORSKI. Thank you very much.

Dr. Stuart Nightingale.

STATEMENT OF STUART L. NIGHTINGALE, M.D.

Dr. NIGHTINGALE. Mr. Chairman, thank you for this opportunity to discuss the Food and Drug Administration's activities in combating the problem of health fraud, a term we prefer to the less comprehensive term "quackery."

I am accompanied by Mr. Mervin Shumate, Director of our Enforcement Policy staff. I will summarize my testimony and submit the full text for the record.

FDA classifies health fraud into three general categories: direct health hazards; indirect health hazards; and economic frauds.

Products in the direct health hazard category are those that present a very real hazard to the user and, therefore, are given the highest priority by FDA. Such products include those whose use has been documented to cause injury or death and whose use has a reasonable potential for causing direct serious adverse effects.

When such products are encountered, the agency uses all available civil and administrative sanctions to ensure that, within practical limitations, the product is removed from the market. Publicity is used as an appropriate means to warn consumers and health professionals about such products. Prosecutions are considered and pursued when the agency's criteria for criminal prosecution are met.

Artificial hair implants, which have caused serious infections, and the Relaxacizor, which was an electrical device sold for exercising and waistline reducing, are examples of direct health hazards.

Laetrile, a cyanide-containing substance, represents both a serious direct and indirect hazard. It is one of a long and sad roster of substances purported to cure or alleviate cancer. The saga of laetrile, probably the most economically successful and certainly the most controversial cancer remedy promoted to the American public in this century or any other, is still unfolding and highlights certain important issues.

As have most other "quack" remedies for cancer, laetrile benefited from the fears and anxieties of patients and their families which were most intense immediately following the diagnosis of the disease. The promise of a cure, or even of a palliative not available from so-called orthodox or traditional medicine obviously is enormously attractive to cancer patients.

In addition to a variety of enforcement actions, including seizures and prosecutions, FDA took a number of steps to educate and warn the public, health professionals, and State legislatures about the direct and indirect health hazards of Laetrile use. The vehicles included specially prepared leaflets for consumers, articles in the "FDA Drug Bulletin", sent to over 1 million health professionals, testimony presented at State legislatures, and a special widely disseminated public warning—only the second time in FDA's history that such a warning was issued.

In 1977, a U.S. District Court enjoined FDA from interfering with the interstate movement of laetrile intended to be used for certain "terminally ill" cancer patients. The government appealed, and despite more than 9 years of litigation, including a Supreme Court decision in favor of the government, the district court has still refused to remove the injunction. The government is pursuing additional judicial remedies.

And I would also note here that contrary to what Mr. Miller stated earlier, this situation does not permit laetrile to be used by anyone who wants it in the United States.

An indirect health hazard is one which does not pose a direct health hazard when used according to directions, but may have a significant adverse impact on a patient's health especially due to the delay or denial of proper medical treatment.

What distinguishes this category from a direct health hazard is that the product itself is not toxic or hazardous per se. Removal of the product from the market may be of secondary importance to making sure that the product itself is not misrepresented or misused.

A relatively recent example of an indirect health hazard is a sobriety-aid product that was purported to counter the effects of consuming alcohol. The hazard, of course, is that persons who have been drinking, believing themselves to have been magically made sober by using the product, can endanger themselves and others when, for example, they try to drive.

After we notified the distributor of the product that the labeling of the tablets contained therapeutic drug claims and that the FDA was unaware of any scientific studies supporting such claims, we seized the product as an unapproved new drug and successfully terminated its promotion and sale. Simultaneously, FDA issued a widely used press release that warned consumers not to trust this unproven product. I might add that this was an example of the government's ability to stop the promotion and sale of a product before its use became widespread.

Products characterized as economic frauds do not pose any direct health hazard and little or no indirect health hazard. These products are generally not very sophisticated in appearance or operation and are usually promoted in newspapers, magazines, or other lay media. They include such items as baldness remedies, sex aids, some health foods with unsubstantiated medical claims, such as preventing cancer, and many weight reduction products.

A recent example of an economic fraud involves the promotion and sale of a product ostensibly consisting of cruciferous vegetables—brussels sprouts and broccoli—in dehydrated tablet form. The product was promoted to prevent cancer on the premise that cruciferous vegetables have been associated with a reduction in the incidence of cancer. The product was seized by FDA as an unapproved new drug. The Federal Trade Commission also obtained an injunction in Federal court, prohibiting the firm from advertising any cancer prevention claims for this product.

FDA has repeatedly expressed its concern about promotional material that can easily misrepresent specific foods as being in and of themselves of value in the prevention or treatment of disease. The problem is exacerbated by the clever way in which the promoters

of such health frauds are able to exploit legitimate medical research findings to suit their own purposes. The agency on its own and in cooperation with the FTC has initiated regulatory action against specific conventional food products so misrepresented.

There are a number of arthritis frauds that I will not elaborate on now, except to say some of these include potent drugs disguised as Chinese herbal medicines. Victims hope in vain that their suffering will be relieved, while at the same time exposing themselves to real hazards.

Now, I would like to say a few words about our strategy to combat health fraud.

As part of its enforcement program, which includes routine inspections, FDA investigates individual complaints, obtains information and collects evidence regarding potential violations of the Federal Food, Drug, and Cosmetic Act. Decisions as to the significance of the findings obtained from an investigation and what action should result are made in accordance with established compliance policy that reflects factors such as health hazard potential, extent of product distribution, nature of the misbranding, jurisdiction of other agencies, and available resources.

Whenever possible, FDA coordinates its health fraud investigations and enforcement strategies with other agencies such as the Postal Service, Federal Trade Commission, and State officials.

We do have a rather extensive public education and information program which I would like to very briefly mention. While regulatory activity is a major aspect of FDA's efforts against health fraud, another important aspect is education of the consumer. In fact, educating the public on health fraud is a continuing concurrent and complementary program for FDA.

For example, we currently have 11 publications plus a slide presentation on health fraud. Some 3 million copies of those 11 publications have been printed for distribution by the agency, by private groups, and by the Consumer Information Center at Pueblo, CO.

The agency's magazine, "FDA Consumer," devotes about 15 percent of its editorial space to health fraud and in the last year has included 10 major articles on health fraud.

FDA is also working with private groups to combat health fraud. Two current projects involve the Council of Better Business Bureaus and the Pharmaceutical Advertising Council. Last week a letter signed by the acting FDA Commissioner and president of the Council of Better Business Bureaus was mailed to advertising managers of 9,500 newspapers and magazines.

The letter contained important information for reviewing ads and suggested that advertising managers check with local FDA and Better Business Bureau offices if they had questions about the validity of claims made in health or medical advertising that was submitted to them for publication.

And I would note that we hope this will respond to the kinds of concerns raised earlier by Mr. Horowitz which we indeed share. This approach does not really deal with electronic media, and the "talk show" problem referred to earlier by Dr. Wachsman and one which we believe is a significant problem—where anybody can appear on a program and promote various products in any way they wish.

The project we have with the Pharmaceutical Advertising Council we believe is very important. Our joint project on health fraud will use all media to reach the public with information about how to recognize, avoid and help stop health fraud.

This is a pioneering effort, the first time that a public awareness program on health fraud has been tried on a nationwide basis.

We recently awarded a contract for a pilot demonstration program in health promotion for the elderly. Part of this program will involve a curriculum dealing with fraudulent devices and claims. The ultimate goal of this program is to teach the elderly to become informed consumers by recognizing questionable advertising products and claims.

The program is scheduled to be presented to groups of senior citizens in eight locations in southern Ohio this summer. This is a pilot demonstration program that we think may have great relevance after the initial evaluation period.

IDA is also working closely with national consumer groups. We will coordinate a workshop on health fraud for the annual meeting of the National Association of Consumer Agency Administrators to be held in June. This is an association composed of the directors of over 100 city, county, and State consumer protection agencies. The primary functions of these groups are law enforcement, complaint handling, and consumer education. These are very important groups that we have already heard something about earlier today.

The goal of this workshop is to develop ways in which the Federal and local agencies can work more closely with each other to combat health fraud.

During the past 5 years FDA consumer affairs officers throughout the country have conducted health fraud consumer education programs. The program provides guidance that enables consumers to recognize fraud, evaluate product claims, and make informed decisions.

It also provides information to consumers on how to register complaints and concerns about fraudulent products.

Now, I will turn to the issues of our management of health fraud concerns. Since the committee's October 1980 hearing on this matter, the agency has continued to address health fraud at the highest levels of management in order to continue to focus resources on more effective educational and enforcement activities.

As a further step to strengthen our program, we have decided to establish health fraud as a separate project in our program management system [PMS] of planning beginning in fiscal year 1985. This decision assures agencywide direction, monitoring, and evaluation of the program and includes separate planning, budgeting, and reporting, as well as the compilation of more accurate program data.

In conclusion, FDA is seeking to protect the consumer as effectively as possible from health fraud associated with products subject to its jurisdiction. Considering agency resources and overall priorities, this is accomplished by:

Educating the general public and the media to be aware of promotional and other techniques to sell fraudulent products with unproven claims.

Giving notice to the industry and specific firms of practices that the agency considers to be in violation of the laws it enforces.

Seeking the assistance, when it is appropriate to do so, of the Department of Justice in initiating civil and criminal proceedings against perpetrators of health fraud.

Coordinating, wherever possible, our educational and enforcement efforts with other Federal and State agencies.

We will be pleased to answer any questions you or your colleagues may have.

[The prepared statement of Stuart L. Nightingale follows:]0

PREPARED STATEMENT OF STUART L. NIGHTINGALE, M.D., ASSOCIATE COMMISSIONER FOR HEALTH AFFAIRS, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, thank you for this opportunity to discuss the Food and Drug Administration's (FDA) activities in combatting the problem of health fraud.

We recently concluded that the term "medical quackery" is not broad enough to cover the wide range of abuses that occur as the result of the over-promotion of traditional and familiar foods, and of vitamin-mineral, weight control, diet-aid, drug, device, and cosmetic products. For this reason, we have begun to use "health fraud" as a more comprehensive term.

Unfortunately, the consumer usually thinks of quackery or health fraud as related to a product that merely does not do what it is advertised to do but can cause little or no harm. However, health frauds often can result in direct or indirect health problems. FDA classifies health fraud into three general categories: direct health hazards; indirect health hazards; and economic frauds.

DIRECT HEALTH HAZARD

Products in the direct health category are those that present a very real hazard to the user and, therefore, are given the highest priority by FDA. Such products include those whose use has been documented to cause injury or death and whose use has a reasonable potential for causing direct serious adverse effects.

When such products are encountered, the Agency will use all available civil and administrative sanctions to ensure that, within practical limitations, the product is removed from the market. Publicity will be used as an appropriate means to warn consumers and health professionals about such products. Prosecutions are considered and pursued when the Agency's criteria for criminal prosecution are met.

Artificial hair implants, which have caused serious infections, and the Relaxacizor, which was an electrical device sold for exercising and waist-line reducing, are examples of direct health hazards. FDA found the Relaxacizor to have a serious potential for damage to the heart and other vital body organs. The device was found by a United States District Court to be dangerous to health, in that there is "a wide spectrum of conditions in which the Relaxacizor is hazardous and contraindicated, such as intra-abdominal, gastrointestinal, orthopedic, muscular, neurological, vascular, dermatological, kidney, gynecological, and pelvic disorders."

Laetrile, a cyanide-containing substance, represents both a serious direct and indirect hazard. It is one of a long and sad roster of substances purported to cure or alleviate cancer. The saga of Laetrile, probably the most economically successful and certainly the most controversial cancer remedy promoted to the American public in this century or any other, is still unfolding.

As have most other "quack" remedies for cancer, Laetrile benefited from the fears and anxieties of patients and their families which were most intense immediately following the diagnosis of the disease. The promise of a cure, or even of a palliative not available from so-called orthodox or traditional medicine obviously is enormously attractive to cancer patients.

Although amygdalin overdose—amygdalin is the chemical name for Laetrile and is naturally occurring in apricot pits—had been documented to cause the deaths of individuals who had ingested ground apricot pits, oral amygdalin in the form of Laetrile was alleged by its promoters to be safe. However during Laetrile's heyday at least two individuals were known to have died from its toxic effects and countless others died or lost valuable years of life because they failed to get appropriate medical care.

Because Laetrile was used widely and there was serious national concern over the hazards associated with its use, a clinical trial was conducted with NCI support by a multi-institutional team. The results showed that Laetrile produced no discernible benefit in cancer patients. Moreover, several patients in the study had symptoms suggestive of cyanide toxicity or blood cyanide levels that approached the toxic range (or both). Thus, the study demonstrated that Laetrile is neither safe nor effective.

In addition to a variety of enforcement actions, including seizures and prosecutions, FDA took a number of steps to educate and warn the public, health professionals, and state legislatures about the direct and indirect health hazards of Laetrile use. The vehicles included specially prepared leaflets for consumers, articles in the FDA Drug Bulletin, sent to over one million health professionals, testimony presented at State legislatures, and a special widely disseminated Public Warning—only the second time in FDA's history that such a warning was issued.

In 1977, a United States District Court enjoined FDA from interfering with the interstate movement of Laetrile intended to be used for certain "terminally ill" cancer patients. The Government appealed and despite more than nine years of litigation, including a Supreme Court decision in favor of the Government, the district court has still refused to remove the injunction. The Government is pursuing additional judicial remedies.

INDIRECT HEALTH HAZARD

An indirect health hazard is one which does not pose a direct health hazard when used according to directions but may have a significant adverse impact on a patient's health due to (1) the delay or denial of proper medical treatment, and (2) the promotion of the product for a use for which it is not effective.

What distinguishes this category from a direct health hazard is that the product itself is not toxic or hazardous per se. Removal of the product from the market may be of secondary importance to making sure that the product itself is not misrepresented or misused.

A relatively recent example of an indirect health hazard is a sobriety-aid product that was purported to counter the effects of consuming alcohol. The hazard, of course, is that persons who have been drinking, believing themselves to have been magically made sober by using the product, can endanger themselves and others when, for example, they try to drive.

After we notified the distributor of the product that the labeling of the tablets contained therapeutic drug claims and that the FDA was unaware of any scientific studies supporting such claims, we seized the product as an unapproved new drug and successfully terminated its promotion and sale. Simultaneously, FDA issued a widely-used press release that warned consumers not to trust this unproven product. I might add that this was an example of the Government's ability to stop the promotion and sale of a product before its use became widespread.

ECONOMIC FRAUDS

Products characterized as economic frauds do not pose any direct health hazard and little or no indirect health hazard. These products are generally not very sophisticated in appearance or operation and are usually promoted in newspapers, magazines, or other lay media. They include such items as baldness remedies, sex aids, some health foods with unsubstantiated medical claims, and many weight reduction products.

A recent example of an economic fraud involves the promotion and sale of a product ostensibly consisting of cruciferous vegetables—brussels sprouts and broccoli—in dehydrated tablet form. The product was promoted to prevent cancer on the premise that cruciferous vegetables have been associated with a reduction in the incidence of cancer. The product was seized by FDA as an unapproved new drug. The Federal Trade Commission also obtained an injunction in Federal court, prohibiting the firm from advertising any cancer prevention claims for this product.

In this connection, some unscrupulous promoters are taking advantage of recommendations of the American Cancer Society, the National Academy of Sciences, and the National Cancer Institute to increase the total dietary intakes of a variety of foods as a possible means of preventing certain cancers. FDA has repeatedly expressed its concern about promotional material that can easily misrepresent specific foods as being in and of themselves of value in the prevention or treatment of disease. The problem is exacerbated by the clever way in which the promoters of such health frauds are able to exploit legitimate medical research findings to suit their

own purposes. The Agency on its own and in cooperation with the FTC has initiated regulatory action against specific conventional food products so misrepresented.

ARTHRITIS FRAUDS

One specific area of continuing concern is arthritis quackery. Although there are drugs to relieve the pain and reduce the inflammation of arthritis, there is as yet no cure for this crippling disease. It is little wonder, then, that many of those who suffer from arthritis turn to useless nostrums, unapproved devices, unnecessary food supplements and diet books. The total spent on these frauds is estimated to be \$950 million a year.

Vibrating Chairs and mattresses, complex electronic mechanisms, and high pressure enema devices are among the useless and potentially dangerous items that have been found in the arthritis quack's bag of tricks. Everything from cod liver oil, alfalfa, pokeberries, blackstrap molasses, and a mixture of honey, vinegar, iodine, and kelp have been sold for arthritis diets, although diet has not been shown to have any effect on the various forms of the disease.

Arthritis victims have been persuaded to buy powerful drugs, disguised as Chinese herbal medicines, and snake venom treatments in the hope that their suffering will be relieved. In our educational materials we describe the waste, futility, and potential danger associated with these products.

STRATEGY TO COMBAT HEALTH FRAUD

As part of its enforcement program, which includes routine inspections, FDA investigates individual complaints, obtains information and collects evidence regarding potential violations of the Federal Food, Drug, and Cosmetic Act. Decisions as to the significance of the findings obtained from an investigation and what action should result are made in accordance with established compliance policy that reflects factors such as health hazard potential, extent of product distribution, nature of the misbranding, jurisdiction of other agencies, and available resources.

Whenever possible, FDA coordinates its health fraud investigations and enforcement strategies with other agencies such as the Postal Service, Federal Trade Commission, and State officials. For example, as a result of a complaint from FDA, an investigation by the Postal Service (assisted by FDA) led to criminal charges against a promoter of wheat bran tablets, misbranded by a claim to improve the absorption of nutrients by eliminating "black intestinal plague" (a condition unknown to medical science); the promoter subsequently pleaded guilty to one misdemeanor violation under the Act.

PUBLIC EDUCATION AND INFORMATION ACTIVITIES

While regulatory activity is a major aspect of FDA's efforts against health fraud, another important aspect is education of the consumer. In fact, educating the public on health fraud is a continuing concurrent and complementary program for FDA. For example, we currently have 11 publications plus a slide presentation on health fraud. Some 3 million copies of those 11 publications have been printed for distribution by the Agency, by private groups, and by the Consumer Information Center at Pueblo, Colorado.

The Agency's magazine, *FDA Consumer*, devotes about 15 percent of its editorial space to health fraud and in the last year has included 10 major articles on health fraud.

FDA is also working with private groups to combat health fraud. Two current projects involve the Council of Better Business Bureaus and the Pharmaceutical Advertising Council. Last week a letter signed by the Acting FDA Commissioner and the president of the Council of Better Business Bureaus was mailed to advertising managers of 9,500 newspapers and magazines. The letter contained important information for reviewing ads and suggested that advertising managers check with local FDA and Better Business Bureau offices if they had questions about the validity of claims made in health or medical advertising that was submitted to them for publication.

The FDA and the Pharmaceutical Advertising Council plan a joint campaign on health fraud that will use all media to reach the public with information about how to recognize, avoid, and help stop health fraud. This is a pioneering effort—the first time that a public awareness program on health fraud has been tried on a nationwide basis.

FDA recently awarded a contract to the Consortium for Health Education in Appalachia, Ohio, for a Health Promotion Program for the Elderly. It is a pilot demon-

stration consumer education program that utilizes the target audience itself to plan and implement the educational activities. The objectives of the contract are to provide elderly citizens with education and information on food, drugs, and medical devices. A part of this program will involve a curriculum dealing with fraudulent devices and claims. The ultimate goal is to teach the elderly to become informed consumers by recognizing questionable advertisements, products, and claims. This program is scheduled to be presented to groups of senior citizens in eight locations in southern Ohio during June and July of this year.

We are also working closely with National Consumer Groups to help combat health fraud. FDA will coordinate a two-hour workshop on health fraud for the annual meeting of the National Association of Consumer Agency Administrators (NACAA) to be held on June 24-26 in Baltimore. The NACAA members attending this conference are the directors of over 100 city, county and State consumer protection agencies. Their primary functions are law enforcement, complaint handling, and consumer education. A poll of NACAA members indicated that they consider health fraud to be a major consumer problem, especially for the elderly. The goal of this workshop is to develop ways in which Federal and local agencies can work more closely together on this issue.

During the past five years, FDA Consumer Affairs Officers throughout the country have conducted health fraud consumer education programs. In the first three years, there were two programs focusing on "food faddism," and "medical device quackery." In the past two years an "Agency-wide Health Fraud Program" has been implemented covering foods, medical devices, and drugs. The objectives of this program are to increase public knowledge and understanding, including that of senior citizens, of FDA's statutory responsibilities and the limitations of FDA's authority in protecting consumers from misinformation about foods, dietary supplements and nutrition; misrepresented drugs; and deceptive or harmful devices. The program provides guidance that enables consumers to recognize fraud, evaluate product claims, and make informed decisions. It also provides information to consumers on how to register complaints and concerns about fraudulent products.

FDA MANAGEMENT

Since the Committee's October 1980 hearing on this matter, the Agency has continued to address health fraud at the highest levels of management in order to continue to focus resources on more effective educational and enforcement activities. As a further step to strengthen our program, we have decided to establish health fraud as a separate project in our program management system (PMS) of planning beginning in fiscal year 1985. This decision assures Agency-wide direction, monitoring, and evaluation of the program and includes separate planning, budgeting, reporting, as well as the compilation of more accurate program data.

CONCLUSION

FDA is seeking to protect the consumer as effectively as possible from health fraud associated with products subject to its jurisdiction. Considering Agency resources and overall priorities, this is accomplished by: Educating the general public and the media to be aware of promotional and other techniques to sell fraudulent products with unproven claims; giving notice to the industry and specific firms of practices that the Agency considers to be in violation of the laws it enforces; and seeking the assistance, when it is appropriate to do so, of the Department of Justice in initiating civil and criminal proceedings against perpetrators of health fraud; coordinating, wherever possible, our educational and enforcement efforts with other Federal and State agencies.

Health fraud victimizes the innocent, enriches the corrupt, and drains the resources of agencies like the FDA—and hence all taxpayers. It is a problem not just for the victim, but for all citizens. There will always be persons trying to cheat the public where their health is concerned and there will always be persons who might fall victim to such deception. Knowing that, we intend to continue our efforts to combat health fraud whenever and wherever we can.

I will be pleased to answer any questions you or your colleagues may have.

Mr. BORSKI. Thank you very much.
Our next witness is Ms. Carol Crawford.

STATEMENT OF CAROL T. CRAWFORD

Ms. CRAWFORD. Thank you, Mr. Chairman. I have a prepared statement which has been made available to the committee. Pursuant to your request, I will not read my statement, but will highlight a couple of points about the FTC's involvement in this area. First, I would like to thank you for the opportunity to testify and I would like to applaud the committee for giving this subject the attention I believe it deserves.

I would echo what Dr. Nightingale just indicated, and that is the importance of public understanding and public education as a major component of any effort to deal with the problem in this area. Such efforts are necessary to increase the public's awareness of the kinds of claims that are being made—claims that are simply not documented or are not substantiated.

What I would like to do today—and I will try to do it briefly, because I know you have been here a long time—is to summarize how the Commission has looked at this problem and how our efforts fit into the larger framework of the way we exercise our jurisdiction generally.

The Federal Trade Commission has a basic mandate which authorizes us to police unfair or deceptive acts or practices. Now, clearly, advertising or marketing of what are considered quack products are among the most egregious forms of deceptive claims. They are not only among the most egregious, and most fraudulent types of practice, but we believe that they have the potential for very serious injury to those who are purchasers of the products.

The marketing of such products is among the worst types of deceptive practices. I need not tell you this—but to give you a sense of how we have looked at these problems—because of the vulnerability of the people upon whom they prey—they appeal to people's insecurities, fears, and anxieties. Again, I am repeating what many have said previously, but it is a very important part of understanding how we at the Commission view the quackery problem in the context of our larger jurisdiction to police unfairness and deception in the marketplace.

Basically, we have tried to focus the Commission's resources, on the kinds of claims and marketplace practices which have the greatest potential for injuring consumers. And clearly the area of quack claims is high on that priority list.

I would also mention that there are a number of other areas that specifically and very directly affect older Americans that we have also placed high on our list of enforcement priorities. My written statement goes into some of those areas in detail. For example investment frauds frequently prey on senior citizens, who often are the ones least able to absorb the losses that are incurred.

With respect to quack claims—or health care claims that are false or deceptive—we view such claim as having three specific kinds of potential injury. One is obviously the economic injury, the price paid for a product that simply doesn't perform in the way it was promised to perform. Second, in many cases the product itself can be dangerous to the individual. And third—and this has been mentioned previously—in many cases the purchase of a quack remedy deters individuals from pursuing legitimate forms of treat-

ment that may be much more helpful in treating, curing, or ameliorating the condition.

The Commission has taken several procedural steps, to better equip itself to attack these claims. The Commission, in 1983, issued a deception statement that not only more clearly articulated what the Commission's authority is to police deceptive claims, but also clarified that the Commission will view deceptive claims from the perspective of a target group.

Specifically the deception statement clarifies that the Commission not only has the authority, but will, in fact, focus upon claims that are directed at particular groups—such as older people, terminally ill people, or children—who frequently may interpret claims in ways other than an ordinary group of adults would interpret those claims.

We have also made it clear that we will focus on claims as they are interpreted by what we call reasonable consumers. We will not withhold action simply because a claim may be exaggerated or may not have great credibility among many people. The issue is not whether consumers reasonably believe the claim, but whether they reasonably believe the claim was made. This is an important point with respect to medical quackery, because many of the claims—the promises that are made for the products you have here, for which you have taken testimony—are really not the kinds of claims that most people would believe.

For example, a claim is being made that a baldness remedy will cure baldness, that is the claim that we we will look at. We will not ask whether it is reasonable to believe that claim, only whether it was reasonable to believe the claim was made. This has been an area of great misunderstanding. And, it is ironic in a sense because we have specifically focused on clarifying that we will look at the way claims are interpreted, not whether it is reasonable to believe them. That is a very important point in the way we have tried to clarify the commission's jurisdiction in this area.

This is an important point since there has been some inaccurate information about the Commission's role. I would also take issue, Mr. Chairman, with some conclusions in the subcommittee's report on the FTC's involvement. The Commission has, at least since October of 1981—and that is the only period for which I can speak—taken several steps, including the deception statement, to strengthen our ability to police this kind of health care claim, quackery health care claim, and other deceptive claims.

And, we have also in our enforcement protocols made it clear that we are interested in policing deceptive or fraudulent health care claims. There are those among our critics who feel that this is not an appropriate area for the Commission's involvement. Frankly, we disagree. Again, we believe that, because of the vulnerability of the targets of these claims they deserve particular attention from the Federal Trade Commission.

I would also take issue with the suggestion in the report that we do not have a systematic program for dealing with claims. To the contrary, we have taken steps to systematize our efforts at policing the precise kind of claim that you are now addressing. For example, approximately a year and a half ago we instituted a special

monitoring effort for advertising claims for health care products, many of which may fit into the quackery category.

We, of course, have long monitored a wide range of advertising through various media. What we have established is a separate and special monitoring program that focuses on specialized health care publications and the kind of publications that may pick up localized advertisements that we simply have not seen in our normal monitoring process. This has enabled us to spot a number of the kinds of problems that the Commission previously had simply not been aware of.

The two examples of cases criticized in the subcommittees report as not meriting the Commission's attention, razor bumps and acne cures are cases brought before this administration came to the Commission. We have, in fact, refocused the Commission's attention, and I will give you some examples of the kinds of cases that we have felt have deserved the commission's attention.

The first has already been mentioned by the Food and Drug Administration, and that is the area of phony cancer cures. The Commission last summer obtained a preliminary injunction and subsequently a cease and desist order against a company manufacturing Daily Greens, a dehydrated vegetable product.

In addition, we have sued—and we are still in litigation—with General Nutrition Corp. That litigation concerns a product marketed as "Healthy Greens," a dehydrated vegetable product. GNC seeks to relate its product to a reduced incidence of cancer. It does so—I have to be careful what I say because we are in litigation—allegedly by misrepresenting the findings of the National Academy of Sciences study. The cancer cures cases are more typical of the kinds of cases that this commission is focusing on.

Two other specific areas that the committee has had a special interest in, and we do as well, are arthritis claims and antiaging claims. While our investigations are nonpublic at this time, and I am not free to discuss them in any detail or give any names, I can assure you we have for some time had under investigation a number of the arthritis claims in which you have a particular interest, and, in addition, antiaging claims.

Finally, I will mention another case that falls into a specific area that you have mentioned, and that is a case of laser facelifts. This case was brought to our attention by another professional group, plastic surgeons, who indicated to us that there was simply no scientific basis for this treatment. We have since obtained a consent agreement with the chiropractors who were promoting this treatment.

I should also point out that an equally important component of our program is an effort to spread our knowledge and our findings among other State enforcement agencies; as well as to develop consumer education materials and other means of getting this information to the public. These efforts help the public to avoid injury before it occurs. It is always much easier and more efficient to prevent injury through education than it is to remedy it once it has occurred.

Consequently, we have increased the Commission's consumer education efforts in this area. I have brought a number of our publications with me and I would be happy to introduce them for the

record, for your information. Specifically, we have worked with the AARP on a number of publications. One that is in process, and that may be of particular interest to you, is a publication that will be designed to assist older Americans in selecting health care professionals. We think this publication will assist them in knowing what questions to ask and in helping them to make a choice as to what kind of care is most appropriate.

Finally, I will close by saying that there is an important role for Federal regulatory agencies in combatting quackery, and we have taken our mandate very seriously. We also have worked closely with other Federal agencies, the Food and Drug Administration and the Postal Service in particular. And the joint arrangements have been very productive. But I should also say that I believe that this is not a problem that will be successfully addressed just by Federal regulatory agencies.

What we have found is that we badly need the cooperation and the assistance of every State enforcement agency and also, very importantly, State medical boards and other licensing boards, and State professional associations. They frequently are in the best position to observe the kinds of problems that occur at a local level that simply do not come to our attention and that we are simply not able to locate. So I think that is immensely important.

[The prepared statement of Ms. Crawford follows:]

PREPARED STATEMENT OF CAROL T. CRAWFORD, DIRECTOR, BUREAU OF CONSUMER
PROTECTIONI. INTRODUCTION

Mr. Chairman and members of the Subcommittee: I am pleased to appear here today to discuss the Federal Trade Commission's activities to benefit older Americans and particularly to combat "quackery" in the health care area.¹ Deceptive marketing and advertising claims adversely affect the entire population. Deceptive health care claims can be particularly damaging to older Americans, who have a higher incidence of health problems and who may be more vulnerable to such claims. Therefore, we have devoted special attention to deceptive food, drug and health care claims and also to other deceptive claims that may particularly affect older Americans.

My statement today will first describe how we evaluate deceptive claims. I will then discuss some of the Commission's activities that are of particular importance to older Americans, focusing on food, drug and health care claims. Finally, I will describe the remedies available to the Commission to pursue deceptive advertising and marketing claims.

¹ The views expressed are those of Carol T. Crawford, Director of the Bureau of Consumer Protection. They do not necessarily reflect the views of the Federal Trade Commission or any individual Commissioner.

II. EVALUATING DECEPTIVE CLAIMS

The Commission's authority to proceed against deceptive food, drug or other health claims derives from Sections 5 and 12 of the Federal Trade Commission Act (FTC Act). As you know, Section 5 of the FTC Act declares unlawful unfair and deceptive acts and practices in or affecting commerce. Section 12 of the Act specifically prohibits the use of false advertisements regarding food, drugs, devices or cosmetics. The Commission can act under one or both sections to halt certain acts or practices involving deceptive food, drug or other health care practices.

However, the statute contains no definitions of the terms "unfair" or "deceptive." The Commission in December, 1980, developed a statement describing the criteria it applies in reaching a finding that an act or practice is "unfair."² No similar statement had been prepared to define the standards used in determining that a practice is "deceptive" until October, 1983, when the Commission concluded a year-long review of past cases and decisions and issued a formal statement on its deception jurisdiction.³ That statement does not change the law,

² The Commission's enforcement policy against unfair acts or practices is set forth in a letter to Senators Ford and Danforth, dated December 17, 1980.

³ The Commission's enforcement policy against deceptive practices is set forth in a letter (with separate statements of Commissioners Pertschuk and Bailey) to Congressman Dingell, dated October 14, 1983.

as some have suggested, it merely articulates the criteria used by the Commission and the courts over the last several decades in finding trade practices deceptive. The three questions the Commission asks are as follows:

(1) In looking at a representation, omission or practice, the Commission must determine what claims are being made. The Commission interprets claims and promises as reasonable consumers would. The Commission will not act upon "unreasonable" or bizzare interpretations. For example, it is not reasonable to conclude that Danish pastries are made in Denmark. The Commission will determine if the interpretation is one reasonable people -- ordinary consumers -- would read into the ad.

Two points are important here. First, the Commission indicated that it will interpret the claim as would reasonable consumers "in the circumstances." This language is intended to focus attention on claims directed at specific groups, such as older Americans, who may be more vulnerable to exaggerated or quack claims. What might well be overlooked by, or less important to, the general population could be interpreted as conveying a cure message or another type of claim of particular import for older people.

Second, the reasonableness question goes to the interpretation of the claim that is made, not to whether the claim is true or believable. And I should point out that we

have been more aggressive than past Commissions in prosecuting claims targeted at less sophisticated, more credulous buyers, as they are often more seriously injured by deceptive claims.

(2) The second question is whether the claim is likely to mislead people. The Commission is not required to wait until injury has actually occurred, but rather has the authority to halt deceptive practices or claims that are "likely" to mislead people. This criteria simply asks if the claim is likely to mislead.

(3) The third question is whether the claim is "material," a legal way to ask if the claim matters to people. That is, is the claim important to people in deciding whether to buy the product or service. If the purchased product or service does not perform as promised, the buyer has lost the purchase price and may be injured in other ways as well. This concept is also referred to as "detriment." If a claim is "material," that is if it influenced the purchase decision, no showing of injury is required.

III. COMMISSION ACTIVITIES AFFECTING OLDER AMERICANS

A. Non-Health Related Activities Benefitting Older Consumers

The Commission's pursuit of unfair or deceptive activities affecting the elderly extends to many areas beyond food, drug and

other health care claims. I would like to highlight some of the Commission's recent activities in these other areas that involve practices that are either targeted to or have a disproportionate impact on older Americans because of reduced income or other reasons.

Funerals

A prime example of a Commission activity that has great impact on older Americans is the Funeral Rule. This Rule, which just recently became effective, is intended to increase consumer access to accurate information prior to, and at the time of, purchase. The rule has the following requirements: (1) it requires funeral directors to provide consumers with itemized, presale price disclosures; (2) it prohibits misrepresentations of legal and cemetery requirements and of the preservative or protective value of embalming, caskets and vaults; (3) it prohibits funeral directors from requiring a casket for cremation, or any other tie-in arrangements; (4) it prohibits funeral directors from charging for goods and services not specifically ordered, such as embalming; and (5) it requires funeral directors to give, on request, price information over the telephone.

The rule is designed to help all people arranging funerals, but is expected to help older Americans in particular, such as

surviving spouses, to obtain needed information during a painful and vulnerable time.

Credit

Another way in which the Commission has used its authority to protect older consumers is through aggressive enforcement of the age discrimination provisions of the Equal Credit Opportunity Act. While federal law permits a creditor to consider information related to age, credit may not be denied, reduced or withdrawn solely because an otherwise qualified applicant is over a certain age. Furthermore, retirement income must be included in rating a credit application, and credit may not be denied or withdrawn because credit-related insurance is not available to persons of a certain age. The Commission previously had not enforced the age discrimination provisions of the ECOA, largely because of the difficulty of developing evidence. Much discrimination was hidden from detection, as applicants were discouraged from applying or applications were simply destroyed, leaving no record evidence of the discrimination. We have used new and innovative techniques and I am pleased to report that in 1983, we filed the Commission's first age discrimination complaint. The complaint charged that Aristar, Inc.'s subsidiary, Blazer Financial Services, illegally denied loans to older applicants, including those who relied on public assistance or retirement benefits, because of their age or because they were

not employed full-time. According to the complaint, Blazer treated older credit applicants less favorably than similarly qualified younger applicants. The Commission settled these charges through a consent decree, under which Aristar paid a \$90,000 civil penalty and is enjoined from such practices in the future.

In addition to this case, we are investigating several other creditors for possible illegal discrimination, such as discouraging older people from submitting applications, refusing to consider income from retirement sources, and imposing on older borrowers harsher repayment terms that are not justified by legitimate creditworthiness considerations.

Real Estate "Loan" Transactions

The Commission is also pursuing other types of credit activities. During the past few years there have been increasing numbers of foreclosure actions by lenders. This has resulted in "new" businesses that can generally be described as "foreclosure help" companies. These companies advertise and offer foreclosure help to homeowners in financial difficulty.

In October, 1983, we obtained a preliminary injunction against one such company -- R.A. Walker and Associates, Inc. The Commission alleged that the company orally represented the

transactions entered into were "loans," when in fact the transactions were "sales." Older, black homeowners were particularly affected by the alleged misrepresentations.

Investment Frauds

Our activities in the investment fraud area also particularly benefit older consumers because they are often ill-prepared to absorb the losses. While the nature of the frauds we have attacked vary, they frequently involve significant individual losses. Investment fraud firms have often bilked consumers an average of \$5,000 to \$10,000 each by promising large returns for investments in gemstones, precious metals or oil and gas leases. We have been very successful in pursuing the investment fraud cases. In the last two years, we have halted frauds that we estimate could have taken consumers for \$215 million if allowed to continue, and we have obtained court orders freezing over \$25 million in assets. Moreover, we recently announced a proposed settlement in one case which may provide consumers with \$6.7 million in redress in the near future.

Older consumers are also attractive targets for deceptive promotions of franchises. For example, the attributes of business opportunity ventures -- source of supplemental income, control over working conditions (*i.e.*, being your own "boss"), need for few additional skills, may be comparatively modest

investment -- are ones that fit the lifestyles of many older consumers. Although the investment usually is comparatively modest, it involves a significant amount of money for those involved and its loss can affect older consumers more than younger ones because the money is not easily recouped through future earnings and may have been set aside as a retirement "nest egg."

Alleged misrepresentations of the earning potential, right to exclusive territories or product quality by franchisors have led the Commission to challenge such diverse franchise sales programs as auto parts distributorships, energy management microprocessors and snack foods. Again, unsuspecting individuals were investing between \$3,000 and \$24,000 in these franchises based on the alleged misrepresentations. Where these practices are accompanied by violations of our rules, such as the Franchise Rule or Mail Order Rule, we have also sought civil penalties. One franchise case was recently settled with a \$40,000 civil penalty.

Energy Cases

Another type of deceptive claim we have been particularly alert to is deceptive energy savings claims. With the rise of energy costs, people today are seeking ways to conserve. Retired individuals, who are living at home on fixed incomes are

especially likely to be interested in conserving. The marketplace has responded with a host of new devices designed to cut energy bills one way or another. While this response is of course desirable, and most new entrants are honest businesses making honest claims, some give in to the temptation to "over-claim" the benefits of the new product. The public often is unable to gauge the effectiveness of the product: that is, whether it does what it claims to do. And because many of the companies are new, people often lack the "reputation information" that so often serves as a guide to honesty and reliability.

Examples of Commission actions in this area include orders against manufacturers of storm windows, solar energy equipment, and cellulose insulation.

Warranty Issues

In addition to the other activities I've described, we also are investigating possible failures to disclose prior to sale warranty limitations on products sold primarily to older and/or disabled consumers.

The foregoing discussion is not exhaustive of the Commission's non-health activities that have a particular impact on older people, but it serves as an illustration of the agency's ongoing enforcement efforts in this area. I would now like to

discuss Commission activities concerning food, drug and health care claims and practices.

B. Food, Drug and Health Care Practices

FTC initiatives designed to benefit purchasers of health care have particular significance for older Americans because those aged 65 and older spend almost three times as much per capita on health care as other adults. The FTC's health-related activities address nearly every facet of health care delivery that is of concern to older Americans. The remainder of my statement will focus primarily on our law enforcement activities in this area.

Deceptive food, drug and health care claims induce people to purchase ineffective cures and nostrums and are important areas for FTC enforcement activity. The public, and older Americans in particular, are injured by such claims in several ways. They are obviously injured economically by paying for cures and remedies that don't work. In addition, their health and safety may often be jeopardized by the bogus cure itself. A third and important form of injury occurs when ineffective or quack remedies divert older Americans or others from legitimate medical treatment that could often relieve or abate their problems.

As part of our effort to protect the public, we continually monitor advertising for unfair and deceptive claims. We place a great deal of emphasis on monitoring food, drug and health care claims because, as I previously mentioned, the potential for injury is especially severe. Because ads for some types of products (such as those that might be characterized as "quack" remedies), virtually never appear on the radio and television networks or in major newspapers and magazines, which are the main sources for national advertising, we have implemented special monitoring programs. Typically, ads for quack type products appear in health magazines catering to individuals who believe in non-traditional treatments for diseases, and in tabloid publications. Our special programs to gather these advertisements as well as our regular monitoring efforts have proved quite successful in identifying targets for Commission action. We also have initiated projects and identified targets on the basis of our ongoing contacts with other state and federal officials, and private groups such as the American Association of Retired Persons (AARP). I would now like to discuss the Commission's activities involving food, drug and health care products.

Drug Advertising

In the area of drugs we have pursued many types of deceptive claims, including performance, pain relief and safety claims.

Many of our claims are likely to be important to older consumers due to their higher incidence of health problems.

A number of our investigations involve cure claims for arthritis products. Arthritis is a condition that affects millions of older Americans and causes substantial suffering. Because of the long-term debilitating effects of the disease, individuals afflicted with it are particularly vulnerable to claims that a "miracle" product will stop their pain and suffering. Remedies for arthritis seem to appear in cyclical fads -- when waning consumer interest or governmental action ends advertising for one product, another product appears on the market. We have under non-public investigation the marketers of a number of different arthritis products that appear to be ineffective and could be called "quack" remedies.

We also have pursued other products making arthritis relief claims. For example, the Commission several years ago sued Thompson Medical Co. over its claims for the topical rub "Aspercreme," a product which, I should add, does not contain any aspirin. In June 1983, an Administrative Law Judge found that the company had deceptively advertised that Aspercreme was more effective than aspirin. The case is now on appeal to the full Commission.

Pain relief claims are also particularly important to older Americans. We have obtained a signed consent order, which will be before the Commission shortly, against a company allegedly making exaggerated claims of relief from aches and pains.

Our special monitoring activities have led us to examine a number of performance claims, for example, advertising claims for anti-aging products, a relatively new phenomena that also may turn out to be "quack remedies." Although a number of theories recently have been advanced by scientists to explain the process of aging, there is of course no agreement as to the validity of any of these theories. Despite this, a number of companies are using these theories as a means of advertising drugs and food supplements that make bold claims that the process of aging will be retarded. We are investigating ads for several of these companies to determine if they are false or unsubstantiated.

Another case we have brought focused on false or misleading safety claims. A recently issued consent agreement prohibits ads for Efficin from making safety claims comparing the drug to aspirin without also disclosing that the drug may produce side effects similar to those produced by aspirin.

Before discussing the Commission's food advertising program, I would like to discuss a non-law enforcement activity concerning drugs that benefits older consumers.

Persons aged 65 and over comprise 11 percent of the population, but pay 25 percent of the national prescription drug bill. Consequently, savings on prescription drug purchases are especially significant for older consumers. In 1979, the FTC staff completed an examination of state laws which prevent pharmacists from substituting lower cost generic drugs for brand name pharmaceuticals, and concluded that modification of these state laws could result in significant cost benefits with no compromise in quality. The Commission's staff, in conjunction with the Food and Drug Administration, proposed a model drug product selection statute for consideration by the states, and the staff continues to provide assistance to states contemplating legislation on this issue.

Several states have adopted the model law, in whole or part. The Commission's Bureau of Economics has been investigating to determine if drug prices have dropped in states that have adopted the model. The investigation is nearly complete and a report should be available in mid-1984.

Food Advertising

We have placed special emphasis on policing false and deceptive claims in food advertising, an area that is particularly significant for older Americans. We conduct an

extensive monitoring effort to determine current issues in food advertising and have targeted our investigations on new ad campaigns that present the greatest potential for injury to consumers. We have budgeted 5.4 professional workyears just for food advertising cases in fiscal year 1984, up from 1.1 workyears on food cases in 1981. We currently have many more initial phase investigations of food ads than in previous years, and expect that our expanded efforts will pay off, both in terms of the quantity and quality of our actions, and in our ability to move quickly against law violators.

A good example of a case where we moved quickly against an on-going deceptive food campaign, involving prevention claims, is PharmTech. The Commission has obtained a preliminary injunction in federal court and a final consent agreement halting advertising by PharmTech, Inc., which claimed that its dehydrated vegetable capsule, "Daily Greens," would reduce the incidence of cancer. The company had begun a massive national advertising campaign, claiming support from a recent report of the National Academy of Sciences. However, the report did not in fact provide such support.

In March, the Commission brought another action for allegedly false advertising against General Nutrition, Inc., for a similar product called "Healthy Greens." General Nutrition is a large retailer of health related products, with annual sales of

over \$350 million, and over 1,000 retail stores nationwide. The Commission staff is seeking a cease and desist order against this company to prevent false or unsubstantiated claims for "Healthy Greens" and all other products marketed with claims of disease prevention or cure. The case is currently progressing towards trial.

Performance and therapeutic claims also are important to older Americans. In January, the Commission issued a complaint against P. Leiner Nutritional Products for claims made on behalf of its wheat germ oil pill, Octacol 4. In its national advertising, the company claimed the product would improve vigor, stamina, and endurance, claims we believed to be unsubstantiated. This case also is progressing towards trial.

The Commission also has obtained a consent order against Estee, Inc., a manufacturer of food products for diabetics, prohibiting certain misleading claims, including representations that the advertised food will not elevate the blood sugar level of diabetics. The order also contains provisions regulating future low-calorie and sugar composition claims. The provisions of this order can serve as guidelines for other industry members making similar claims.

A final but very important area we have targeted for special staff monitoring is nutritional and other composition claims in food

advertising. Nutritional claims we are examining include low-sodium, low-sugar, low-calorie, nutrient comparisons, fiber content claims, and caffeine claims. While truthful ads in the above categories can provide useful information, deceptive claims can result in significant injury. Therefore we are particularly alert to claims that may not be accurate or substantiated. And we believe our efforts have strong support among the public.

Research conducted by the Roper organization and reported in August, 1983 shows that seventy-six percent of a national sample considered the amount of salt consumed in a day to be "very important" or "fairly important." Forty-nine percent considered it "very important." Similarly, 74% considered the amount of sugar consumed to be "very important" or "fairly important" ("very important," 49%). These data strongly suggest the importance to consumers of low-sodium and low-sugar ad claims, and we intend to continue our aggressive efforts in this area.

Other Health Care Claims or Practices

A wide range of other deceptive claims and practices play upon the health needs and concerns of our older Americans, and I will briefly describe just a few of the practices we have prosecuted.

The Commission has investigated companies purporting to cure or prevent baldness, when in fact, the process was likely to cause

infection or further hair loss. In September 1983, the Commission obtained a consent judgment against Braswell, Inc., permanently enjoining that company from representing that any product or service will cure or prevent hereditary baldness, unless it has approval from the Food and Drug Administration. The Commission obtained \$610,000 in civil penalties from the company, as well.

As major consumers of health care services, the older can be significantly disadvantaged when health care professionals engage in deceptive advertising practices, or when state or local professional associations act to restrict truthful advertising by health care professionals, such as doctors, podiatrists, optometrists and opticians. We are therefore systematically reviewing both advertising restrictions by health care professionals and the advertising itself to protect against deceptive claims.

Vision care is always of great concern to older Americans, and thus the Commission has devoted particular attention to possible problems in this area. Over 90 percent of persons aged 65 and over wear corrective lenses. The FTC has two specific programs designed to lower the price of vision care. The first, the "Eyeglasses Rule," gives individuals the right to obtain a copy of their prescription after having their eyes examined, thereby enabling them to comparison shop for eyeglasses.

We are also examining restrictions on the so-called "commercial" practice of optometry that may have the effect of reducing competition and thereby inhibiting price competition. Restrictions we are investigating include those that prevent optometrists from practicing under a trade name, working for a lay corporation, locating their practice in a commercial setting, and operating branch offices.

Some services are designed solely for older Americans, such as life care facilities, and here too we have been alert for possible unfair or deceptive practices. "Life care" is a concept whereby an older citizen, at a certain minimum age, may purchase a life lease in a living unit through the payment of an entrance fee and the obligation to pay monthly service fees. In addition to the life lease, the resident is entitled to various services and amenities, including guaranteed lifetime nursing care.

In 1983, the FTC investigated certain practices by Christian Services International, Inc. (CSI), which has developed, marketed and/or managed approximately 200 life-care homes in 15 states. CSI's homes guarantee lifetime living accommodations, meals and medical services to its residents, who must pay entrance fees ranging from \$15,000 to \$100,000, and monthly service fees ranging from \$250 to \$500.

CSI implied in advertisements and promotional material that many of its homes are affiliated with religious organizations. In fact, CSI has no religious affiliation. CSI also represented that there is little or no risk in entering into a life-care contract, a representation the Commission charged was false. Under the terms of a consent agreement we obtained with CSI, the company may not represent that any religious group is affiliated with its life-care homes or is legally or morally responsible for the homes' debts, unless that is the case. Also, CSI must provide prospective residents with a statement detailing any religious affiliation or explaining that there is none. CSI also must disclose to prospective residents that entering into the contract may involve significant financial risk, and they should seek independent advice before signing.

In addition to monitoring life-care facilities, the Commission is examining the nursing home industry to determine whether unfair or deceptive practices exist. Currently about 23,000 nursing homes provide care to approximately 1.4 million older residents in the United States. Allegations have been made that some nursing homes fail to disclose important information to potential residents prior to admission. Other charges have been made that some homes charge inflated prices, or even charge for services not rendered, and conceal their practices by failing to provide itemized bills. Our examination is designed to collect systematic evidence on the incidence of these and other alleged practices and their potential

for injury to prospective and actual nursing home residents. It will allow us to pursue unfair and deceptive practices among nursing homes that have great potential for harming older Americans and their families.

The Commission also has investigated chiropractors promoting facial treatments with a "cold" laser, who claimed these treatments were less expensive than traditional cosmetic facelift surgery and represented a revolutionary new method of removing wrinkles. However, when asked to provide support for these claims, promoters of these facelifts were unable to do so.

As a result, the Commission obtained a consent order against two Miami chiropractors who advertised laser facelifts. The order bars representations that laser treatments result in a non-surgical facelift, unless there is reliable support for the claim. In addition to obtaining the consent order, the staff sent advisory letters to all state attorneys general and boards of chiropractic and to the two national chiropractic associations. The letters alerted the officials to the Commission action, attached a copy of the order and offered staff assistance on legal and technical issues. The Commission also used a consumer education project to warn consumers that by purchasing unproven laser treatments, they may lose their money, and not their wrinkles.

IV. REMEDIES AVAILABLE TO THE COMMISSION

Although the above discussion is not exhaustive of Commission activities in the food, drug and health care area, it illustrates the agency's ongoing enforcement and other efforts in this area. In this discussion I have sometimes referred to remedies the Commission has obtained, and I would like to describe in more detail the law enforcement tools available to the Commission.

The Commission, as a civil enforcement agency, lacks authority to initiate criminal proceedings. Thus, the law enforcement tools available to the Commission are civil remedies such as administrative cease and desist orders, federal court injunctions, consumer redress, industry-wide guidelines, trade regulation rules and civil penalty proceedings for violations of standing Commission orders and rules. The Commission also seeks to obtain voluntary compliance where it can be more efficient and effective.

We have been particularly aggressive and imaginative in using those tools to enforce our statutes. Thus, we have developed new investigational approaches, and used more effectively our statutory authority to go to federal court to seek injunctions quickly. Moreover, in fraud cases where we were concerned that the company's assets would be dissipated before we could obtain redress, we have been able to obtain orders freezing assets. When firms seek refuge

in bankruptcy, we go in after them, often pursuing individual as well as corporate assets.

In addition to obtaining substantial civil penalties or consumer redress for individuals, we have been willing to experiment with new remedial approaches to respond to fraud or deception in the marketplace and have obtained relief including creating of consumer arbitration mechanisms, funding of research grants to advance the health sciences, and requiring individual respondents to pay out of their own pocket the costs of remedying the injury their companies have caused.

Finally, in addition to law enforcement, we also emphasize business and consumer education as a means of improving the functioning of the marketplace. In recent years, the Bureau's Consumer and Business Education Office has produced messages on health related topics in a variety of areas -- eyeglasses, generic drugs, contact lenses, food and nutrition. We also have issued a brochure on laser facelifts, which some consider a "quack" medical procedure.

We have worked closely with the AARP in developing a number of consumer education campaigns that are designed to assist older Americans. In 1983, we jointly developed and distributed How to Write a Wrong, a booklet which explains how to complain effectively about consumer problems and get results. The book is particularly

focused on how to avoid and deal with problems that arise in door-to-door and mail order promotions. Over 50,000 copies of this booklet have already been distributed.

We are currently working with AARP on two additional consumer education projects. The first is designed to assist older Americans in selecting the services of health care professionals. The second project is designed to provide older Americans with information on housing options and is focused on both independent and assisted living.

V. CONCLUSION

In conclusion, I hope that my statement has illustrated for you that the Commission has and will continue to take aggressive action against companies that engage in deceptive or fraudulent practices that affect older Americans, particularly practices or claims in the food, drug and health care area, be they "quack" remedies or otherwise false or deceptive.

Mr. Chairman and Members of the Subcommittee: that completes my remarks. I would like to submit for the record Commission responses to questionnaires concerning medicare fraud and abuse and medical and health quackery, submitted to Chairman Pepper on October 21, 1983 and March 12, 1984 respectively. I also am submitting for the record the Federal Trade Commission's 1983 yearly report to the Senate Special Committee on Aging regarding Commission activities affecting older Americans as well as examples of the Commission's consumer education materials that particularly benefit older people. I am pleased to address any questions you may have.

Mr. BORSKI. Mr Tierney.

STATEMENT OF HON. JAMES TIERNEY, PRESENTED BY JAMES
McKENNA

Mr. McKENNA. My name is James McKenna. Attorney General Tierney regrets he cannot be here today. He regards this subject as very important. I would like to present his statement.

This country is now well into a new electronic era of consumer fraud. The mass media techniques of this era are quite sophisticated and our elderly population is becoming a frequent target. Further, legislative tools available to combat such fraud are increasingly inadequate. I recently heard a story about one of Maine's northern cities which illustrates just how far the modern techniques of fraud have advanced.

Years ago when the circus came to Bangor, ME, there would be a long midway that one would have to walk through to get to the main tent. It cost a quarter to see the main show. However, there would be a series of exotic attractions along the midway begging for your money—contortionists, fire eaters, a two-headed cow. But if you kept a steady eye on the main tent, you could make it with your quarter intact. Right next to the main tent was an attraction that simply had a large sign before an entrance to a darkened tent. The sign read: "What every man and boy should know—25 cents." The sign was almost irresistible and many citizens gave up their entrance fee to the main show in order to sample this forbidden knowledge. After paying their quarter, they were led behind a curtain into a large sign which simply said: "When you whittle with a knife, whittle away from your body."

Today such relatively harmless midways have been replaced by a series of sophisticated electronic marketing techniques that utilize computers, customized mailing lists, professionally designed advertisements and sales pitches, and other mass-media advancements. It has become extremely difficult for our citizens, young or old, to resist these modern blandishments. This is the new electronic midway. Two-headed cows are easily ignored compared to the late night phone call to your home by an out-of-state caller who uncanily knows that you are an elderly person suffering from a medical ailment and who can convince you to invest large amounts of money for relief and magic lures.

In the nearly 4 years I have been the Maine attorney general, I have spent an increasing amount of time and resources on the problem of elderly fraud. Today's con artist is no longer a traveling sideshow, moving slowly from town to town. Today, he never even physically enters your State. Instead, he relies on mass mailings, national advertisements, and WATS banks of phone lines. Let me describe some of the techniques we are using in Maine to combat this new electronic midway. I believe that many of these ideas can be adopted at the national level in order to better protect our elderly consumers.

The most effective way to frustrate the ever-more sophisticated mass media techniques of the modern huckster is to educate all American citizens on the most common frauds being aimed at

them. Special efforts must be made to educate the elderly as our statistics indicate they are a "target" of such frauds.

For the past 2 years, in cooperation with the State's bureau of Maine's elderly, I have sponsored a Consumer Law and the Elderly Week. During this week, I send out over 30 assistant attorneys general to all parts of our State to address small groups of elderly people on their basic consumer rights. We speak in churches, in community halls, in Lions' clubhouses. Sometimes we speak before only a handful of people; other times we address nearly a hundred elderly citizens. Armed with a knowledge of our strong pro-consumer laws, Maine's elderly have become leaders in the battle for honesty in the marketplace.

Television and newspapers cover these speeches and our consumer advice reaches many thousands of Maine's elderly. We are now starting to explore the possibility of producing short television and radio dramatizations of the most common fraudulent schemes inflicted upon the elderly. Such use of radio and television is an idea I would urge the Federal Government to become involved in. Federal agencies could effectively use the same mass media techniques that today's modern hucksters have so skillfully mastered. Perhaps the most effective way to counter the ever-new schemes being dreamed up and inflicted on the Nation's elderly would be a series of federally sponsored dramatizations that would depict for the elderly the latest schemes being promoted. These short "ads" could warn them to seek professional advice before investing in oil wells that never produce or medical cures that only deplete their savings. These dramatizations need be no longer than 30 seconds in length and would reach an extremely large audience.

To my mind, the most hopeful testimony I have heard today is Dr. Nightingale's testimony that the FDA is going to be in league with the Pharmaceutical and Advertising Council in preparing mass media advertisements. We need to have 30 seconds, 15-second television spots around this country dramatizing the various solicitations you see, and describe why they are deceptive.

Among the techniques we have been using to combat this new electronic midway is to update our laws to reflect these new techniques. This last year we brought three suits against out-of-State charitable solicitors. We are using a new Maine law which requires professional fundraisers to disclose to their customers if less than 70 percent of the money is not going to the charity.

When less than 70 percent of the contributions are not being used for the charitable purpose, the solicitors have to tell the percentage of the money that is going to the charity. And in one of the suits we brought, only 4 percent of each dollar, only 4 cents of each dollar, was actually going to the charity. Most States do not have this type of disclosure law.

The National Association of Attorneys General currently is working with the National Association of State Charity Officials to promote a national standard for such disclosure laws. Attorney General Tierney thinks this is extremely important, especially in this area of mailing solicitation, in which a few people can get together and promote research foundations that can raise enormous amounts of money in just short periods of time.

One of the big problems today is no longer the door-to-door salesman. Rather, it is the phone call to the home. We have amended our home solicitation law to include not just door-to-door salesmen but also those phone calls into the home. Most States do not provide that protection. But today in Maine if you call in to a consumer's home and manage to persuade the resident to buy something, the consumer has the right to get a written contract, sign that contract and send it back to the caller before that sale becomes final. If the telephone solicitor does not send the written contract, he has committed a misdemeanor. This law has been very valuable in defeating many of the phone solicitors who have deluged Maine consumers with calls.

On newspaper advertisements—and this is one of the key areas to be considered—we have held a seminar for all the advertising editors in our State trying to describe to them how they can evaluate the validity of these ads. In my opinion, if an agency such as the FDA or the FTC has a choice between bringing tax enforcement actions or sending out an attorney to speak to a hundred newspaper editors, I would choose to have the attorney go out to speak, persuade editors to check the validity of the ads they are running.

In conclusion, Attorney General Tierney believes it is essential to the States and Federal Government to realize that the advent of computers, mailing lists, mass media persuasion techniques, and other tools of this new electronic midway have made many of our old laws antiquated and useless.

Our education efforts should be increased and we should adopt the same mass media techniques that the hucksters are so effectively using today.

Further, our laws should be amended to reflect the greater intrusion into the home allowed by modern communication techniques. Looking back, the temptations of the old-time circus midway seem almost nostalgic and harmless, but today the injury to the elderly is great indeed.

Their savings can be lost and their health harmed, and, of course, this new electronic midway does not travel to Bangor, Maine 1 week and another town the next.

It can be in every city every day and every night of the week. Thank you.

[The entire prepared statement of Mr. McKenna follows:]

PREPARED STATEMENT OF MAINE ATTORNEY GENERAL JAMES E. TIERNEY, PRESENTED BY, JAMES A. MCKENNA, ASSISTANT ATTORNEY GENERAL, CONSUMER AND ANTI-TRUST DIVISION, AUGUSTA, ME

INTRODUCTION: THE NEW ELECTRONIC MIDWAY

This country is now well into a new electronic era of consumer fraud. The mass media techniques of this era are quite sophisticated and our elderly population is becoming a frequent target. Further, legislative tools available to combat such fraud are increasingly inadequate. I recently heard a story about one of Maine's northern cities which illustrates just how far the modern techniques of fraud have advanced.

Years ago when the circus came to Bangor, Maine, there would be a long midway that one would have to walk through to get to the main tent. It cost a quarter to see the main show. However, there would be a series of exotic attractions along the midway begging for your money—contortionists, fire eaters, a two headed cow—but if you kept a steady eye on the main tent, you could make it with your quarter

intact. Right next to the main tent was an attraction that simply had a large sign before an entrance to a darkened tent. The sign read: "What Every Man and Boy Should Know—25¢." The sign was almost irresistible and many citizens gave up their entrance fee to the main show in order to sample this forbidden knowledge. After paying their quarter, they were led behind a curtain to a large sign which simply said: "When you whittle with a knife, whittle away from your body."

Today, such relatively harmless midways have been replaced by a series of sophisticated electronic marketing techniques that utilize computers, customized mailing lists, professionally designed advertisements and sales pitches, and other mass media advancements. It has become extremely difficult for our citizens, young or old, to resist these modern blandishments. This is the new electronic midway. Two headed cows are easily ignored compared to the late night phone call to your home by an out of state caller who uncannily knows that you are an elderly person suffering from a medical ailment and who can convince you to invest large amounts of money for relief and magic lures.

In the nearly four years I have been the Maine Attorney General, I have spent an increasing amount of time and resources on the problem of elderly fraud. Today's con artist is no longer a travelling sideshow, moving slowly from town to town. Today, he never even physically enters your state. Instead, he relies on mass mailings, national advertisements, and WATS banks of line phones. Let me describe some of the techniques we are using in Maine to combat this new electronic midway. I believe that many of these ideas can be adopted at the national level in order to better protect our elderly consumers.

ELDERLY EDUCATION

The most effective way to frustrate the ever-more sophisticated mass media techniques of the modern huckster is to educate all American citizens on the most common frauds being aimed at them. Special efforts must be made to educate the elderly as our statistics indicate they are a "target" of such frauds.

For the past two years, in cooperation with the State's Bureau of Maine's Elderly, I have sponsored a Consumer Law and the Elderly Week. During this week, I send out over 30 Assistant Attorneys General to all parts of our State to address small groups of elderly people on their basic consumer rights. We speak in churches, in community halls, in Lions' clubhouses. Sometimes we speak before only a handful of people; other times we address nearly a hundred elderly citizens. Armed with a knowledge of our strong pro-consumer laws, Maine's elderly have become leaders in the battle for honesty in the market place.

Television and newspapers cover these speeches and our consumer advice reaches many thousands of Maine's elderly. We are now starting to explore the possibility of producing short television and radio dramatizations of the most common fraudulent schemes inflicted upon the elderly. Such use of radio and television is an area I would urge the federal government to become involved in. Federal agencies could effectively use the same mass media techniques that today's modern hucksters have so skillfully mastered. Perhaps the most effective way to counter the ever-new schemes being dreamed up and inflicted on the nation's elderly would be a series of federally-sponsored dramatizations that would depict for the elderly the latest schemes being promoted. These short "ads" could warn them to seek professional advice before investing in oil wells that never produce or medical cures that only deplete their savings. These dramatizations need be no longer than 30 seconds in length and would reach an extremely large audience. What, then, are some of the major consumer frauds being pitched to the elderly on this new electronic midway?

CHARITABLE SOLICITATIONS

Maine elderly consumers are currently being exposed to an ever-increasing number of illegal charitable solicitations. In the past year, my office has filed three lawsuits against solicitors alleging that they have failed to meet the disclosure requirements of Maine law. The Maine Charitable Solicitations Act (9 M.R.S.A. § 5001) requires State registration and bonding for professional fundraisers and, in certain instances, financial reporting to the State. A critically important section of the law requires that professional fundraisers provide a financial disclosure to prospective donors when less than 70% of the contributions are used for the charitable purpose. The disclosure must state, among other things, the percent of each dollar contributed that will be used for the charitable purpose and the professional fundraiser's compensation. We have found that charitable fundraisers frequently do not make these disclosures. In one case, only 4% of the monies being contributed for a fund-

raising drive were turned over to the charity for benevolent purposes. Unfortunately, few states have such strict disclosure requirements as Maine's.

Currently, my office is working with the National Association of Attorneys General and the National Association of State Charity Officials in order to produce a national approach to this problem. This era of mass media solicitations has increased the urgency of this project. For example, the elderly are increasingly asked to contribute money to research organizations that are supposedly seeking cures for the most common ailments suffered by the elderly. These requests for money can be easily produced on a nationwide basis by only a few people who are expert not in medicine but in mass mail solicitations. An attractive brochure and the purchase of the proper mailing lists can ensure rapid, massive profits. However, if such solicitors were made to disclose the percentage of money actually being donated to a charity or used for medical research, the elderly would be quickly able to separate legitimate solicitations from the fraudulent. I would urge you to assist in the formulation of national standards for charitable solicitations.

PHONE CALLS TO THE HOME

Increasingly, the modern huckster is setting up banks of phones, renting WATS lines, and then flooding the country with phone calls to the homes of the elderly. Maine has enacted a powerful deterrent to this practice. The Maine Consumer Solicitation Sales Act (32 M.R.S.A. § 4662) specifically includes phone calls to the home in the same category as door to door salesmen. For any sale over \$25 made pursuant to a phone call to the home, the seller must provide the buyer with a written contract that the buyer must sign and return before the sale is completed. Violation of this law is a misdemeanor in the State of Maine. Few states, however, provide this protection to their consumers and the federal government should consider a national approach to this problem.

NEWSPAPER ADVERTISEMENTS

Perhaps one of the most cost-effective schemes for fraudulently raising money is to place bogus newspaper ads in a number of respected newspapers. It is not uncommon to see clearly deceptive ads each Sunday in some of our most prominent newspapers. In Maine, we have tried to attack this problem by holding a seminar for the advertising editors of all of our weekly newspapers. At this seminar, we discuss with them the most common fraudulent advertisements and urge them to make an effort to first determine that any advertisement they ran was legitimate. The federal government can provide such training on a national basis. Perhaps our only defense against such advertisements is the aggressive editor who insists that the legitimacy of an advertisement be checked before it is accepted by his or her newspaper. Additionally, newspapers could be urged to run their own "advertisements", which would warn readers that before sending money for medical cures or investments based only on an advertisement, they should first seek professional advice.

CONCLUSION

In conclusion, I believe it is essential that the states and federal government realize that the advent of computers, mailing lists, mass media persuasion techniques, and the other tools of the electronic midway have made many of our old consumer protection laws antiquated and relatively useless. Our efforts at consumer education of the elderly should be increased and we should adopt the same mass media techniques that hucksters are so effectively using today. Further, our laws should be amended to reflect the greater intrusion into the home allowed by modern communication techniques. Looking back, the temptations of the circus midway in Bangor, Maine seem almost nostalgic and harmless. But in today's new electronic midway, the injury to the elderly is great indeed. Their savings can be lost and their health harmed. And, of course, this electronic midway does not travel to Bangor, Maine one week and to another town the next; it can be in every state and every city every day and night of the week. Thank you for accepting this testimony. My office will be glad to give you greater details on any Maine law or education project designed to help the elderly fend off consumer fraud.

Mr. BILL HALAMANDARIS. Thank you, Mr. McKenna.

You may have noticed Chairman Borski had to go make a vote.

Mr. Wortley is on his way back here and had a couple of questions he would like to ask.

In the meantime, maybe I can indulge a fantasy and ask you a couple of questions myself.

Starting with Mr. McKenna, I like the electronic midway concept. That is a very visual way of stating what clearly is the problem.

I acknowledge the suggestion you made about what needs be done to address the problem in that form.

One of the problems in general we are concerned about is how do we encourage more States to do basically what Maine is doing? There are a number of States that are not nearly as active as you are. What can be done? what kind of support do they need?

Mr. MCKENNA. Well, the National Association of Attorneys generally does hold consumer conventions every year. The last one was held in Boston. I noticed the FDA was not there. At least I didn't see them.

I would think the Federal Government should become much more involved in meeting with the States and saying, "Look, there is a good idea going on in this part of the country. You can promote it in your part of the country."

One of the suggestions made earlier today was that all medicines come with a label on them that says it is approved or not approved by the FDA. But, once you get the bottle, you have already bought it.

I think a much more effective way would be to have every ad displayed today before the committee to have a label on it. That label would say the medicine is approved or not approved by the FDA. Newspaper editors then would be able to look at these ads and decide whether they are going to run an ad for a medicine that does not have a label.

Mr. BILL HALAMANDARIS. You are saying the product should be label approved or not by the FDA.

Mr. MCKENNA. Yes. Newspaper editors need some ready handle with which to winnow out the ads that are clearly deceptive. That might be one way of doing it.

Mr. BILL HALAMANDARIS. One other area. You mentioned that Maine is having increasing difficulty with solicitations from out of State.

Give me an example of what you mean.

Mr. MCKENNA. Well, as I tried to express—and I go into further detail in our written material—I cannot comment on the name of the company we are currently in negotiation with, but we have noticed that more and more of these medical foundations are springing up which are soliciting money in order to promote research, such as research into nutritional cures for common diseases.

The brochures are wonderfully designed. It comes to your home. It seems to know whether you are a woman or a man. It picks on women if it is a woman's disease. It looks quite sophisticated, and it comes from a quite sophisticated sounding research institute.

What these people are, they are not experts in medicine; they are experts in mail solicitations and computer-generated mailing lists. We are trying to stop them through our solicitation law. We are going to require them to reveal in their brochure if less than 70 percent of the money is going to the charity and typically 70 to 80 percent of the money is going to fund-raising.

Mr. BILL HALAMANDARIS. So it is a specific disclaimer. If something less than 70 percent is being directed to charity, they have to say "We are not doing what you want us to do."

Mr. MCKENNA. Yes; I think we would be satisfied if their brochure probably mentioned the percentage of the money going to charity, to research, to education, et cetera. I think that would stop a lot of the contributions.

Mr. BILL HALAMANDARIS. This is different than a financial statement.

Mr. MCKENNA. Yes.

Mr. BILL HALAMANDARIS. Mr. Wortley has returned.

Mr. WORTLEY. Thank you.

Dr. Nightingale, a little while ago Clinton Miller of the National Health Federation said that laetrile was readily available and was legal. I think you take issue with him. Could you site for us the law that affects this, so we can get this squared away? What is the number of the statute?

Mr. SHUMATE. We consider it to be a new drug, when claimed for medical purposes, so we would charge 505 of the act. Section 505. But I think there needs to be a little clarification here. This has gone to the Supreme Court and back to the district court, and was finally terminated, and we thought we were through with laetrile.

Just this week the order was vacated and fully put back in effect in an affidavit system, so people in this country can receive laetrile under an affidavit system set up by court order.

It would not be legal unless we were under court order.

Mr. WORTLEY. I would like to ask each of the agency representatives here—Ms. Crawford, Dr. Nightingale, Mr. Nelson—if you think there is enough statutory enforcement authority today to combat quackery?

Let's start with Ms. Crawford.

Ms. CRAWFORD. Well, again, our statutory mandate goes well beyond quackery. Our mandate is to police and prevent unfair or deceptive acts or practices.

Quackery is, we believe, one of the more egregious forms of deception that is particularly harmful, particularly to older Americans. I believe that we have the necessary weapons. I think that in the last 2½ years, since this administration has been at the Commission, the Commission has shown a greater interest in these problems.

I also think we have been more effective in targeting our resources on this specific kind of problem. I should point out again that many of our critics consider these problems to be fringe claims. For example, we have been criticized by some as looking at laser face lifts or at some health cases involving an energizing claim.

We believe these are not fringe claims; that they are in fact the kinds of deceptive claims that have great potential to do serious harm, in particular, to older Americans.

Moreover, I do think that we have been able to use our remedial authority in more innovative ways which have allowed us to be more effective in going after these problems.

Mr. WORTLEY. Do you folks ever get together and discuss this problem among yourselves, or does everybody do a solo performance?

Ms. CRAWFORD. No, we do not do sole performances. We have continuing working relationships with both the FDA and with the Postal Service. On a case by case basis, we work very closely with the Justice Department and with State law enforcement officials. That has been—I believe you had gone to your vote when I mentioned this earlier—I believe, from our experience, a very important part of the effort to address this problem; that it is not going to be solved by one Federal agency. A concerted effort on the part of all the Federal agencies along with State enforcement agencies, and State boards and professional associations is needed.

I think it requires a very broad-based effort.

We definitely have worked very closely on that.

Mr. WORTLEY. Thank you.

Dr. Nightingale.

Dr. NIGHTINGALE. I would second that. Indeed, we are in very close contact.

It is mostly on an ad hoc basis, depending on what the particular health fraud is.

We probably could become more involved with some of the State agencies. One attempt to do this is our involvement in the upcoming workshop in June of the National Organization of State Consumer Agencies.

Also there was mention of the State attorneys general meeting. We would like to try to become more involved with them.

Mr. WORTLEY. Mr. Nelson.

Mr. NELSON. I assume that you are directing the statutory authority to our ability to investigate. I think from that standpoint I would have to say that it is adequate.

Of course, there are always ways you can improve it.

Mr. WORTLEY. What are your suggestions for improvement?

Mr. NELSON. What I was going to address next is something I alluded to I guess in my testimony, and certainly in the lengthy testimony.

I think Mr. Braswell testified he was making a million dollars a month, maybe \$75 million during his career, something like that, and you have a mail fraud statute that was enacted a hundred years ago, many, many years back. And you have courts that generally do not give first offenders incarceration sentences. And a thousand dollars fine for a plea of guilty to one mail fraud count for somebody who has made hundreds of thousands of dollars, or millions of dollars, if that be the case, isn't much of a deterrent. That is one thing that this subcommittee might possibly want to look at.

Mr. WORTLEY. It is only a drop in the bucket.

Mr. NELSON. Absolutely. A very small drop.

Mr. WORTLEY. How big a force do you have looking into fraud?

Mr. NELSON. We have about 1,900 inspectors, give or take, 20 or 30 at any one time. We would have 425, 430 inspectors involved in mail fraud investigations.

Now, they will not all be working on it, but what I am saying is, the total resources would equate to about 425 or 430 individuals.

Mr. WORTLEY. I missed your testimony, unfortunately. Did you state in that how many claims or how many people file a complaint about medical quackery with you in the course of a year?

Mr. NELSON. On medical quackery, I don't know if I can give you a firm figure. I would take a very ballpark guess and say 50,000 to 60,000. We get in excess of 200,000 fraud complaints yearly. That is probably optimistic.

Mr. WORTLEY. How long does it take from the time a person files a complaint until somebody gets detailed to investigate it?

Mr. NELSON. That depends on the case. Medical fraud and frauds against the elderly are what we categorize as category 1 investigations. We give those immediate attention. If it is something lesser, say a complaint with a real estate type fraud or something like that, they probably will not get attention as fast.

But on those that we are talking about today, it is promptly.

Mr. BRASWELL. May I ask a question?

Mr. WORTLEY. Do you folks at the other Federal agencies actually receive complaints or do you initiate your own investigations?

Mr. SHUMATE. I would say for FDA we receive complaints from many different sources, from citizens, by our own surveillance, by counterpart officials. Many different means, and we too, as the Post Office, will follow up on those depending upon the nature of the violations.

If it is a violation that represents a danger to health, somebody could be injured, we would probably go by injunction, if we think it is going to continue, unless we can stop it by some other means. So we have to set priorities as well.

Mr. WORTLEY. Are most of your investigations prompted by complaints or are they self-initiated?

Mr. SHUMATE. I really don't know precisely. We do maintain pretty good surveillance over what is going on in our respective areas.

I would say we mostly do our own.

Mr. WORTLEY. Ms. Crawford.

Ms. CRAWFORD. We also have both means of detecting these problems. We have a systematic monitoring effort that, which, as I mentioned, covers the major media nationwide, both print and broadcast.

In addition, we have expanded that monitoring effort to include the media where we are more likely to find quackery claims. For example, we monitor many health care publications and other specialized publications, where we are likely to find many of these advertisements.

But I think the committee should not underestimate the importance of what I think of as tips.

Individual consumer complaints are important. But also important is information we receive from professional associations and from competitors, who in many cases are in the best position to know that a product simply cannot produce the results that it is claiming.

Tips are a very good source of leads for us in the advertising area. But I think I would concur in the comments of the other agencies, it is a dual program that consists both of outside information coming in and our own monitoring efforts.

Mr. WORTLEY. Of your overall caseload, how many would be problems for the elderly?

Ms. CRAWFORD. Among our deception cases?

Mr. WORTLEY. Yes.

Ms. CRAWFORD. My statement lists a whole range of activities we have been involved in. Not all are health care cases.

I have tried to give a sense of the way in which we have approached deception in claims, marketing and advertising claims that are particular problems for older Americans.

If you narrow that to the health care claims, it is hard to distinguish because we don't specifically say that we are going to target a health care problem for the elderly.

For example, the two cases we have brought that are directed at anyone concerned about cancer, presumably given the overall statistics about concern of older people for health, and the amount of health dollars that are spent by the older people, we are assuming that these cases will a greatly benefit and help protect older Americans.

Another similar example, is a consent order we reached with a company called Estee, a producer of products for diabetics. That order settles allegations that there were deceptive claims about the content of the diabetic products.

We also have had under investigation other health related claims—for example, claims about medicare as eligibility for orthopedic devices, wheelchairs, et cetera.

There is a very broad range of cases that would affect the elderly.

Mr. WORTLEY. In the Postal Service in 1982 I understand you investigated 79 cases that involved health products, and FDA, recommended 29 cases for legal action in 1982 that was up about 250 percent by 1983 when we had 74 cases that were recommended for action. It is gratifying to know that our enforcement agencies are out there protecting the elderly.

I yield back the balance of my time.

Mr. BORSKI. I have one final question that I would like to ask Mr. Nelson, Dr. Nightingale.

We heard a lot of testimony this morning concerning organized quackery, involving a number of practitioners and clinics.

What authority do you have to control these kinds of activities and what can we in Congress do to help you do your job better?

Mr. NELSON. From the Postal Service standpoint, we would really have no authority unless there was some use of the mails in advertising their product or in sending their product, and there were misrepresentations made.

Mr. WORTLEY. Dr. Nightingale.

Dr. NIGHTINGALE. We have rather extensive authority in this area, spread throughout the acts we administer, as we stated in our response to the committee's earlier survey questions on this topic. We feel that our new efforts in terms of increased educational activities and new instructions to the field in terms of reporting and developing cases will be quite effective.

Mr. BORSKI. Ms. Crawford.

Ms. CRAWFORD. The advertising or marketing of deceptive health care goods or services is really not treated any differently then

other forms of marketing and advertising. I believe we currently have under investigation, cases in which a clinical setting is involved, and I believe it has not posed any particular difficulties for us.

Mr. BORSKI. OK. Thank you very much. If there are no other questions, I want to again thank our witnesses for testifying and for your patience. It has been a long hearing.

[Whereupon, at 3:55 p.m., the hearing was adjourned.]

APPENDIX 1

(Responses to written questions submitted by the Subcommittee on Health and Long-Term Care)



AMERICAN MEDICAL ASSOCIATION

535 NORTH DEARBORN STREET • CHICAGO, ILLINOIS 60610 • PHONE (312) 751-6000 • TWX 910-221-0300

JAMES H. SAMMONS, M.D.
Executive Vice President
(751-6200)

May 30, 1984

The Honorable Claude Pepper
Chairman
Subcommittee on Health and Long-Term Care
Select Committee on Aging
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Pepper:

The American Medical Association takes this opportunity to respond to your correspondence in which you set forth a number of questions concerning the problem of health fraud, commonly referred to as medical quackery. Below I have restated the questions along with our answers.

1. How do cases/complaints concerning medical quackery come to the attention of your office?

We receive questions and complaints concerning health fraud by telephone and by letter from physicians, other health professionals and members of the public.

2. What office within your organization is responsible for responding to complaints of medical quackery?

The AMA Division of Library and Archival Services, the AMA Department of Physician Credentials and Qualifications, and the AMA Office of General Counsel are the areas within the Association primarily responsible for responding to complaints concerning health fraud.

3. What action does your office take on such complaints?

We routinely refer serious allegations of health fraud to the postal authorities, state boards of medical examiners and consumer protection divisions of the state Attorney General's office as appropriate. In addition, if the complaint concerns a direct AMA

member, our policy is to revoke the membership of any physician who is determined to have committed health fraud. If the complaint involves a physician who is not a direct AMA member, we will refer the complaint to the appropriate state or local medical society or state medical licensing board.

4. How many cases/complaints of medical quackery were received by your office in 1982? In 1983? How many of these cases/complaints involved victims over the age of 65?

In 1982, the AMA received 870 inquiries or complaints concerning health fraud. In 1983, we received 714 inquiries or complaints. We do not have a breakdown concerning how many inquiries and complaints were from persons over age 65.

5. Please provide examples indicative of typical cases/complaints which are likely to come to your attention.

We have attached a list of the most common health fraud inquiries we receive.

6. What features distinguish conventional diagnostic techniques and treatment modalities from those termed "alternative methods"?

The overriding difference between conventional diagnostic techniques and treatment modalities and so-called "alternative methods" is that the former are based on sound scientific evidence as to safety and effectiveness while the latter frequently are not.

7. Are there any major differences in the manner in which conventional methods are promoted as opposed to alternative methods? Please describe the difference.

Alternative methods often are promoted through the use of newspaper advertisements, advertising brochures, and direct mail advertising. Conventional methods rarely are promoted through these means.

8. Do you believe that medical frauds promoted through the mails are increasing?

We have no information to indicate whether or not health frauds promoted through the mails are increasing.

9. What does your organization see as its role in the medical quackery area?

The primary role of the AMA in combatting health fraud is through education of the public and the profession concerning questionable medical practices. As noted

above, the AMA also plays an important role in referring persons with complaints about health fraud to the appropriate government agency. Finally, we believe we play a key role in policing the ranks of AMA members. Our policy is to deny direct membership to or revoke the membership of any physician who is a direct member and is determined to have committed health fraud.

10. Please describe any formal and informal relationships between your organization and agencies or other organizations concerned with this issue.

In our efforts to educate the public concerning health fraud, we have established informal relationships with a number of groups including the American Cancer Society, the American Lung Association, the Multiple Sclerosis Foundation and the Better Business Bureau.

11. In your opinion, is Federal law currently adequate to address these problems? If not, please discuss any suggestions you have to improve enforcement efforts and prevent medical quackery crimes against the elderly.

We believe changes should be made in federal law that would allow appropriate governmental agencies greater power and funding to fight health fraud. For example, we believe that the Food, Drug and Cosmetic Act should be amended to grant the Food and Drug Administration (FDA) the authority to regulate vitamin-mineral and dietary supplements as over-the-counter drugs. Such action could save the American people millions of dollars a year which otherwise will be spent on products whose safety and efficacy have never been demonstrated.

We also recommend that Congress carefully oversee the activities of the Federal Trade Commission and the FDA to ensure that the agencies are allocating sufficient resources to deal with health fraud issue.

12. Would you be willing to testify before the Subcommittee relative to the activities of your organization in this area?

The AMA will be pleased to testify before the Health and Long-Term Care Subcommittee concerning our activities in this area.

If we can be of any further assistance, please let us know.

Sincerely,

James H. Sammons, M.D.

James H. Sammons, M.D.

Most Common Inquiries Regarding Health Fraud

- Age prevention - including:
 - Gerovital
- Allergies - including:
 - Cytotoxic diagnostic testing
 - Yeast theory of etiology
- Arthritis Inquiries - including:
 - DMSO
 - Rheumatoid Arthritis Foundation
- Baldness remedies - including:
 - Massage
 - Hair transplantation
 - Creams and lotions
- Cancer therapies - including:
 - Immunoaugmentative therapy from the Bahamas
 - Laetrile
 - Gerson's treatment - Coffee enemas
 - Livingston - Wheeler Vaccine therapy
 - American Institute for Cancer Research
 - Antineoplastic therapy
 - Greek Cancer Cure
- Cardiovascular Disease therapy - including:
 - Chelation therapy
- Chronic Pain therapies - including:
 - Acupuncture
 - DMSO
- Empesyma therapy - including:
 - Glomectomy
- Gastrointestinal therapy - including:
 - Colonic irrigation
- Multiple Sclerosis therapies - including:
 - Snake Venom
 - Laetrile
 - Metabolic Diets
- Nutrition - including:
 - Bee pollen
 - Megavitamin therapy
- Posture - including:
 - Alexander Technique
 - Rolfing

The General topic, "Quackery":

1. How to recognize fringe practitioners.
2. Who to complain to about a questionable practice.

Systems of Practice - including:

Homeopathy
Faith Healing
Reflexology
Naprapathy
Naturapathy
Iridology
Kinesiology
Herbology

1447p



COUNCIL OF BETTER BUSINESS BUREAUS, INC.

INTERNATIONAL ASSEMBLY OF BETTER BUSINESS BUREAUS

WILLIAM H. JANKERSLEY
President

MAY 31 1984

May 25, 1984

The Honorable Claude Pepper
United States House of Representatives
Washington, DC 20515

Dear Congressman Pepper:

We welcome the opportunity to share with the House Select Committee on Aging the experience of the Council of Better Business Bureaus, and the Better Business Bureaus network, in the area of medical and health-related mail order frauds.

Our responses to your questions are attached.

In addition to the general Better Business Bureaus activities referred to in the attachment, we have published two booklets that may be of interest to you -- 1) "Consumer Problems of the Elderly, and 2) "Tips on Choosing a Long-Term Care Facility." Our educational efforts have also included alerts to consumers on the following subjects: health insurance, medical quackery, medicare/medicaid, supplemental insurance, senior citizen insurance fraud, fad diets, miracle drugs, quick weight-loss gimmicks, starch blocker diet pills and body wraps. We have addressed these subjects in our weekly radio interview program and in radio public service announcements.

In December 1983, the Council sponsored a Forum on "The Older Consumer -- Today's Marketplace Challenge" in which the needs and behavior of older consumers, and marketplace responses to those needs, were examined. A Forum summary is enclosed. The Forum was an immense success, evidence of the interest in the concerns of older consumers, only one of which is health. We will continue our efforts in this arena and will advise you of programs we undertake in the future.

On May 31, a representative from our Philanthropic Advisory Service Division (PAS) will give testimony to the Committee on Council of Better Business Bureaus standards for charitable solicitations, and on PAS experience with specific charitable organizations.

We hope that testimony and the information provided herewith prove helpful.

Sincerely,

Enclosures

NATIONAL HEADQUARTERS • 1515 WILSON BOULEVARD • ARLINGTON, VIRGINIA 22209 • (703) 276-0100

RESPONSES TO QUESTIONS FROM REPRESENTATIVE PEPPER
RELATING TO MEDICAL QUACKERY

BY
WILLIAM H. TANKERSLEY, PRESIDENT
COUNCIL OF BETTER BUSINESS BUREAUS

1) How do cases/complaints concerning medical quackery come to the attention of your office?

Most such matters are reported directly to local Better Business Bureaus by the general public.

2) What office within your organization is responsible for responding to the complaints of medical quackery?

Each local Better Business Bureau would designate a staff member, or department, to respond to complaints of this nature. The Division of Industry Standards of the Council of Better Business Bureaus handles complaints in parts of the country in which there are local BBBs.

3) What action does your office take on such complaints?

In most instances these matters are brought to the attention of appropriate law enforcement agencies, such as the U.S. Postal Service or the Food and Drug Administration. In cases where a violation of law does not appear to be involved, the Bureau would communicate with the company on the consumer's behalf. For example, the Bureau would correspond with a mail order firm in an effort to receive a refund for an ineffective health product ordered through the mail.

4) How many cases/complaints of medical quackery were received by your office in 1982? In 1983? How many of these cases/complaints involved victims over the age of 65?

The CBBB statistical summary does not contain a discrete category for complaints alleging medical quackery. Complaints of this nature would be included in the "Miscellaneous Health & Personal Improvement" category. Please refer to the enclosed Better Business Bureau Inquiries and Complaints Statistical Summary of 1982 data, pp. 11 and 13.

	1981	1982	1983
Complaints	4,345	3,981	3,846
Inquiries	54,388	60,161	52,193

Some complaints of this type may also be included in the category "General Mail Order," as many medical quackery sales are made via the mails.

We cannot provide you with data regarding the age of complainants as Better Business Bureaus do not request this or any other type of demographic information for consumers, except for occasional surveys. (Enclosed please find a copy of a recent survey on BBB services and the elderly.)

5) Please provide examples indicative of typical cases/complaints which are likely to come to your attention.

Typical complaints include objections to receipt of unsolicited material through the mails for sexual performance aids; dissatisfaction with performance of health related products, such as nutritional supplements, or complaints related to mail order weight loss offers or bust developer products.

6) What features distinguish the conventional diagnostic techniques and treatment modalities from those termed "Alternative Methods?"

7) Are there any major differences in the manner in which conventional methods are promoted as opposed to alternative methods? Please describe the differences.

(Answer to 6 & 7)

The Better Business Bureau is not qualified to discuss or review issues relating to treatment or diagnosis of medical conditions. However, BBB experience indicates that offers for questionable health products or treatments often rely on nebulous language, utilize unverifiable testimonials, promise "miracle" cures for serious diseases and often offer drastic or immediate results. Offers for weight loss products often promise results with little emphasis on dietary restriction or exercise, for example.

8) Do you believe that medical frauds promoted through the mails are increasing?

Our statistical data is insufficient in this area to track any trends, however, practical experience would seem to indicate it is not diminishing. Although complaint activity in the "Health and Personal Improvement" category (see question #4) decreased slightly between 1981 and 1983, the "General Mail Order" category no doubt includes other complaints of this nature.

9) What does your organization see as its role in the medical quackery area?

Our role is primarily educational. The Better Business Bureau places great emphasis on providing information to the consumer before the sale. As you will note from the enclosed inquiry and complaint statistics, requests for information significantly outweigh requests for complaint assistance. The general public contacts local BBBs millions of times every year for impartial, factual information on which to make sound buying decisions. In no case is this quest for information more important than in the area of health quackery. While the dollar amount involved in these transactions is not always large, the risk of injury from an unsafe product, or the delay in receiving conventional treatment, make this a high priority concern.

The Council and its 160 local Better Business Bureaus provides information on specific companies and offers, as well as general precautionary advice on a wide variety of schemes and promotions. Each year the system disseminates thousand of tip booklets and fact sheets. A new Tips booklet on health quackery is currently being developed and will be available to the public in late Spring, through any local BBB.

Another important facet of educational activities by the BBB system involves working with media and advertisers in creating accurate and truthful advertising. Advertising clearance personnel, in both print and broadcast media, regularly contact local Better Business Bureaus, the Council's Division of Industry Standards and the National Advertising Division of the Council to obtain information on potential advertisers and to seek guidance in preparing copy that is in compliance with Federal Trade Commission and Better Business Bureau guidelines.

10) Please describe any formal and informal relationships between your organization and agencies or other organizations concerned with this issue.

The Better Business Bureau system, both at the national level and at local Bureau level, works with law enforcement agencies on an ongoing basis. In most instances these contacts are initiated by the Bureau, usually upon receipt of a complaint or inquiry related to activities of the Postal Inspection Service of the Food and Drug Administration (for health quackery matters). These contacts are not usually a part of a formal program, but rather on an as-need-arises basis.

11) In your opinion, is Federal law currently adequate to address these problems? If not, please discuss any suggestions you have to improve enforcement efforts and prevent medical quackery crimes against the elderly.

We are not convinced of a need for additional legislation to address health quackery. More enforcement activity of existing laws could prove more valuable than any new laws. In our experience many advertisers or promoters of these scams utilize small "back of book" advertisements or relatively small mailing lists, and this modest approach may make enforcement activities seem non cost effective. However, the cumulative effect of these fraudulent activities is probably far greater than the sum of the individual participants in terms of loss to the victims. Increased prosecutions of these fraudulent operators could well be the greatest deterrent to crimes of this nature.

12) Would you be willing to testify before the Subcommittee relative to the activities of your organization in this area?

I am not certain we have sufficient expertise or documentation to warrant this.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

MAY 21 1990

National Institute of Arthritis,
Diabetes, and Digestive and
Kidney Diseases
Bethesda, Maryland 20205
Building: 31
Room : 9A52
(301) 496-5877

The Honorable Claude Pepper
Chairman, Subcommittee on
Health and Long-Term Care
Select Committee on Aging
House of Representatives
Washington, D.C. 20515

MAY 30 1990

Dear Mr. Pepper:

Thank you for your letter requesting information on the role of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) in combating fraud due to medical quackery directed towards arthritis patients, particularly the elderly.

As you know, NIADDK leads and coordinates the national biomedical research effort in all forms of arthritis, their underlying causes and effective diagnosis, treatment and prevention. NIADDK encourages the dissemination of the results of research, including that which evaluates potential arthritis treatments. We are not specifically mandated to combat unproven therapies and believe these activities are best left to such regulatory agencies as the Food and Drug Administration and to the private sector, such as the Arthritis Foundation and their professional section, the American Rheumatism Association. However, some of our work does touch upon the area of quackery and unproven remedies, and we have described these efforts in the enclosed pages, in response to your specific questions.

Should you or your staff director, Mr. Bill Halamandaris, have any additional questions concerning quackery and unproven remedies or concerning any area of arthritis research, I would suggest that you contact Dr. Lawrence Shulman, Director of the NIADDK Division of Arthritis, Musculoskeletal and Skin Diseases. Dr. Shulman would be happy to assist you in any way possible; his phone number is (301) 496-4353.

I hope you find the enclosed responses helpful. Again, please let us know if we can provide additional information or be of any other assistance.

Sincerely yours,

Lester B. Salans, M.D.
Director

Enclosure

RESPONSES BY THE NATIONAL INSTITUTE OF ARTHRITIS, DIABETES,
AND DIGESTIVE AND KIDNEY DISEASES (NIADDK) TO LETTER
OF CONGRESSMAN CLAUDE PEPPER

- 1) How do cases/complaints concerning medical quackery come to the attention of NIADDK?

Generally cases concerning medical quackery or unproven remedies for arthritis are brought to the attention of the Institute in the form of written or telephone requests for information from the public, including patients, reporters and Congressional offices, and health professionals. Sometimes the requestor wants to know if a method is legitimate, or he or she may believe a certain unproven method is legitimate and wishes to bring it to our attention or obtain research support to further evaluate it. Thus, these inquiries are not necessarily complaints.

- 2) What office within NIADDK is responsible for responding to complaints of medical quackery?

The NIADDK Office of Health Research Reports answers inquiries and publishes and distributes articles, pamphlets, and reports describing the various research areas of the Institute. Of the large volume received, occasional inquiries concern unproven methods of treatment for arthritis.

In addition, there are other NIADDK components whose work, in part, touches upon the area of quackery and unproven remedies as well.

For example, the NIADDK-supported Arthritis Information Clearinghouse was established by the Institute in response to recommendations of the congressionally-mandated National Commission on Arthritis and Related Musculoskeletal Diseases. The Clearinghouse serves health professionals by identifying printed and audiovisual materials on arthritis and related disorders. Its services include publishing bibliographies and catalogs and conducting searches of its database on diverse arthritis-related subjects, including unproven remedies as well as established treatments. Health professionals not fully acquainted with appropriate arthritis therapies can thus locate materials that describe established therapies.

There is also a congressionally established NIADDK Multipurpose Arthritis Centers Program through which 18 centers across the country engage in: biomedical research; professional, patient, and public education; and health services research and community demonstration programs. One of the many goals of the Centers program is education "to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment and control methods and unapproved and ineffective drugs and devices." Arthritis information and education efforts for patients and the public include formal classes and seminars, as well as individual patient instruction, that encourage self-help and awareness. Other educational efforts that can help dispel misinformation include Center participation in local health fairs, public presentations by Center scientists, and cooperation with local Arthritis Foundation chapters.

The Centers have a few small projects related to education in arthritis treatment. The Center at Stanford University in California has developed and is evaluating a model patient education program to help patients deal with their disease. Part of the program describes approved remedies and the dangers of unproven remedies, as well as self-evaluation of these remedies. This self-help program has been adopted on a nationwide scale by the Arthritis Foundation.

The Center at Downstate Medical Center in Brooklyn, New York, has a project looking at how patients of different ethnic backgrounds (especially Hispanic and Black) interact with the health care system in order to improve compliance with established therapies (and thereby reduce reliance on unproven remedies).

- 3) What authority does this office have to take action on such complaints?

NIADDK has no authority to take action on complaints concerning unproven remedies. However, as described in the answer to Question #17, we do try to work with the Food and Drug Administration, the Arthritis Foundation, and other groups who are in a position to act on such complaints.

- 4) What was the budget of this office in 1982? 1983?
5) How many full-time employees (FTE's) are assigned to this office? How many professionals? How many clerical?

We are unable to offer accurate budget or personnel figures as it is not possible to determine the proportion of effort devoted to information about unproven arthritis remedies by the NIADDK Office of Health Research Reports. This is only one of many areas of information covered by the office.

- 6) How many cases/complaints of medical quackery were brought to the attention of this office in 1982? 1983?

Inquiries that mention unconventional therapies in arthritis are probably on the order of a few hundred per year, out of a total of approximately 15,000 inquiries answered per year by the NIADDK Office of Health Research Reports. Inquiries on unconventional arthritis therapies may not be complaints per se. People often ask whether a remedy is legitimate or describe a remedy they already believe is legitimate.

- 7) How many of these cases/complaints involved victims over the age of 65?

People who bring unproven remedies to our attention do not necessarily mention their age. However, we expect that a significant portion of them are over 65, as arthritis afflicts a great many of the elderly.

- 8) What was the disposition, by category, of cases/complaints involving medical quackery in 1982? 1983?

Generally people who inquire about unproven remedies are given information about what established therapies are available for their arthritis and, whenever possible, statements from the Arthritis Foundation and sometimes the Food and Drug Administration or other agencies concerning the remedy.

- 9) Please describe examples of typical cases/complaints which are likely to come to your attention.

Topics of inquiries concerning unproven remedies include: special diets, food supplements and vitamins, special clinics, ointments, and devices such as copper bracelets and polarity pillows.

- 10) What features distinguish conventional diagnostic techniques and treatment modalities from those termed "alternative methods?"

In the case of drugs, conventional treatments involve those approved by the FDA following a series of basic, animal and clinical investigations which have proven them to be safe and effective for treatment of arthritis. Generally, conventional diagnostic and treatment modalities are those developed through years of research and experience with patients.

As for alternative methods, the Arthritis Foundation describes these features:

- The method offers a "cure."
 - The remedy is described as an "exclusive," "special," or "secret" formula or device.
 - Testimonials and case histories of patient successes are offered as proof.
 - The method is described in sensationalized articles in the popular press (including supermarket tabloids and special health interest publications) or advertised through magazines or special mailings.
 - The method offers quick, simple pain relief.
 - Promoters may claim it rids the body of toxins.
 - Drugs and surgery are described as damaging, dangerous, and unnecessary.
 - No reliable evidence or scientific proof is offered.
 - Special nutritional therapy is promoted.
 - The "medical establishment" is accused of conspiracy.
- 11) Describe the approach taken by the Institute in its drug development program.

NIADDK does not have a specific program designed to develop arthritis drugs or other forms of arthritis therapy. We do support research investigations of drugs and other therapies for arthritis. Generally, these projects are investigator-initiated, that is, the researcher has the idea, and applies to NIH for research support. Examples

are studies of retinoids for experimentally-induced arthritis, of removal of inflamed joint tissue by radiochemical methods rather than surgery, and of modified forms of corticosteroids. Some NIADDK-supported work is done under contract or cooperative agreement. An example of a contract-supported project is the Cooperative Systematic Studies in the Rheumatic Diseases, in which several centers are coordinated to carry out clinical trials of therapies for rheumatic diseases, such as methotrexate for psoriatic arthritis or oral gold therapy for rheumatoid arthritis.

- 12) Are there any major differences in the manner in which conventional methods are promoted as opposed to alternative methods?

NIH does not promote any particular therapeutic approaches. The results of research studies are published in peer-reviewed journals and presented for open comment at scientific and technical conferences. As these results become widely accepted by the medical profession, established methodologies are presented in review articles and textbooks, as well as guidelines for treatment prepared by professional organizations. Drug manufacturers generally promote arthritis medications to the medical profession through advertisements in journals, exhibits at medical meetings, and special mailings to doctors. In the past few years, these companies have begun to promote new drugs directly to the public as well as to physicians.

Information about "new" arthritis therapies, whether conventional or unproven, is disseminated to the public via television, newspapers, magazines, radio, friends and relatives, and books. Unproven remedies are also promoted to patients by advertising in mass market tabloids and health publications and by direct mail.

- 13) How does the Institute become aware of alternative therapies? How do you respond?

The Institute becomes aware of alternative therapies through: inquiries we receive from patients, reporters or Congressional offices; materials sent to us by the Arthritis Foundation; and the media, such as newspapers, magazines, radio, and television. We generally respond by providing information to answer specific questions.

- 14) Please cite some examples of alternative approaches to diagnosis and treatment and your evaluation of their efficacy.

Examples of alternative approaches to arthritis are listed under question 9. Generally, NIADDK is not in a position to evaluate or judge any particular form of therapy. Rather, we rely on the judgments of Federal agencies, such as the Food and Drug Administration, or private nonprofit national organizations, such as the Arthritis Foundation.

- 15) Do you believe that medical frauds promoted through the mails are increasing?

It is possible, but we do not have sufficient information to judge this.

- 16) What does the Institute see as its role in the medical quackery area?

The Institute does not have specific authority to judge or intervene in the area of medical quackery. Our primary role is to foster and support basic and clinical biomedical research that expands our understanding of the underlying causes of arthritis and that develops improved methods of diagnosis, treatment, and prevention.

- 17) Please describe any formal and informal relationships between your office and other agencies concerned with this issue.

NIADDK works closely with at least three other organizations concerned with appropriate arthritis treatment.

The National Arthritis Advisory Board (NAAB) is an independent Federal advisory board mandated to review and make recommendations concerning national efforts in arthritis. One of several areas of NAAB concern is that of education, including the strengthening of education for patients and health professionals.

In addition, last summer, NIADDK formally requested that NAAB review antimycoplasma therapy for rheumatoid arthritis, a form of therapy that has a great deal of public and congressional interest. Their review and recommendations were used by NIADDK in reporting to the Congress on this therapy.

The Arthritis Foundation, a private, national, voluntary organization, has maintained for several years a strong program against arthritis quackery and has taken the lead in this area. The Foundation has developed numerous activities, including public information programs and an investigative committee, for combating quackery and unproven remedies. The Institute has been cooperative with and supportive of the Foundation in these activities, and there is active sharing of information between the two organizations.

We also work, primarily on an informal basis, with the Food and Drug Administration, our sister agency that is charged with the approval of safe and efficacious drugs and devices. The FDA can provide us with information on a given remedy and occasionally NIADDK-supported research contributes to the evaluation and approval of a therapy. The FDA is also represented on the NIADDK-led Arthritis Interagency Coordinating Committee.

- 18) In your opinion, is Federal law currently adequate to address these problems? If not, please discuss any suggestions you have to improve enforcement efforts and prevent medical quackery crimes against the elderly.

NIADDK's expertise and role is in the arena of biomedical research. We are not fully cognizant of existing Federal legislation regarding medical quackery and do not have any specific suggestions on improvements that might be made. However, other parts of the Department of Health and Human Services do have expertise and a role in the control and prevention of medical quackery. We feel this question would be more properly directed to the Department.

- 19) Would you be willing to testify before the Subcommittee relative to the activities of your office in this area?

Requests for appropriate witnesses in the area of quackery should be directed to the Department of Health and Human Services for consideration.

Appendix 2

(Submitted for the record by Stuart L. Nightingale, M.D., Associate Commissioner for Health Affairs, Food and Drug Administration)

STUART L. NIGHTINGALE, M.D., and FRANK D. ARNOLD, Ph.D.

How Laetrile Laws Affect MDs

Physicians are put on the spot as an unproved cancer regimen wins 'approval' in 17 states and is pushed in others

MUCH has been written about laetrile in both the lay press and medical journals over the past several years. While very little differentiates the issues surrounding laetrile from those of various other quack cancer cures and unproven remedies during this century, the passage of laws by a number of states does set this substance apart from other highly touted remedies of the past.

This substance has been given an implied stamp of approval by state legislative bodies in approximately one-third of the states. These acts and the publicity generated at hearings tend to create, in the public's mind, the view that laetrile is either effective, almost proven effective, or is at least respectable enough to warrant a trial. Diversion of cancer patients from appropriate therapy, either initially or during a course of such therapy, is an important consequence of such legislation.

Since physicians and other health care providers are the ones who are pressured to prescribe, administer, or dispense laetrile, it behooves them to learn the exact language of their state law and to seek legal counsel regarding its implications. We will attempt to examine the kinds of state laetrile laws that exist, highlight their diversity, and discuss some of the problems that have arisen from them. No attempt will be made to analyze any specific state laws.

At the outset, it should be noted that under federal law, laetrile is still an unapproved new drug that cannot be shipped in interstate commerce unless an exemption as an investigational drug has been granted. Passage of state laws does not protect sponsors, promoters, distributors, dispensers, or sellers of laetrile from applicable civil or criminal sanctions under the federal Food, Drug and Cosmetic Act.

There is currently one limited method by which laetrile can be provided to terminal cancer patients. In the spring of 1977, U.S. District Court Judge Luther Bohanon (sitting in the Western District of Oklahoma) issued several class action orders enjoining the FDA from impeding or preventing the importation and interstate transportation of laetrile for

the personal use of terminally ill cancer patients, provided a practicing physician submits an affidavit attesting to the status of each patient. On appeal of that case, a decision was handed down on July 10, 1978, by the 10th Circuit Court of Appeals that has the effect of outlawing laetrile with one narrow exception: its medically supervised use in the injectable form in patients certified by a physician to be terminally ill. FDA is seeking review of the appellate court's decision in the U.S. Supreme Court.

Current Status of Laetrile Bills and Laws

As of September 1978, 17 states have legalized laetrile at the state level (see Chart I). In 1976, two states saw the introduction of one bill each, but only one of these, Alaska, enacted a statute that year. In 1977, 53 laetrile bills were introduced in 30 states, and 12 were enacted into law. In 1978, so far, such bills have been introduced in 25 states, with four enacting bills into law (see Chart II).

During 1978, however, laetrile bills have been rejected (killed or allowed to die) in 20 states. The states that have rejected laetrile bills in 1978 are listed in Chart III.

Characteristics of Laetrile Bills and Laws

Chart I shows the comparative provisions of the 17 laetrile statutes. In many cases, the bills do not actually legalize laetrile but decriminalize its prescription.

The bills were constructed to afford protection to physicians who prescribe, dispense, or administer laetrile at the request of a patient. In 14 of the 17 states, the laws contain specific prohibitions against disciplinary actions by either the state licensing board or the medical society. None of the laws passed, however, has exempted physicians from any malpractice liability. (Indeed, the malpractice cases that have been brought may have a chilling effect on the use of laetrile in states whether or not a state law legalizing laetrile exists.) In far fewer states (four out of the 17), similar provisions protect pharmacists who dispense laetrile. Interestingly, laetrile is declared to be a nutritional or

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CHART I—Summary of Selected Provisions of Enacted State Legislation Relating to Laetrile

PROVISIONS	ALASKA	ARIZONA	DELAWARE	FLORIDA	IDAHO	ILLINOIS	INDIANA	KANSAS	LOUISIANA	MARYLAND	NEVADA	NEW HAMPSHIRE	NEW JERSEY	OALABAMA	OREGON	TEXAS	WASHINGTON
Protects physicians	no	no	no			no	no	no	no	no	no	no	no				no
Protects pharmacists			no							no		no					
Requires prescription							no	no	no	no		no	no				no
Permits manufacture		no	no			no	no	no	no	no		no	no	no	no	no	no
Includes quality control		no	no			no	no	no	no	no		no	no	no	no	no	no
Designates responsible agency		no	no			no	no		no	no		no	no	no	no		no
Provides assessment of fees for inspecting manufacturer			no				no		no								
Is specific for cancer patients					no			no	no								no
Requires written informed consent or records				no	no	no	no	no	**	no		no	no				no
Written records to be filed and reviewed					no		no					no	no				
Provides for restriction if found harmful by state medical authority	no		no	no					no	no							no
Requires statement of nonapproval		no	no	no		no	no	no		no		no	no				
Declares laetrile not to be a drug		***	no	no			***	***									

*Parenteral form only

**Does not specify written consent

***Declares amygdalin to be a nutritional supplement

dietary supplement or not recognized as a drug in four states.

While the wording of the bills is generally such that patients must request laetrile and also be informed of other (orthodox) therapy, in only slightly more than half the states (nine out of 17) does written informed consent actually have to be obtained.

Of particular interest is the fact that in six out of the 17 states there are provisions for potential "inactivation" of the part of the laetrile law that protects physicians if a specified state authority finds laetrile is unsafe. In none of those six states, however, is laetrile prohibited, pending positive demonstration of safety by such an authority. In Florida, one of the six states with such a provision, a safety hearing before the designated state authority was held, but no conclusion was reached.

While the earliest laetrile laws did not purport to legalize manufacturing, the more recent bills and laws generally contain such provisions. Manufacturing provisions, theoretically, would enable laetrile to be entirely manufactured, distributed, and utilized within state boundaries, potentially avoiding a conflict with the federal Food, Drug and Cosmetic Act. However,

it is highly unlikely that a manufacturer would not run afoul of federal law since, for example, very few states have adequate intrastate sources of amygdalin. For the most part, such laws mandate the development of standards as a prerequisite to state sanctioned intrastate production of laetrile. As of this time, laetrile is not legally available in any state through such authorized production. Three states, Delaware, Kansas, and Nevada, provide for the assessment of fees for inspecting manufacturers.

The terms *laetrile* and *amygdalin* are used interchangeably in many of the state laws. Since there is no set composition for laetrile and amygdalin and much disagreement on their exact chemical identity, it is not surprising that there is confusion at the state level as to what substance is purported to have been legalized under state law. Samples of laetrile and amygdalin imported into this country that have been analyzed vary widely in their identity and composition.

A potential conflict between the laetrile laws and other statutes already enacted in a state (e.g., the state's food and drug law) has been cited by the attorneys general of at least two states that have enacted laetrile laws—Alaska and Florida. Florida's

CHART II—Legislative Actions Taken

	1976	1977	1978
Number of states with introduced laetrile bills	2	30	25
Number of bills introduced	2	53	50
Number of bills passed	1	12	5*
Number of bills killed or not passed	1	41	36
Number of bills still pending	0	—	9

*One state amended a previously enacted laetrile law.

CHART III States Rejecting Laetrile Bills During 1978

State	Reason for Failure to Enact
Alabama	Adjourned—Died in committee
California	Defeated by Senate vote
Florida	Adjourned—Died on the House calendar
Georgia	Adjourned—Died in committee
Hawaii	Adjourned—Died in committee
Illinois	Tabled by House committee
Iowa	Died on the House calendar
Kentucky	Adjourned—Died in committee
Massachusetts	Defeated by House vote
Minnesota	Adjourned—Died in committee
Mississippi	Adjourned—Died in committee
Missouri	Adjourned—Died in committee
Nebraska	Adjourned—Died in committee
New York	Vetted by the governor
Rhode Island	Vetted by the governor
South Dakota	Adjourned—Died in committee
Tennessee	Continues study for one year
Vermont	Adjourned—Died in committee
West Virginia	Adjourned—Died in committee
Wisconsin	Adjourned—Died in committee

laetrile law addresses only the prescription and administration of the drug, not the source. The Florida laetrile law deals with the physician-patient relationship, possibly avoiding a conflict with the state drug statute.

These bills and laws are by no means all laetrile-specific. For example, many of these legalize various other unproven remedies such as enzymes, pseudo-vitamins, rejuvenation products, etc., at the same time. Most of these substances have not undergone adequate and well controlled clinical trials, while others have been under study to determine safety and efficacy. In the case of "Gerovital," an investigational new drug application filed with the FDA was withdrawn by the sponsor concurrent with passage of joint laetrile and "Gerovital" legislation in Nevada. Most of the other substances do not have a specific "lobby"



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of their own but have gained increased public attention through the promotional efforts of the laetrile proponents and their highly organized national network. At any rate, a spinoff of laetrile's apparent success has been the introduction of laetrile-type bills purporting to legalize other unapproved drugs.

Conclusion

A variety of problems exist in the 17 states that have passed laetrile laws. The precise legal relationship of these statutes to state food and drug laws and state medical practice acts is not well defined. The variability of the laws, state to state, is great and substances other than laetrile are sometimes involved.

The passage of substance-specific legislation confers "pseudo-approval" status on that substance in the public's mind. This results in a shifting of the drug approval process away from normal health regulatory channels into the political arena. Physicians should become familiar with the legal, medical, and social implications of such laws in their own states.

More importantly, they need to articulate clearly to legislators the inherent problems and dangers in passing such legislation. ■

LAETRILE: THE REGULATORY CHALLENGE OF AN UNPROVEN REMEDY

Stuart L. Nightingale, M.D.

Associate Commissioner for Health Affairs

Food and Drug Administration

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Bethesda, Maryland

Few episodes in the history of drug regulation or of cancer quackery rival that of Laetrile in terms of the public clamor that accompanied its promotion and the public policy issues surrounding its brief appearance on the stage of unorthodox therapy. The controversy of Laetrile itself is nearly at an end, its worthlessness having been demonstrated beyond any reasonable doubt. Yet the Laetrile experience raised important public policy questions concerning the roles of medicine and science, of regulatory and research agencies, of law makers and courts of law, and of the drug regulatory system embodied in the Federal Food, Drug, and Cosmetic Act and carried out by the Food and Drug Administration. Some of those questions remain unresolved and all are worthy of examination.

I. BACKGROUND

Laetrile is one of a long and sad roster of substances purported to cure or alleviate cancer. The cancer "cure" developed by Harry Hoxsey before World War II victimized countless patients until State and Federal action brought about the end of this obvious fraud. By the 1950's, another unproven, secret cancer remedy, Krebiozen, achieved wide acclaim, partly because of the support of Dr. Andrew C. Ivy, who had been a distinguished teacher and investigator. Krebiozen was never approved for use in the

United States, and by the beginning of the decade of the 1970s this substance, too, had faded from the scene.

Its place was taken by Laetrile, quietly in the 1960's and early 1970's and then with great fanfare and public acclaim in the mid-to-late 1970's. Laetrile is probably the most economically successful and certainly the most controversial cancer remedy promoted to the American public in this century or any other.

While it is agreed that Laetrile is obtained from apricot kernels, there have been conflicting statements from its proponents and others as to precisely what it is. Proponents claim that Laetrile is 1-mandelonitrile beta glucuronide from which the name "Laetrile" is derived. Analysis of confiscated samples generally revealed amygdalin. It has been promoted to the public as amygdalin, vitamin B-17, a drug, and a food. Nor is there uncertainty only about what Laetrile is; claims for its value in treating cancer (and for other medical uses) are equally varied and obscure. In the approximately 25 years that Laetrile has commanded more or less attention in this country, its advocates have claimed variously that Laetrile is effective in the cure or mitigation of cancer, that it prevents cancer, that it promotes the action of other cancer therapies, that it is an analgesic, and that it has value in

the treatment of sickle cell anemia, parasitic diseases, and hypertension. None of these properties of Laetrile has ever been demonstrated in a controlled investigation.

II. SUCCESS OF LAETRILE

The spectacular "success" of Laetrile in the mid-to-late 1970's can probably be attributed to a variety of factors--some psychological, some political, and some undoubtedly reflecting the skill and, mostly, resourcefulness of its promoters. As have most other "quack" remedies for cancer, Laetrile benefitted from the fears and anxieties of patients and their families which were most intense immediately following the diagnosis of a highly fatal and severely painful disease. The promise of a cure, or even of a palliation not available from so-called orthodox or traditional medicine obviously is enormously attractive to cancer patients. Their fears and anxieties were capitalized on by Laetrile promoters, who alleged that organized medicine in collusion with the pharmaceutical industry, the American Cancer Society, and the government were engaged in a conspiracy to prevent Laetrile from occupying its rightful place in health care. Thus, cancer patients were encouraged to feel that by using Laetrile not only were they availing themselves of a safe and effective remedy, but also they were somehow collaborating in an effort to "show up" the

establishment, a powerful incentive, especially for those who philosophically distrust any government regulation or those with special credentials. This was particularly true for the patient who felt he was "cured" by Laetrile after being told by his personal physician that he only had weeks or, at most, a few months to live. Also, promoters and patients to varying extents cherished the "illicit" nature of their actions and viewed theirs as acts of defiance.

Another rallying cry on which the advocates of Laetrile capitalized was "freedom of choice," the notion that cancer patients and those who care for them should be free to obtain and use Laetrile whether or not it had received official sanction from FDA or, equally important, approval by the medical/scientific community. As the argument ran, if a patient had not been helped by conventional treatment or elected not to have it, that patient and the physician should be free to use Laetrile because the drug might prove beneficial and, in any case, was harmless. Even though there was no evidence for these assertions, they were widely reported and--surprisingly to government officials, medical leaders and practitioners--not infrequently championed in the public press, and they powerfully influenced public opinion in general and State legislative bodies in particular. These arguments proved most difficult to deal with since many

members of the public were, if not in agreement, at least sympathetic to these views.

III. LAETRILE AVAILABILITY

At the height of its popularity, "black market" traffic was the most common source of Laetrile.

The United States District Court for the Western District of Oklahoma, in a ruling handed down in the spring of 1977, enjoined the FDA from impeding or preventing the importation and interstate transportation of Laetrile for use by a "terminally ill" cancer patient, provided a practicing physician submitted an affidavit attesting to, among other things, the "terminal" nature of the patient's illness. On appeal, the Tenth Circuit Court narrowed the ruling somewhat. The Circuit Court ordered that Laetrile in the injectable form only could enter the country and move in interstate commerce for the personal use of patients certified by a physician, in an affidavit, to be "terminally ill." Affidavits signed by a physician were widely used in the late 1970's. In April of this year, the Circuit Court ordered the District Court to dissolve all the injunctions entered against the government. Thus, the lawsuit appears to be drawing to a close. The judicially sanctioned distribution system and the black market (conducted in

violation of the Court Order) together provided a "safety valve" by allowing easy availability of Laetrile and facilitated its widespread use and popularization.

At the height of the Laetrile controversy, legislation of one kind or another was introduced in the majority of states to permit and protect its use by licensed physicians despite the fact that it remained a Federally unapproved drug. Twenty-four states had enacted pro-Laetrile legislation as of October, 1982. The laws, enacted mostly between 1977-79, varied in their specific provisions: some prohibited disciplinary action against physicians who prescribe, dispense, or administer Laetrile; still others contained provisions authorizing the manufacture of Laetrile, limited its use to cancer patients only, required informed consent, or ruled that Laetrile is not a drug and thus not subject to drug regulations. The extent of this legislative activity is testimony to the effectiveness of the campaign to promote Laetrile. "Model Legislation" developed by proponents had been disseminated to each state, and lobbying at the state level was intensive. Teams of Laetrile proponent "experts" consisting of at least one "scientist," were dispatched to state legislatures to testify on behalf of the bills.

IV. LAETRILE AND THE FDA DRUG REGULATION PROCESS

Under the American system of drug regulation, a drug may not be marketed in interstate commerce (or imported for marketing in the United States) until it has been approved by the FDA. FDA approval is predicated on proof of safety and effectiveness established through adequate and well-controlled double blind clinical trials conducted by qualified experts. Clinical trials of an investigational drug cannot begin until FDA has granted a Notice of Claimed Exemption for an Investigational New Drug, an IND. Such an application for Laetrile was submitted in 1970. It was not permitted to proceed, however, because uncertainty about the identity of the drug made questionable the results that might be obtained in clinical trials. Even earlier (1962) when a New Drug Application (NDA)--that is, an application for approval to market Laetrile--was submitted to FDA, the claims for efficacy were in conflict with those made by promoters of Laetrile. The NDA referred to Laetrile as a cancer palliative. Literature promoting Laetrile at the time, however, stated that "laetrile does not palliate. It acts chemically to kill the cancer cell selectively. . . ."

During the period of intense public and legislative interest in Laetrile, organizations whose members are experts in cancer drug evaluation--the American Cancer Society, the

American Medical Association, and the Committee on Neoplastic Diseases of the American Academy of Pediatrics--as well as an overwhelming majority of the Nation's most eminent and well-qualified experts in the field did not recognize Laetrile as effective. Proponents of Laetrile insisted that these organizations were part of an industry-government-orthodox medicine conspiracy. In response, they identified their own medical and scientific "experts" and had them "testify" before state legislatures. There was, however, little objective scientific evidence available to convince state legislators and the public that the drug was ineffective. No results of rigorous controlled studies had been published. Furthermore, because of the variability in the prescribed treatment and questions (noted earlier) about the identity of the administered drug itself, there was little opportunity for scientific critique of uncontrolled clinical experience. Unfortunately, the lack of scientific evidence and the views of responsible, orthodox spokespersons on Laetrile issues were viewed as of no consequence by State legislators and the public. Consumer groups were notably and mysteriously silent on this major public health issue.

The other Federal agency most directly involved in the Laetrile controversy was the National Cancer Institute (NCI)

of the National Institutes of Health. As the principal cancer research organization of the Federal government, NCI was, like FDA, under considerable public pressure generated by its promoters to sanction Laetrile, to affirm the claims made for it, and under pressure from other quarters (e.g., State legislators and segments of orthodox medicine) to agree to undertake clinical studies to establish whether or not the substance was effective.

Laetrile had been repeatedly screened by NCI against a broad spectrum of animal-tumor systems. Most of these tests were completely negative. Others showed only marginal levels of activity which could not be reproduced. The lack of a positive effect in test animals was considered to be of major importance, since a clear showing of success in animals traditionally served as a precursor to clinical testing.

Questions were raised about the drug's safety, particularly with regard to the oral dosage form. Amygdalin, taken by mouth, is broken down in the gastrointestinal tract with the release of cyanide. Studies have demonstrated that in sufficiently large doses oral amygdalin will kill experimental animals due to cyanide poisoning. Human deaths due to amygdalin overdose had been documented involving individuals who had ingested ground apricot pits. Oral amygdalin in the form of Laetrile was alleged by its

promoters to be safe, but during the height of the controversy two patients died--an infant who had taken Laetrile tablets and a young woman who drank the parenteral formulation manufactured in Mexico. All human evidence of safety and effectiveness in humans was testimonial or anecdotal and was usually provided either directly or indirectly by Laetrile's promoters.

Although it was generally believed at the time that a clinical trial was at least feasible, there were strong ethical objections in some quarters to the prospect of offering cancer patients a drug for which there was no demonstrated anticancer activity, either in animals or in man. In addition, many in and out of government objected to spending public funds on what they believed to be a worthless nostrum. The use of Laetrile, however, continued to be widespread and was a public issue with strong emotional overtones. To perform a clinical trial without objective evidence of preclinical efficacy would be unusual, but FDA regulations did not preclude such a trial.

Retrospective Case Review

After much discussion, the NCI in 1978 determined that before a decision was made to conduct a clinical trial, a

retrospective review of case records should seek to establish whether bona fide responses to Laetrile had occurred. On the recommendation of a Task Force of government epidemiologists, oncologists, and regulatory officials, cases thought to have shown objective benefit from Laetrile were solicited by mail request to 385,000 physicians and 70,000 other health professionals and by direct contact with pro-Laetrile groups. Although it was estimated at the time that 70,000 Americans had used Laetrile, only 93 cases were submitted for evaluation, of which 68 included histologic proof of pre-existing cancer and objective evidence of tumor reduction not attributable to any known cancer treatment other than Laetrile. A panel of 12 oncologists conducted the blind review of 160 courses of treatment, 68 Laetrile, 68 chemotherapy, and 24 "no treatment." The panel judged six Laetrile courses to have produced responses, two complete and four partial. These results, however, allowed no definitive conclusion supporting the anticancer activity of Laetrile. The public remained unsatisfied and confused.

Laetrile continued to be a dominant unresolved problem for American medicine and the drug regulatory system. Pressure on State legislatures to approve the drug continued to mount. Shortly after the results of the retrospective review were published, NCI decided to sponsor a clinical trial of Laetrile. Reasons for pursuing a clinical trial varied. A

compelling reason for many was that while the Laetrile issue was fraught with ethical and legal concerns, basic humanitarian considerations required a resolution of the issue. Thousands of cancer patients were being exposed to a drug of no known effectiveness, dubious safety, and poor manufacturing quality. It was hoped that such a scientific trial would be convincing to the great majority of thoughtful Americans, to the mass media, and to State legislators and others who, in order to make Laetrile available, were willing to accept on faith the word of Laetrile promoters. Moreover, the legalization of Laetrile on a state-by-state basis was undermining the entire drug approval process.

Clinical Trial

A clinical trial was conducted with NCI support by a multi-institutional team led by a distinguished cancer researcher at the Mayo Clinic. Although the study could be neither controlled and randomized nor blinded, the lack of concurrent controls was partially offset by the fact that all patients were in the advanced stages of a disease known to be almost uniformly and rapidly fatal. Ethical objections were minimized by requiring fully informed consent from all patients. In anticipation of criticism by Laetrile advocates, only patients in otherwise good general condition

and fully a third had never received chemotherapy or radiotherapy and therefore would be considered good candidates for Laetrile treatment. (Laetrile "failures" were ascribed by proponents to the fact that cancer patients had been weakened by prior orthodox therapy--"cutting," "burning," and "poisoning".) "Metabolic" therapy using Laetrile combined with "vitamins" and a "natural" diet--a regimen advocated by many Laetrile proponents--was incorporated into the study. As a safety precaution, blood levels of cyanide were monitored to assure that potentially toxic levels were not exceeded.

The final report of the clinical trial (New England Journal of Medicine, January 28, 1982) made clear that in the group of 178 patients with a variety of types of advanced cancer, Laetrile produced no discernible benefit as measured by decreased tumor size or prolongation of survival compared with historical controls. More than three quarters of the patients had died of their disease by the end of the study and their survival times seemed fully consistent with those of patients receiving no treatment. Moreover, several patients had symptoms suggestive of cyanide toxicity or blood cyanide levels that approached the toxic range (or both).

Thus, the study demonstrated that Laetrile could not be considered either safe or effective.

The study results received widespread publicity and those who pressed for a scientific study as a means of dealing with public concern and pressure from various responsible and not-so-responsible quarters, were pleased. However, concurrent with these results, Laetrile as a "fad" already seemed to be fading.

Enforcement and Publicity

In addition to a variety of enforcement actions, including seizures and prosecutions, FDA took a number of steps to educate and warn the public, health professionals, and state legislatures about the direct and indirect health hazards of Laetrile use. The vehicles included specially prepared leaflets for consumers, articles in the FDA Drug Bulletin, sent to over one million health professionals, testimony presented at state legislatures, and a special widely disseminated Public Warning--only the second time in FDA's history that such a warning was issued.

V. POLICY ISSUES

As a medical/scientific controversy, the case of Laetrile has pretty much been closed for several years. It is no longer in the news nor a major subject of debate in state or Federal legislatures. As a public policy issue, however, the Laetrile affair raised public policy questions that continue to command our attention. Could the flagrant promotion of this unproven remedy have been avoided? Did the regulatory system perform as it was intended to? Or did it bend nearly to the breaking point in the face of powerfully effective promotion and intense public pressure? And perhaps the most salient policy question: can the same thing happen again?

1. Could the Laetrile phenomenon have been prevented?

Laetrile, an unapproved drug, was moving illegally in interstate commerce (and being imported) in direct violation of the Federal Food, Drug, and Cosmetic Act. Those associated with this traffic at its inception when Laetrile was a relatively local issue could have been prosecuted vigorously. We can only speculate as to whether convictions would have been obtained and upheld. State licensing bodies had the authority to punish physicians who prescribed or administered Laetrile and pharmacists who dispensed it. Only

after State laws were enacted and a Federal District Court established the "affidavit system" for Laetrile was the use of this substance by health professionals able to don the cloak of "legality." Leaving aside the major question of the availability of manpower and other resources to pursue vigorous enforcement action against Laetrile and its proponents, there is no doubt that United States law provided a means to attempt to halt traffic in Laetrile soon after it began.

2. Did the regulatory system perform as intended?

FDA initially failed to approve an application to conduct clinical investigations of Laetrile because the sponsors were unable to supply the kind and quality of data required under FDA regulations. This was not only appropriate, but for FDA to do otherwise would have been illegal. Laetrile promoters then followed an extra-legal course, rather than attempt to supply the additional requisite information. The fact that Laetrile continued to be traded and promoted without approval is evidence that the system did indeed bend, if not break, in the presence of public pressure fanned by skillful promotion. Because sufficiently early vigorous enforcement action was not carried out, such action at a later date was more difficult and could not in itself effectively deal with public policy concerns. The passage of State laws and the

establishment, by the Court, of the "affidavit system" would seem to imply that dissatisfaction with the regulatory system was sufficiently great to effectively override the system when it was felt to be in conflict with the public will. However, the collection of preclinical and clinical information by a non-regulatory agency (NCI) and its subsequent funding of clinical trials meant that the regulatory procedures for clinical testing were eventually followed. Without NCI's Retrospective Case Review developed by epidemiologists, the definitive trial would not have been performed. Publication of the report of the NCI study satisfied the general public, the press, and by inference, state legislatures, which have enacted no new laws permitting the use of Laetrile.

3. Could there be another Laetrile?

As one who was deeply involved in FDA's role in the Laetrile matter, who testified before State legislative bodies that were considering pro-Laetrile legislation, and who helped to orchestrate public and professional education efforts to warn of the hazard of Laetrile use, I would prefer to be able to say that we will never again see perpetrated on the American public, a medical fraud of this magnitude. Unfortunately, I cannot.

The drug regulatory system administered under law by the FDA, like any other system carried out by government in a free society, functions only so long and so far as the public will allow. Survey after survey shows that there is overwhelming support by the American people for the consumer health protection activities of the FDA. But, as the case of Laetrile proves, that support is neither absolute nor permanent. It can be selectively or totally withdrawn.

In those circumstances, it would seem that the best, perhaps the only, recourse in a free society is for those institutions and groups that have a responsibility for protection of the public health--institutions outside government as well as within it--to identify, expose, and halt quackery that threatens the public health and welfare. Their weapons in such a struggle are facts as well as laws, credibility as well as confidence, compassion as well as the scientific method. Arrayed against them are cunning deception on the part of the promoters of quackery and the fear and ignorance of desperate people, coupled often with a conviction that the "establishment" is bent on crushing those who oppose it.

While the role of a drug regulatory agency may be limited, submission of scientific data (as part of an investigational permit) should be encouraged. If a promoter of an unproven remedy does not follow the usual channels to demonstrate

safety and efficacy, however, consideration must be given by others to sponsoring such studies. Regulatory (enforcement) and public education activities, however, are to be encouraged concurrently and should not be seen as conflicting. It is noteworthy that at the same time FDA was permitting a clinical trial of Laetrile it issued a nationwide Public Warning about its use. Both actions were viewed as responsible, salutary, and not inconsistent.

The challenge of quackery is formidable and seemingly unending. Experience tells us that a successor to Laetrile is almost surely on the horizon, if not in our midst. It is to be hoped that those of us in medicine and science, in and out of government, will be better able to meet the next challenge of quackery.

Appendix 3

(Additional material received for the record.)

Statement

of

Denham Harman, M.D., Ph.D.
Millard Professor of Medicine
Professor of Biochemistry

to the

Subcommittee on Health and Long-Term Care

of the

Select Committee on Aging

of the

House

May 15, 1984

Mr. Chairman and Gentlemen:

My name is Denham Harman, Millard Professor of Medicine and Professor of Biochemistry at the University of Nebraska College of Medicine, Omaha, Nebraska. I am pleased to have the opportunity to briefly discuss the role of free radical reactions in aging and disease.

The average life expectancy at birth is a rough measure of our years of healthy productive life, i.e. the functional life span. Average life expectancy increased rapidly from a value of 47.2 years in 1900 to 67.2 years in 1954-1955 and then increased progressively more slowly to the present value of about 74 years today on an advance towards a limiting figure of less than around 76 years. For all practical purposes we are no longer living longer. Further disease oriented biomedical aging research will increase average life expectancy only slightly. For example, complete elimination of cancer as a cause of death would increase the average life expectancy about 2 years while the figure for cardiovascular disease is around 5 years. It is now the aging process which nullifies all attempts to increase the healthy life span. The aging process determines the maximum life span of a species as well as the maximum average life expectancy. For man the maximum life span is about 100 years while maximum average life expectancy, that is average life expectancy in the absence of overt disease, is about 85 years.

If we could slow the aging process those diseases which kill us, such as cancer and cardiovascular disease, would be put off in time. Prospects for slowing the aging process are very promising. Free radical reactions appear to play a major role in both aging and disease. The adverse effect of such common, widespread reactions can be diminished by compounds known as antioxidants or free radical reaction inhibitors. Addition of antioxidants to the diet increase the life span of mice, rats, *Drosophila*, nematodes, rotifers and the "life span" of neurospora. Antioxidants have been shown to have a beneficial effect on the incidence of cancer - at least of some forms, the immune response, autoimmunity, and amyloid formation. Free radical reactions have been implicated in all the major diseases of man, raising the possibility that all such disorders may benefit to some extent by the addition of one or more free radical reaction inhibitors to the diet.

Available biomedical aging research data indicate that it may be possible to increase the average life expectancy of man, the functional life span, by 5 to 10 or more years without significantly increasing the maximum life span. In other words the working life span would be increased and the period of senescence decreased; these effects would be of obvious benefit to Social Security, medicare and medicaid.

I have appended a paper "Role of Free Radicals in Aging and Disease" which summarizes the data supporting the role of free radical reactions. I have also included a copy of the paper "Free Radical Theory of Aging: Effect of Dietary Lipids in Lipofuscin Accumulation in the Hippocampus of Rats" that I believe to be of particular relevance to two of our major health problems, senile dementia of the Alzheimer's type and Parkinson's disease. These two papers are in press.

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June 3, 1984

The Honorable Claude Pepper
The House of Representatives
Washington, D.C. 20510

Dear Mr. Pepper,

On May 31, the Subcommittee on Health and Long-Term Care of the House Select Committee on Aging held a hearing on the victimization of elderly Americans by health-care frauds. We saw a TV broadcast of this hearing and heard you, as Chairman, note that 20 TV stations were airing the proceedings nationwide.

During the course of the hearing, Harvey Waxman, (who has a medical degree but has, for the second time, been denied membership in the Nassau County Medical Society) now an attorney whose specialty is medical malpractice, singled out one physician, Dr. Emanuel Revici, and called him a quack. You may not be aware of how maliciously slanderous Dr. Waxman's allegation was.

Waxman represents three clients who have malpractice suits pending against Dr. Revici (the only ones ever in six decades of patient care!) Their claims total \$40 million, taken on a contingency basis. In December, 1983, Waxman's clients presented their cases on the NBC Today show. This one-sided presentation before millions of viewers was a flagrant instance of trial by media.

Less than a month later, Dr. David Axelrod, Commissioner of Health, State of New York, ordered Dr. Revici to discontinue his practice, and a Board of Professional Medical Conduct was convened to determine if grounds exist to revoke Dr. Revici's license permanently. (Revici is, incidentally, a lifetime member of the AMA.) Administrative proceedings began Jan. 4, 1984 and are currently in progress. Dedicated patients who attended the second hearing on Jan. 11, 1984, convinced the Board to recommend that the commissioner lift the suspension (promising to hold these officials legally and ethically responsible for any deaths that occurred during the suspension) and Dr. Axelrod did so. The Board continues to hear evidence and while it does, Dr. Revici provisionally sees and treats patients. As of this writing, several hundred people depend on his treatment for their survival, and there are many more cancer survivors whose cases we

are documenting.

It is important to understand that it would enormously improve Wachsman's chances of winning the malpractice suits should the NY State Board for Professional Medical Conduct decide against Dr. Revici. Wachsman and his clients stand to gain if media exposure pressures the Board into a decision to terminate the proceedings before Dr. Revici concludes his defense.

It is even more important to remember that the charges against Dr. Revici have not been proved: no judge or jury or panel has reached a verdict of fraud. Wachsman's allegation of quackery is based simply on a presumption of guilt, and in court he would be required to prove it. On national TV, however, he apparently feels proof is not required because there is no one representing Dr. Revici to challenge him.

Our generation may be the last to keep faith with the fundamental ideals we learned as part of our country's revolutionary heritage. It outrages us to hear Wachsman's allegation meet with no objection...a defamatory use of a public forum for personal gain. It goes against the cherished American beliefs; that every one of us should receive a fair, open hearing and should be presumed innocent until proven guilty in an appropriate court. Wachsman's allegation over nation television injures Dr. Revici's name, but ultimately, its wider effect may be to deprive his patients of their lives. It has been difficult enough to obtain a fair hearing in New York (encl.1). After the exposure your subcommittee gave Wachsman, it will be even more difficult. We respectfully request an opportunity to present to your subcommittee evidence that Dr. Emanuel Revici's treatment for control of cancer has substantial merit. (encl.2). We further request that you enter this letter and enclosures into the Congressional Record.

We applaud your intention to protect the nation's elderly by investigating health-care quackery. Yours is a difficult task since it is never easy to make the distinction between a quack and a genius without benefit of hindsight. As you probably know, the history of medical science is replete with examples of persons derided as quacks in their own time who eventually came to be regarded as medical geniuses or heroes e.g. Pasteur, Harvey, Semmelweis. Therefore, before you let your subcommittee be used to aid and abet Dr. Revici's demise, please look more closely into what he has accomplished. You just may be the rare legislator who can draw the distinction between genius and quackery. And you know, sadly, from personal political experience, how easily the efforts of a creative and constructive person can be destroyed in a smear campaign.

Dr. Morris Fishbein, a former president of the AMA, defined a quack as someone who promises a cure, charges exorbitant fees and offers worthless treatment. Fishbein's definition might well apply to your average orthodox oncologist who often charges very

high fees, uses substances with seriously toxic side effects and promises cures.

It cannot apply to Dr. Revici who, until 1970, charged his cancer patients nothing. As recently as four years ago, he charged \$30 a visit (mainly because his patients insisted on paying something so they would not feel like guinea pigs). Today, facing enormous financial pressures, he has been persuaded to raise his initial examination fee to \$150 and fees for subsequent visits to \$75. (encl. 3-Affidavit) He still does not charge patients who cannot afford to pay and he does not know who are his paying patients and who are not. All medications, prepared in his laboratory, are provided without charge. Patients must sign a consent form before receiving treatment which informs them that Dr. Revici's methods are not FDA approved. We have at least two dozen affidavits from patients stating he does not promise to cure patients and does refer patients to traditional practitioners when indicated. He is available to his patients without charge by phone day and night and on weekends.

In the last two years, Dr. Revici's methods for control of cancer have undergone tests in Naples, Rome and at the University of Milan. The results were so impressive that in September of 1984, it is expected that Revici's treatment will become the official one throughout Italy. Requests are pending from Morocco and Egypt to establish facilities employing Revici's methods and pharmacological agents.

Kindly note that Revici's work in cancer, prior to 1965, was of considerable interest to person's prominent in the USA in medicine. e.g. the President of the New York State Medical Society and two county medical societies served simultaneously on the Board of the Institute of Applied Biology. More than one nationally prominent Cancer authority privately referred patients with advanced cancer to the Institute of Applied Biology but were afraid to openly support the Institute or Dr. Revici for fear of losing their positions.

In 1965, a two-year study of Revici's methods, financed by his Institute of Applied Biology, was published in JAMA. The Clinical Appraisal Group (CAG), which conducted the trial, concluded that Revici's method of cancer control was of no value. This CAG report might be called the Watergate of the American Medical Establishment. We are prepared to furnish evidence that will attest to gross misconduct-both during the study and in the preparation of the CAG report. We have photographs of objective improvement, for example, signed by one of the two physicians who actually observed patients throughout the study.

You may yourself recall testimony on narcotic research and treatment given before the House Select Committee on Crims which we believe you chaired in 1971. It was given by Drs Casriel, Rosen and Davidson in support of Perse and Bionar-two substances

developed by Dr. Revici to detoxify addicts without withdrawal symptoms. The above mentioned doctors were among a sizeable number of physicians and government officials who had personally seen remarkable results at the Institute of Applied Biology and Trafalgar Hospital, where Dr. Revici was Director. Dr. Revici treated nearly 3,000 patients for physiological addiction. No issue was made over efficacy but New York City forced the abandonment of Dr. Revici's treatment by claiming "Medicaid Fraud". This charge was disproved and Trafalgar Hospital was awarded most of the money in dispute, but, as usual, the charges of fraud made the headlines and the exoneration did not. Meanwhile methadone with its lasting toxicity was adopted and Perse, which has no addictive effects, was discarded.

We do not write this letter as disinterested parties. We believe Harold Ladas owes his present good health to Revici's treatment. He had carcinoma of the tonsil. Full professor at Hunter College of the City University of New York, with a speciality in summarizing research, Harold bet his life on Dr. Revici after carefully studying all the evidence he could get about traditional and non-traditional approaches.

There are times when it seems to us easier to give up on getting a fair hearing in America. We could afford to follow Revici to Italy or Egypt, where people are setting up clinics for him. But we are also patriots; we want to make a try for justice in the United States. So does Revici. He does not wish to leave his adopted country or New York, and especially, he does not want to abandon his patients. Devotion and bravery are qualities that distinguish Dr. Revici. He comes from a family of physicians in Rumania. He was decorated for services at the front in WWI, offered the French Legion D'Honneur, and was a key member of the French underground during WWII. Molotov came to him personally in Mexico to offer him the Stalin Prize and \$50,000 in 1944. Characteristically, he declined the prize and the money.

Significant political and medical issues are involved in the Revici case. Traditional medical science gives the impression that it has proven treatments for many of the conditions discussed during the hearings. Nothing could be further from the truth. The office of Medical Technology of the Congress of the USA estimated in 1978 that only 10-20% of medical technology was proven safe and effective. A study by the National Research Council in 1984, showed over 60% of drugs were not safe and effective. Particularly with diseases like cancer, there is no sharp demarcation between proven and unproven. It is interesting to note that while you were personally investigating the relationship between cancer and diet as early as the 1940s, the American Cancer Society consistently ridiculed the notion that there is any relationship until after the US Government issued their report on DIET NUTRITION AND CANCER.

Politically, the issue is how government can oversee scientific research and medical practice in ways strict enough to

discourage, and if necessary, penalize incompetance, favoritism and fraud, while fostering innovation and real improvement in basic science and treatment. It is not conducive to that process to permit someone with vested interests to make unanswered slanderous statements on national television, particularly if the person slandered is someone who may have made a major contribution to man's conquest of disease.

We assume that Wachsmann's mention of Revici was not part of the planning of your Committee, although we are fairly certain that Wachsmann himself proceeded with careful calculation. Nevertheless, he may, inadvertantly, have offered you an opportunity to help the USA lead the way toward control of cancer. We believe that the tactics used against Dr. Revici, and the reason he has been singled out for attack (although he is by no means alone), is because of the intrinsic value of his work and that fact that its importance is now gaining increasing international recognition.

Again, we request that you put this letter into the Congressional Record and allow us to appear before your Committee to refute the charge of quackery made against Dr. Revici on national television.

Sincerely,

Alice and Harold Ladas

Alice & Harold Ladas

Encls.

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STATEMENT FOR THE RECORD

from the

NATIONAL CANCER INSTITUTE
National Institutes of Health
Bethesda, Maryland 20205

for the

HOUSE SELECT COMMITTEE ON AGING
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

U.S. HOUSE OF REPRESENTATIVES

May 31, 1984

Mr. Chairman and members of the committee, the National Cancer Institute appreciates this opportunity to submit testimony to the House Select Committee on Aging on the topic of unproven therapies and advances made in treatment through systematic research and careful testing.

There will be 870,000 new cases of cancer diagnosed in the United States in 1984. Overall, there are five million Americans who are alive with a previous diagnosis of cancer. Half of the patients diagnosed with cancer this year are curable and the National Cancer Institute (NCI) is committed to further reduce cancer mortality by 50% of today's rate by the year 2000. These statistics reflect the increasing treatability and curability of cancer made possible by both basic and clinical research. Future advances can be anticipated with optimism as new therapies are discovered and more standard treatments are used more effectively.

Several cancers have entered the ranks of advanced malignancies curable with drugs in the past ten years and are summarized in Table 1.

TABLE 1		
CHANGE IN PROGNOSIS FOR PATIENTS WITH ADVANCED MALIGNANCY 1973-1983		
Type of Cancer	Long-Term Disease-Free Survival	
	1973	1983
Acute lymphocytic leukemia	30%	50%
Hodgkin's disease	50%	60%
Diffuse histiocytic lymphoma	5%	65%
Testicular cancer	10%	70%
Burkitt's lymphoma	20%	35%
Choriocarcinoma	80%	90%

Further, progress has been made in increasing the percentage of patients with Hodgkin's disease who are cured with chemotherapy, and, as shown in Table 2, other malignancies, previously somewhat responsive, are now curable in some patients. As can be seen, the majority of patients with ovarian

TABLE 2

CHANGE IN PROGNOSIS OF PATIENTS WITH ADVANCED CANCER 1973-1983			
Majority of Patients Now Respond to Therapy, Fraction Cured.			
Type of Cancer	Response Rate		Long-Term Disease-Free Survival
	1973	1983	
Ovarian cancer	30%	90%	20%
Acute non-lymphocytic leukemia	50%	80%	15%
Small-cell carcinoma of the lung	30%	90%	10%
Nodular lymphoma	70%	90%	10%
Head and neck	30%	50%	40%

cancer, acute non-lymphocytic leukemia, small-cell lung cancer, nodular lymphoma, and head and neck cancer now achieve significant improvement in disease. Of additional interest, nearly 20% of patients with advanced ovarian cancer or acute non-lymphocytic leukemia and 40% of patients with head and neck cancer enter a complete remission of their disease, and remain so for greater than five years.

In addition, the possibility of eradicating cancer by administering chemotherapy soon after primary surgery to kill residual tumor cells has been firmly established through studies of breast cancer and soft tissue sarcoma in recent years (Table 3) and stands as one of the major achievements of the past ten years.

TABLE 3

CHANGE IN PROGNOSIS FOR CANCER PATIENTS - 1973-1983

Adjuvant therapy prolongs survival

Breast cancer, Stage II
Soft tissue sarcoma, extremity
Childhood sarcomas

Adjuvant therapy possibly delays recurrence

Gastric cancer, Stage II
Rectal cancer
Osteosarcoma

To make such advances in the treatment of cancer, each year the NCI tests a variety of new approaches, including new antitumor drugs and novel drug combinations (chemotherapy), innovative surgical techniques, novel radiation particles (radiotherapy), and recently available biological compounds such as monoclonal antibodies, interferons, lymphokines, and cytokines.

Each one of these new methods of treatment must undergo rigorous, scientific testing before it enters the arena of accepted medical practice. The development of effective drugs to treat cancer illustrate this meticulous process.

We have refined our systems for screening compounds as our knowledge of cancer biology and cancer treatment has increased. Only after prospective agents have been proven by careful testing to have anticancer activity in animals and to be safe for administration to man are they allowed to enter trials in patients. These initial clinical trials are conducted within guidelines set by the Food and Drug Administration (FDA), and only by experienced

investigators approved by the NCI. Between six and ten new agents enter clinical trial under NCI sponsorship each year. Nearly all of the anticancer agents, as well as drug analogs that retain anticancer activity with fewer patient side effects, now used by the cancer specialists of this country were developed by this approach. The newest agents shown to be useful in treating cancer--such as monoclonal antibodies, interferon, and other biological response modifiers--are also screened using similar screening systems to identify the agents with the most promise in treating cancer.

The careful testing of potential new agents for the treatment of cancer must be conducted with an open mind; therefore, we have tried to remain receptive to the evaluation of all new proposals, even those which do not seem to be supported by traditional scientific evidence. To this end, the NCI willingly tests any material in its screening systems that are believed to be potentially effective in the treatment of cancer. The only qualification is that the NCI must be informed of the composition of the material or its source before such screening is undertaken. If a clinical trial of the material is subsequently contemplated, all background information must satisfy FDA requirements.

In spite of the many effective treatments developed for cancer, the fears the cancer patient has of the disease, side effects of treatment, and the possibility of death provide a prime opportunity for exploitation by those at the fringes of science who fraudulently and flagrantly promote treatments that have not been subjected to rigorous testing, but borrow on the validity of similar methods concurrently under scientific investigation.

A case in point is immunoaugmentative therapy (IAT) as administered by Lawrence Burton, a Ph.D. zoologist, in his clinic which is located in Freeport, Bahamas. Dr. Burton treats cancer patients with human blood extracts and claims that his method benefits people with a wide range of malignancies. Despite the fact that this treatment has received much publicity in the lay press, Dr. Burton has never reported the details or results of his methods in the scientific literature. Thus, no data exist to evaluate his claims to have developed a treatment which is in any way effective against cancer. The importance of testing this material has been heightened by the fact that Dr. Burton treats patients whose disease may be curable by other, more conventional therapies such as radiotherapy or drugs. These curable diseases include Hodgkin's disease, non-Hodgkin's lymphoma, and acute leukemia.

In our effort to gain a scientific assessment of IAT, NCI staff have had frequent correspondence over the past few years with Dr. Burton and his supporters. We have expressed the willingness of the Institute to learn more of Dr. Burton's therapy. To date, Dr. Burton has been consistently unwilling to supply such material or even provide details of its preparation. We also offered to evaluate patients treated by Dr. Burton to verify their response to his agent, but these attempts have been similarly unsuccessful. In fact, our letters have remained unanswered. We remain willing to evaluate IAT, but insist on analyzing samples for purity and sterility, as well as Dr. Burton's direct participation in these negotiations. IAT remains a scientifically unproven therapy, and patients who seek such care may only be denying themselves early use of effective treatments.

We have, however, had the opportunity to study IAT specimens provided to us by patients and physicians. Our analyses reveal these samples to be simple dilutions of blood proteins, and have not contained any evidence of one of the proteins (complement) Dr. Burton claims to use. All of the eight samples analyzed were contaminated with bacteria. We are also distressed by recent reports of at least one patient treated within the last six months developing hepatitis. We have had similar, but as yet unverified, reports of hepatitis in patients treated at Dr. Burton's facilities. Since IAT is a blood preparation, the possibility of transmission of hepatitis and other viral illnesses is a concern.

In summary, the National Cancer Institute has a major responsibility to the development and support of novel means to effectively treat cancer. Our commitment is also to the cancer patient who deserves what can be proved not just what can be offered by means of false promises.

TESTIMONY
of the
**NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY
AND MEDICARE**
to the
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE
Select Committee on Aging
House of Representatives
June 14, 1984

The National Committee to Preserve Social Security and Medicare supports Congressional action to thwart medical quackery which preys on older Americans. We agree with the Subcommittee that a national clearinghouse on unproven remedies should be established. Moreover, we propose that the clearinghouse information be made available through local Social Security offices.

It is a national tragedy that 60 percent of the victims of quackery are senior citizens. The elderly, who live on limited retirement incomes, cannot afford to waste money on false medical cures. However, because they are often desperate to cure their disabling health problems, personal health care expenditures can quickly impoverish them.

We read with approval the Subcommittee's recommendations for reform, and we encourage prompt action on the part of Congress, federal executive branch agencies and the states. In particular, we support the recommendation to establish a clearinghouse on unproven remedies, to be administered by the Department of Health and Human Services.

Merely establishing such a clearinghouse is only half the task, however. In addition, the elderly must have access to the information collected by it. The National Committee is of the opinion that the best way to disseminate this information is through local Social Security offices. Senior citizens are already familiar with their local Social Security office for information about retirement income and health care. It would be confusing and ineffective to expect older Americans to hunt for information about medical quackery among other government agencies.

The National Committee to Preserve Social Security and Medicare is dedicated not only to the protection of the Social Security and Medicare programs but to safeguarding the retirement income and health of senior Americans. Quackery threatens these goals and we urge this Subcommittee to continue its work in exposing these shams. Our next newsletter, to be sent to our 550,000 members, will include an article on the Subcommittee's findings as well as recommendations on how to avoid predatory medical practices.



National Nutritional Foods Association

ANN 1 - 1984

June 1, 1984

Honorable Claude D. Pepper, Chairman
Select Subcommittee on Health
and Long Term Care
United States House of Representatives
Washington D.C. 20515

Dear Chairman Pepper:

The National Nutritional Foods Association wishes to thank you and other members of the subcommittee for the opportunity to give our comments regarding your investigation into medical quackery.

Our association is comprised of approximately 3,000 retailers, wholesalers and manufacturers of health foods with members located throughout the United States.

We, as well as most Americans, oppose the perpetration of fraud, in any form, including medical, upon the elderly of this country. In this regard, we applaud the efforts of your committee effortlessly to ferret out examples of baseless medical fraud throughout the United States.

However, we are concerned about the standards which you have chosen to judge whether a product, device or procedure is a medical fraud or not. It is quite clear from the text of your published report, as well as the testimony received at your hearings held on May 31, 1984, that medical concepts which go against the general beliefs of the established medical profession are the ones labeled as "quackery". On page after page of the report, descriptive references are made to a particular product, followed by a statement that the product was reviewed by a physician or other health professional, and that that person found that the product or procedure was ineffectual or unsafe and thus a fraud.

I believe that you will agree, Mr. Chairman, that many of the established nutritional concepts that are widely accepted today were historically labeled as quackery. Much of the evidence linking dietary factors and cancer, which are still on the cutting edge of research, were, as little as ten years ago, considered to be way out in left field.

In addition, I am sure that you will recall, Mr. Chairman, that for a period of almost twenty years ending in 1970, the FDA attempted to regulate vitamin and mineral supplements as prescription drugs in the United States. It was only through efforts of individuals such as yourself and Senator Proxmire that this move by the FDA, as supported by the established medical profession, was aborted by legislation. Now the American consumer is able to purchase a wide selection of tailor made nutritional supplements, not only in health food stores but also in grocery stores and pharmacies throughout this country. The idea of nutrient supplementation, viewed by many as quackery in the 1960's, is now routinely accepted as fact by the vast majority of Americans.

A second concern, Mr. Chairman, are characterizations made by some of your hearing witnesses, particularly Dr. Victor Herbert of New York, that the nutrition field is made up of a giant web of nucksters who prey upon elderly consumers and who rake in tremendous profits at their expense.

In an effort to dispute these charges, we have prepared the attached demographic fact sheet about the health food industry. As you can see, the average health food shopper is young rather than old (average age is 39). In fact, only 13% of those surveyed were over the age of 65, while 35% were under 30 and 61% were under 40. In addition, the average health food shopper comes from an income bracket which averages 20% above the national average (\$30,450). Over 50% are college educated.

At the same time, the average health food retailer is not unlike the "mom and pop" grocery store of three decades ago. Of the stores surveyed by Health Food Business (March, 1984), average per store sales were only \$211,854 per year and average per store profits stood at only \$17,697 per year.

Health food stores sell an amazing variety of products including vitamin and mineral supplements, groceries, body-care products, beverages, dairy products, grains, nuts, seeds, herbs and produce. While nearly 40% of average sales are in the nutritional supplement area, nearly 60% of those sales are in the form of multivitamins, Vitamin C, B, and B-complex.

In closing, Mr. Chairman, we wish to again express our support for the committee's efforts to expose baseless health fraud. However, at the same time, we urge you and the other members of your committee to exercise restraint when there is a legitimate question as to the usefulness and validity of a product or procedure. Just because the established medical profession may have some doubts, that opinion does not and should not mandate that the product or procedure be labeled as a fraud and the promoters labeled as quacks.

We appreciate the opportunity to offer our comments. In the future, we hope that you will call upon us to assist you in your efforts, be it in the form of further investigation or in the preparation of legislation.

Sincerely,


Bernard Fensterwald, III



National Nutritional Foods Association

DEMOGRAPHIC FACTSHEETTotal Retail Sales:

1982-\$2.437B
1983-\$2.008B

Total # of Retail Stores:

1982-7900
1983-7700

Store Location (%)

Major City 25
Small City 47
Suburban 15
Rural 13

Annual Sales (% of stores)

	<u>1982</u>	<u>1983</u>	
\$500,000+	11	23	Average (1982)-\$264,859
\$300-500,000	2	11	Average (1983)-\$211,854
\$200-300,000	7	15	Median (1982)-\$180,000
\$100-200,000	36	26	Median (1983)-\$150,000
\$ 0-100,000	27	26	

Annual Net Profit (% of stores):

	<u>1982</u>	<u>1983</u>	
\$50,000	7	10	Average (1982)-\$10,596
\$40-50,000	2	7	Average (1983)-\$17,697
\$30-40,000	11	7	Median (1982)-\$10,000
\$20-30,000	16	13	Median (1983)-\$15,000
\$10-20,000	19	30	
\$ 0-10,000	29	23	
Loss	16	10	

This information was obtained from the eighth and ninth annual surveys of health food stores in America conducted by Health Food Business and published in their March, 1983 and March 1984 editions, respectfully.



National Nutritional Foods Association

CUSTOMER PROFILE

Age (% of customers)

Under 21	7
21-30	26
31-40	26
41-50	14
51-60	12
Over 60	13

sex (% of customers)

Male	38
Female	62

Household Income (% of customers)

Under \$10,000	9
\$10-20,000	16
\$20-30,000	24
\$30-50,000	26
Over \$50,000	13

Marital Status (% of customers)

Single	37
Married	51
Widowed / Divorced	12

Length of Time Shopping at Health Food Store (% of customers)

Under 1 year	9	Average- 3.91 years
1-2 years	20	
2-4 years	21	
5 years	9	
Over 5 years	41	

Average Sales per Store Visit: \$10.22

This material was obtained from Health Food Retailing, January, 1984.

THE KUSHI FOUNDATION

POST OFFICE BOX 108 • BROOKLINE, MASSACHUSETTS 02147 • TEL. 617/852-1111

May 29, 1984

To the U.S. House Subcommittee on Health and Long-Term Care,

First, I would like to thank the members of the Subcommittee for inviting us to submit this statement on behalf of macrobiotic educational organizations in North America. We would also like to acknowledge and support the Subcommittee's goal of helping to improve the quality of life for the elderly in our country.

As the Subcommittee already knows, millions of people suffer the debilitating effects of degenerative disease, often without the benefit of any treatment which holds promise for improving their conditions. Because of this suffering, unscrupulous individuals attempt to take advantage of the misery and desperation of others to make a profit.

Macrobiotic educational organizations fully support the identification and elimination of health schemes which exploit suffering. However, we are disturbed that the macrobiotic diet has been unjustifiably maligned by being grouped with harmful practices in a report entered into The Congressional Record on November 16, 1983 (Parade Magazine, "Medical Advice You Should Avoid," November 13, 1983).

The Parade Magazine article did not represent macrobiotics correctly, but, instead, focused on a more restrictive version of the diet which was recommended over 20 years ago as a short term fasting program. This more restrictive diet, which consisted primarily of brown rice, has not been recommended for more than 18 years.

The macrobiotic diet is a commonsense approach to nutrition which emphasizes whole grains, beans, fresh vegetables, seeds and nuts, fruits, and fish along with the healthful reduction of saturated fats, refined sugars and flours, overly processed foods, alcohol, drugs, and harmful stimulants. (Please refer to the attached "A Nutritional Overview of the Macrobiotic Diet".) These recommendations, which have been advocated for the past 18 years, are consistent with the Dietary Goals established by the U.S. Senate Select Committee on Nutrition and Human Needs. Americans were advised to reduce their consumption of meat, fat, sugar, dairy, and processed foods in favor of whole grains and fresh vegetables. The macrobiotic dietary recommendations are also similar to those advocated by the American Heart Association and, most recently, the National Cancer Institute. We are pleased that the recommendations of these prestigious organizations now closely parallel our own.

The macrobiotic diet is not a fad diet; it has been adopted from traditional eating patterns, more closely resembling the traditional diets of our grandparents rather than the present day American diet.

The macrobiotic diet, as recommended and practiced, is fully outlined in the accompanying document entitled "Standard Macrobiotic Dietary Practice." It is nutritionally balanced and completely safe. In fact, the macrobiotic diet has been hailed by many health professionals as a positive step forward in establishing a practical program for dietary change as it effectively eliminates many of the major risk factors associated with the onset of heart disease, cancer, and a wide variety of degenerative processes where nutritional factors have been determined as a major contributing influence.

In reference to studies done at the Harvard University School of Public Health comparing blood cholesterol levels, Dr. William Castelli, Director of the Framingham Heart Study, stated, "The macrobiotic vegetarians we studied incidentally had a ratio of 2.5. Boston marathon runners were at 3.4. These are ratios at which we rarely, if ever, see coronary heart disease."

Dr. Robert Mendelsohn, M.D. of the Abraham Lincoln School of Medicine, University of Illinois, said, "...In these twilight years of death-oriented, run-away medical technology, the macrobiotic approach to disease and healing comes like a breath of fresh air..."

Regarding blood testing of a group of macrobiotic male adults, J.P. Deslypere, M.D., of the Academic Hospital of the Ghent University of Belgium, said, "In the field of cardiovascular and cancer risk factors, this kind of blood is very favourable. It's ideal, we couldn't do better, that's what we're dreaming of. It's really fantastic, like children, whose blood vessels are still completely open and whole. This is a very important matter deserving our full attention."

Dr. Mark Hegsted, former Professor of Nutrition at Harvard University School of Public Health, and primary author of the U.S. Senate Select Committee's Dietary Goals, wrote a congratulatory letter (June 16, 1983) to the Lemuel Shattuck Hospital when a macrobiotic food program was established.

Macrobiotic organizations have not only welcomed, but have actively promoted, scientific research into the diet and its effects. Research projects have included three studies by the Harvard University School of Medicine which were printed in the American Journal of Epidemiology, the New England Journal of Medicine, and the Journal of the American Medical Association, respectively (Sacks, F.M. et al., "Blood pressure in Vegetarians" 1974; Sacks, F.M. et al., "Plasma lipids and lipoproteins in vegetarians and controls" 1975; Sacks, F.M. et al., "Effect of ingestion of meat on plasma cholesterol of vegetarians" 1981). These studies all indicated that the macrobiotic diet is beneficial to cardiovascular health in adults.

Research is currently planned by Tulane University School of Medicine to investigate the link between macrobiotics and cancer recovery. Our openness and encouragement of research is most contradictory to any accusations of quackery and reinforces the sincerity of macrobiotic organizations. (Attached is a more detailed list of macrobiotic educational activities involving the medical and scientific communities).

We are fully aware that no diet is a panacea and any diet can be applied improperly. Also, nutritional needs vary according to a person's condition, background and environment. Every attempt is made by us to take these factors

into consideration in our educational programs, and to provide extensive training and certification programs for our teachers and counselors. We also encourage people to consult with their physicians for advice. The Foundation does not advise individuals to forego conventional medical treatment in favor of macrobiotics. We see our role as an educational one -- advocating the benefits of good nutrition and a healthy lifestyle. We encourage them to choose the type of treatment they want after research and consultation.

The practice of medicine and the provision of health care in America and the world is in constant state of change. We believe that the immensity of the health problems which face our society now demand a more dynamic and creative approach to the systems of health care delivery as well as the services themselves.

We realize that the recovery from serious illness experienced by many thousands of people following the macrobiotic way of life has not been studied or documented in a way which gives it scientific credibility. We are educators, not scientists. As we mentioned earlier, we welcome and encourage any sincere attempts to investigate the benefits which people have experienced through their daily practice of macrobiotics.

As responsible citizens, we are concerned with any practices detrimental to health, whether they are practiced within or outside of the medical community. We believe that the creation of a healthy society can only happen through cooperation and dialogue between all members of our communities. Education and active exchange of opinions and points-of-view are cornerstones of American society. Our macrobiotic educational organizations are actively pursuing the creation of a healthy and peaceful society. It is in this spirit that we submit this statement to your Subcommittee and welcome any requests for additional information.



William Tara
Executive Director

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