

# HEALTH FRAUDS AND QUACKERY

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## HEARINGS

BEFORE THE

SUBCOMMITTEE ON FRAUDS AND MISREPRESENTATIONS AFFECTING THE ELDERLY  
SPECIAL COMMITTEE ON AGING  
UNITED STATES SENATE

EIGHTY-EIGHTH CONGRESS

SECOND SESSION

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### PART 2

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MARCH 9, 1964

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NOTE.—Hearings on health frauds and quackery were held and they are identified as follows:

Part 1—San Francisco, Calif., Jan. 13, 1964.

Part 2—Washington, D.C., Mar. 9, 1964.

Part 3—Washington, D.C., Mar. 10, 1964.

Part 4a } Washington, D.C., April 6, 1964. (Eye care.)

Part 4b }

# CONTENTS

## CHRONOLOGICAL LIST OF WITNESSES

	Page
Opening statement of the chairman.....	163
Mrs. Esther Peterson, Chairman, President's Committee on Consumer Interests.....	166
George P. Larrick, Commissioner, Food and Drug Administration; accompanied by Dr. Martin Dobelle, Medical Officer, Device Branch, Bureau of Medicine, and Maurice Kinslow, staff assistant, FDA.....	172
Dr. Martin Dobelle, medical officer, Device Branch, Bureau of Medicine, FDA.....	182
Jerry Walsh, Special Educational Consultant to the Arthritis and Rheumatism Foundation, accompanied by Dr. John Calabro, Director, Arthritis Clinics, Seton Hall and Jersey City Medical Center, and Fred Walczyk, Bayonne, N.J.....	217
Dr. John Calabro, Associate Professor of Medicine and Director of the Arthritis Clinics of Seton Hall and Jersey City Medical Center, Jersey City, N.J.....	222
Lorraine Allen, Kearney, N.J.....	223
Fred Walczyk, Bayonne, N.J.....	226
Robert B. Throckmorton, General Counsel, AMA, accompanied by Oliver Field, director of investigation, AMA, and Paul Donelan, attorney, Department of Legislation, AMA.....	229

## STATEMENTS

Appendix.....	255
American Medical Association, by Robert B. Throckmorton.....	229
Larrick, George P., Commissioner, Food and Drug Administration.....	176
Miner, John W., deputy district attorney, chief medical-legal section, Los Angeles County, Calif.....	255
Murphy, Dr. Emmett J., Director of Industrial Relations, American Chiropractic Association, Washington, D.C.....	255
"The Concept of Chiropractic," by Dr. John Q. Thaxton, president, International Chiropractors Association.....	252

## ADDITIONAL INFORMATION

Conclusions and recommendations in the report of the medical disciplinary committee to the board of trustees, AMA, June 1961.....	234
FDA reports on medical quackery—"How Government Protects the Consumer," speech by George P. Larrick.....	199
Highlights: "Report on Arthritis Quackery in the United States, 1964".....	219
Quackery, by Edward R. Annis, M.D., president, AMA.....	237
Recent enforcement actions in Federal courts involving food supplements, January 1 to December 31, 1963.....	209
Recent enforcement actions involving therapeutic devices, January 1 to December 31, 1963.....	204

# HEALTH FRAUDS AND QUACKERY

## Part 2

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MONDAY, MARCH 9, 1964

U.S. SENATE,  
SUBCOMMITTEE ON FRAUDS AND  
MISREPRESENTATIONS AFFECTING THE ELDERLY  
OF THE SPECIAL COMMITTEE ON AGING,  
*Washington, D.C.*

The subcommittee met at 9:40 a.m., pursuant to call, in room 4200, New Senate Office Building, Senator Harrison A. Williams, Jr. (chairman of the subcommittee) presiding.

Present: Senators Williams, Smathers, Neuberger, Kennedy, Yarborough, Keating, and Fong.

Staff members present: William E. Oriol, professional staff member; Gerald P. Nye, minority professional staff member; Patricia Slinkard, chief clerk, and Marion Keevers, minority chief clerk.

Senator WILLIAMS. The subcommittee will come to order, please.

You know, we face the probability that this hearing must end at noon because of the debate that will begin in the Senate today on civil rights. Therefore, I am offering my opening statement for the record and will summarize some of the major points. We hope that the witnesses today will also feel free to do the same. We want to hear from all those scheduled because each witness has valuable information for this subcommittee.

To sum up, then, today our subcommittee continues its investigations of quacks, phony health products, and high pressure "cure factories" that offer attractive promises and heartbreaking results.

Much of our testimony will be concerned primarily with the need for consumer education effective enough to save lives that would otherwise be lost through modern, deadly techniques of quackery and fraud.

Our interest in consumer education was heightened at a hearing last month in San Francisco when we heard about promising local programs that expose cures and treatments for what they are. The California hearing also gave us additional information on enforcement problems. We will hear more about this, today, too, and also tomorrow morning.

### OPENING STATEMENT

SENATOR HARRISON A. WILLIAMS, CHAIRMAN

Today this Senate subcommittee continues its investigation of quacks, phony health products, and high-pressure "cure factories" that offer attractive promises and heartbreaking results.

Much of the testimony today will mark a turning point in our inquiry.

Until now the subcommittee had concerned itself primarily with enforcement problems faced by those who are trying to reduce the high cost of quackery in terms of human life, suffering, and financial loss.

We'll hear more about the inadequacies of existing law today and tomorrow. In fact, our second witness today is Food and Drug Commissioner George Larrick.

But we'll also hear much from witnesses who will discuss ways to help all citizens identify and combat quackery. In other words, we're trying to give at least as much attention to education as we are to enforcement.

One reason for our interest in consumer education is that several witnesses at our San Francisco hearing on quackery last month gave us specific information about effective, promising local programs.

Everybody, it seems, has been talking about education against quacks for years, and we all agree that it is a laudable objective. The witnesses in California have done more than praise education, however; they've put it to work.

Many other good ideas are also at work elsewhere in the Nation, and the time has come for us to nail down the best of these ideas and make them part of a structure.

President Johnson's pledge for broad action on consumer problems was of great interest to this subcommittee. I'm particularly glad, therefore, to welcome Mrs. Esther Peterson, Chairman of the President's Committee on Consumer Interests, as the first witness. Her presence here today leads me to believe that we're about to nail down some of these ideas while we develop new ones, too.

#### A \$38 BILLION MARKET

Our hearing on quackery and health frauds continues the work begun last year when the Senate Special Committee on Aging began its inquiry into major frauds and misrepresentations that victimize older Americans.

Three days of preliminary testimony gave us broad, dismaying insight into the magnitude and impact of these schemes.

We were shocked that so many Americans apparently do not have sufficient protection or information to be safe from salesmen of fraud, sorrow, and loss.

Some 18 million persons in this Nation are past retirement age. One recent estimate put their purchasing power at \$38 billion.

To the schemer in search of easy dollars, this is an irresistible lure. To the promoter who offers bogus health products or treatments, it is an especially lucrative field, even though his victims—men and women who need more medical treatment than other age groups—may be living on the dwindling savings of their lifetimes or on inadequate monthly pensions.

Although quacks are the worst of these promoters and pitchmen, we sometimes seem to regard them as comical folklore characters.

But they are all too real.

Several years ago, experts made an educated guess that quackery costs all consumers at least a billion dollars a year.

That estimate, I believe, is much too low. We don't know how bad the situation is because the quack has secrecy and the embarrassment of his victims on his side.

If we had economic losses of more than a billion dollars annually in any other part of our society, we'd cry out for action. Quacks take more than dollars, however. They sometimes prevent cure or the hope of cure.

I hope this hearing helps everyone understand the stakes that quacks are playing for.

They are large-scale merchandisers who use every modern method. They make mass mailings. They send salesmen from door to door. They advertise in high- and low-pressure ways.

They are bilking consumers, and so consumers must have facts to help them distinguish the reputable practitioner from the fraudulent one.

Since this is a subcommittee of the Committee on Aging, we are particularly concerned with the quackery problem as it affects our older consumers—the most victimized group of all. Older Americans will benefit if they and those around them have the facts to help them recognize quackery and health fraud for what they are.

#### CONCLUSION

If the Senate floor schedule permits, the next 2 days will bring this subcommittee far along in its investigation of quackery and health frauds.

We'll hear from Commissioner Larrick and others who have information on enforcement problems; we'll also hear from representatives of volunteer agencies, experts on consumer attitudes, the American Medical Association, the National Better Business Bureau, and others. We will also hear more about the most profitable health promotions of all—nutritional sales campaigns.

I'd also like to point out that the subcommittee is continuing staff investigations begun last October. We are inquiring into some mail order land sales, fraudulent or questionable investment plans, work-at-home projects, and other enterprises that affect the elderly.

The subcommittee is also cooperating with the health subcommittee in an investigation of claims made for some mail-order health insurance plans, and we are working with the Joint Subcommittee on Long-Term Care in its studies of nursing home conditions.

We have a full schedule in the next few months and at today's hearing, and so I think we had better begin.

We here are particularly honored, therefore, to welcome as our first witness, Mrs. Esther Peterson, chairman of the President's Committee on Consumer Interests.

I believe everybody knows your background, Mrs. Peterson, and the various responsibilities the President has called you to.

So, without further ado, please proceed. We, I know, will be enlightened.

STATEMENT OF MRS. ESTHER PETERSON, CHAIRMAN, PRESIDENT'S  
COMMITTEE ON CONSUMER INTERESTS

Mrs. PETERSON. Thank you very much, Senator Williams. I am delighted to have this opportunity to appear before the Subcommittee on Frauds and Misrepresentations Affecting the Elderly of the Special Committee on Aging. I wish to congratulate you for your very strong and vigorous role in bringing the attention of our citizens to the need for some corrections in this field.

In my capacity as Special Assistant to the President for Consumer Affairs, I am concerned, of course, with the myriad problems facing consumers of all ages and conditions.

Yet, I confess willingly to a special concern for our aged, whose capacity to resolve many of their problems independently is considerably less than that of our younger citizen-consumers.

The aging men and women in our society are becoming increasingly a more significant percentage of our total population. As their numbers increase, so also will the incidence of fraud and quackery increase. For these people, removed—as many of them are—from the mainstream of daily business activity, cut off from the stimulation of regular “back fence” exchanges with neighbors, become in their loneliness evermore susceptible to the blandishments of facile hucksters.

I receive daily in my office scores of letters from older people all over the country. The range of subject matter with which these people are concerned is broad and varied, but there has been a heavy emphasis on health frauds and quackery.

Many of the writers have despaired long since of any redress of their grievances; they want simply to share their disappointment, their sense of loss, with someone, with anyone who will offer a bit of understanding. I am tremendously impressed with this dread of loneliness that seems to run through so many of the letters and interviews with people as I run around the country.

Others of them, confident still that frauds and quacks will somehow be searched out and restrained, plead with the eloquence of age for the Government to take some kind of action against those who would victimize the weak and the innocent.

Perhaps I can best convey to you the depth of feeling of these people by quoting directly from a few of the letters they have sent me. These cover a broad range of anxieties. Not all of them derive from out and out fraud, or deception, but all do stem from situations which cry out for correction.

One of the most indefensible deceptions being practiced constantly against elderly people is that of mailing them, unsolicited, products ranging from Christmas cards to beds of flowers.

One woman here in Washington, a resident in one of our homes for the aged, wrote me in January. She complained that she is tired, and rightly so—“of receiving packages which I haven’t ordered and then when opened, find a bill inside.”

She wrote:

I returned such a package this morning. I carried (it) six blocks to the post office and had to pay 43 cents to return (it) because I’d looked into the package.

Many of the people in this home—  
she went on—

have received these boxes, and some were more astute than I. They sent the box back without opening it.

She concluded with a suggestion that I feel has merit. She asked whether these packages might be stamped on the outside by the sending company to the effect that the package contains merchandise to be paid for by the person addressed if opened. The incidence of misuse of the mails is probably not news to the members of this subcommittee. But I am aghast at the apparent extent of this particular abuse.

I have in my files scores of letters telling of failure on the part of manufacturers or distributors to fulfill the terms of their mail offers. In some of these cases the consumers suffered real hardship, and in all of them, considerable inconvenience and expense.

Some were plainly cases of mail fraud and were referred to the Post Office Department. Each of these letters relates an experience that is appalling, whether it was criminal or not.

Our elderly people depend heavily on mail order. They are frequently unable because of health, foul weather, or lack of transportation, to shop personally and to make comparisons in price. They must rely on the integrity of suppliers with whom they must, of necessity, deal only through the mails or by telephone.

Surely, the reputations of some of the large mail order houses and other organizations that operate mail order services warrant our respect. Over the years they have conducted their business always in an ethical manner.

Without demeaning their good names, therefore, some action is required to assure the American consumer, whether old or young, that he can deal confidently with any advertiser who purveys goods through the mails. Mr. Montague, in his testimony, will discuss efforts of the Post Office Department in their regard.

One type of quackery that is most repugnant to all of us, I believe, is that which feeds upon the fears of the aged who are ill. The hordes of medicines, "cures," devices, and treatments that quacks have perpetrated on the public are legion. Mr. George Larrick, Commissioner of the Food and Drug Administration, will deal with some of these in his testimony, I understand.

I should like, however, to mention one specific problem in this area which has caused a veritable flood of mail to my office. That is the matter of hearing aids. A widow in my home State of Utah, 66 years old, writes:

I can't hear a word without my hearing aid. This hearing aid graft is the worst thing in the United States. This is nothing but highway robbery.

A California pensioner points to a hearing aid costing \$298 while she lives on a total income of \$201 per month.

From Monroe, Mich., the rising cost of hearing aid batteries was described to me in a letter from an elderly person who gives me her \$103 per month budget and asks how she can continue to make time payments on her hearing aid, buy batteries, and still subsist.

But I think the most vicious aspect of the hearing aid question, separate and aside from pricing and financing, is the deceitful approach taken by too many sharp operators in this field. There is no question that cynical advantage is often taken of the elderly here.



For example, a New York woman wrote a carefully documented account of this kind of operation.

Outside of New York, advertising of various hearing aid firms is done in such a way as to imply philanthropic and medical background. "Community Hearing Clinic" is an example. If you file a request for (a sample advertised) you will get a salesman.

This salesman has with him a device which tests the range of your hearing. He is not a medical man, but he will tell you that your hearing trouble cannot be helped by an operation. My own physician of many years had some time ago told me I was developing otosclerosis and would eventually need a hearing aid. One salesman told me this was "nonsense."

He said no doctor could see enough of the ear to make such a diagnosis. Each of the two salesmen I saw recommended hearing aids for both ears, costing \$600. I was examined by a real nonprofit clinic and told my hearing loss was only 30 percent (in one ear) and one was ample.

This woman, an exception to judge by my mail, evaded the gyp artists. But in her same letter, she goes on to describe an elderly friend who was talked into a special hearing device for her television for \$600 and a new hearing aid for \$700.

Too often, the replacement of batteries is a burdensome expense. As one deaf pensioner in the State of Washington wrote, a new hearing aid would cost \$300. To send his present hearing aid back to the factory for repair would cost about \$50. Both alternatives were out of the question for him. His more realistic concern was that the cost of batteries had risen from 15 cents to 45 cents.

There was one letter on hearing aids that came in just Saturday, that I would like to read from. The woman writes:

Are the prices fair profit over their cost of production, or is this an outrageous racket? Has an investigation already been made? What is a fair profit? What is the actual cost of production per aid?

She bought a certain model about a month ago, paid \$210 and since then it has required \$12.84 worth of batteries to operate it, and this for only part-time use. All through the letters she mentions the cost of batteries, but, the following intelligent paragraph was particularly touching:

I can see this amount of money spent on a beautiful watch with its intricate and delicate works \* \* \* or on a piece of furniture, or on a TV set \* \* \*. But a hearing aid made of plastic with no machinery, depending only on batteries that cost extra, is something I am too stupid to understand. \* \* \* Who is fleecing us, if it is fleecing? And what can be done about it? I shall appreciate a satisfactory answer. I think I have intelligence enough to understand and accept the truth.

We do know this is a complicated area, but I have stacks of letters that are constantly asking about this cost. One grandma wrote and said:

My little boy who works with transistor radios has taken apart one of these plastic things, and said, "Grandma, I can't see how it costs this much. If I had a transistor cell, maybe I could make one for you.

This is worrying people, and hearing aids are such indispensable items to those who need them. So these schemes that victimize all consumers are especially bad for the elderly. I know it is difficult to understand or appreciate the truly vital importance these aged people attach to making each and every penny count. Yet, that is the case.

The witnesses from the Food and Drug Administration and from the Post Offices will supply you with many specific examples of cases

they have handled, graphically demonstrating just how fraud and deceit zeros in on those least able to cope, the elderly and retired.

But let me just list for you if I may a few fraud areas that are particularly vicious when the victimized consumer is an elderly pensioner.

Swindlers lure victims to invest in vending machines on the false representation that arrangements have been made for their installation in profitable locations.

The Federal Trade Commission has clamped down on the advertising of a vitamin preparation which claimed to overcome tiredness and loss of happiness, after finding that the chances are 10 to 1 that persons suffering from the symptoms described would not be victims of vitamin deficiency.

A variety of work-at-home schemes, falsely promising easy supplementary income and often requiring substantial investment in equipment bilk many elderly persons.

A food product advertiser is under charges that his product falsely claims to prevent arthritis and rheumatism. The tragedy of products such as this is in draining limited funds and often valuable time which could be well used in ethical treatment.

Land frauds play especially on the elderly, as you know, as do some shady savings and loan operators, food faddists, and gyp artists. And I might add at this point that our agencies with the authority they now have, are doing a remarkable enforcement job, by and large. But I expect and insist that where we find gaps, State or Federal, calling for additional legislative authority, we will speak out in a loud and clear voice for a remedy.

One of the major objectives of the President's Committee on Consumer Interests' upcoming regional conferences will be to identify these gaps. The letters coming to me leave no doubt in my mind that elderly consumers have a story to tell that will shed much light on the particular problems they face as consumers. We plan to pay particular attention to insure that our elderly consumers will have a ready forum to make known their problems.

At the same time, we hope to bring to all consumers, old and young alike, the best information available from business, government, and other experts on the services and protections already available to them.

This committee, as well, is performing a needed function in spotlighting the special problems the elderly have. While many of the fraud schemes you will be examining do cut across age groups, their particularly easy target is the aged.

When President Johnson announced my appointment to this new consumer post in January, he charged me with paying particular attention to four key rights of every consumer, first enunciated by President Kennedy: The right to safety, the right to be informed, the right to choose, the right to be heard.

And certainly, Senator Williams, you have placed it very firmly in mind when you say education is needed. I feel if we can have informed citizens, they can act intelligently and wisely.

In each of these areas, the elderly are handicapped. Their choice is severely limited by static income; their safety is more precarious because of the infirmities of age; their access to information is curtailed by their isolation from the give and take of daily business life; and their right to be heard suffers the more from that isolation.

Really, elderly consumers ask no more than their more youthful counterparts, except that we take into account their special handicaps in the marketplace as I have noted. They only ask that they be permitted to live out their lives in dignity and honor, with justice.

I know you agree with me that we owe them our respect and the fruits of our joint labor to assure that their special rights as American consumers will be protected, and I know that the work of your committee will do a great deal toward achieving that goal.

Thank you.

Senator WILLIAMS. Thank you very much, Mrs. Peterson. We hope that we are contributing to the pool of information on the frauds, indeed the quackeries, that are being perpetrated on elderly people. Out of this pool of information we can find effective ways to educate, to let people know what is being done and what wrongs are being perpetrated.

I certainly appreciate your statement.

Mrs. PETERSON. Thank you for giving me the opportunity to appear.

Senator WILLIAMS. I wonder if any of our friends here on the committee have any questions.

Senator NEUBERGER?

Senator NEUBERGER. No, thank you.

Senator WILLIAMS. Senator Kennedy?

Senator KENNEDY. No, thank you.

Senator WILLIAMS. Senator Fong?

Senator FONG. Mrs. Peterson, in your position as chairman of the Committee for Consumers, what are you doing?

Mrs. PETERSON. We are going to conduct a good, broad information program. As much as we can, we will work with the Federal Trade Commission, the Post Office Department, and others. A great deal of our work is education, and we are now studying very carefully with the appropriate agencies what needs to be done. You know we are supporting legislation that was outlined in the President's consumer message to Congress, and we think that enactment of these measures will help a good deal. Of course, we are new, but we seek to fill in the gaps, and to see that the laws and the power we do have is used to the fullest. We seek to give information, and I feel, in a way, that education and information are the best ways we can get people to understand the tricks that are involved. So, a tremendous education program is needed.

Use of that authority that the Government has, and determining what legislation we need to close the gaps, are the main areas.

Senator FONG. So, your committee is studying this problem?

Mrs. PETERSON. Yes. We are, of course, working through the agencies. The President's Committee on Consumer Interests did meet on this. They endorsed this program, and have a subcommittee working on this question, and on how they can be helpful.

Senator FONG. Your committee studies the problems of aging?

Mrs. PETERSON. Yes, we have just had our first meeting.

Senator FONG. How big is that? How big is your staff?

Mrs. PETERSON. The committee is about 22. We have the council members that were reappointed by President Johnson to fill out their terms, plus the 10 Government members who represent the agencies largely involved with consumer affairs.

Senator FONG. What kind of a staff have you?

Mrs. PETERSON. We are now just in the process of formulating the staff. We will have a modest staff, I think around five professionals and enough supporting clerical people to make this effective.

Senator FONG. What will be the expenses of that staff?

Mrs. PETERSON. It will be again, a modest amount. This is being worked out by the White House. It will be enough to take care of a professional staff of about five, plus the clerical help.

Senator FONG. Thank you.

Senator WILLIAMS. Senator Keating?

Senator KEATING. I was interested in your statement and certainly agree that this quackery cuts across age lines well illustrated by the advertisement I read in the morning paper by the Coordinating Committee for Fundamental Freedoms, Inc. If I ever saw a piece of quackery, that is it. It does not have anything to do with your efforts; it is something we will have to deal with in the Congress.

Mrs. PETERSON. That is correct, Senator.

Senator KEATING. I had a letter the other day from a concern—I don't know why they wrote me, a young fellow like me—but they said, you can take 5 years off your life if you eat a pound of this stuff every day, and 10 years if you eat 2 pounds. I guess that is the type of thing that we are talking about here.

Mrs. PETERSON. It is.

Senator NEUBERGER. Mr. Chairman, I would like to comment on what Senator Keating has said. Does this say "you can" add 5 years to your life by using this product?

Senator KEATING. Add five to your life.

Senator NEUBERGER. I don't think we need to be very worried about that. The Surgeon General's report on smoking and health has said the same thing about ceasing the use of tobacco.

Senator KEATING. I meant take off from your age, really. But I do want to ask you, Mrs. Peterson, are you and your committee doing anything regarding this smoking hazard that Senator Neuberger has referred to?

Mrs. PETERSON. We have not moved in on this; we discussed it very briefly. Our agenda is long, and since this is really being handled very well and is receiving a great deal of attention, and since we felt there are so many areas where the consumer is directly affected that are not receiving attention, the committee decided not to go into this at this time.

If I would be excused, may I tell about one of the cigarette letters I received which is very interesting.

A person sent me an advertisement for a certain brand of cigarettes, and the lady said that the advertisement said if she smoked one pack a day of this brand of cigarettes for 150 years she could get a mink stole. If she smoked one pack a day of this brand of cigarettes for 50-something years, she could get a St. Bernard dog.

"Of course," she said, "I know St. Bernard puppies will be around in 50 years but will brand X cigarettes still be around? If I smoked two packs a day, in order to get these gifts sooner I'd only get cancer.

There is a great deal of interest in the mail that is coming through on this.

Senator FONG. Mrs. Peterson, outside of the question of puffing up the value of the article that has been sold, do you have recourse to these people through the misrepresentation statute of the State?

Mrs. PETERSON. Of course, we need to inform our people where they can go for help, and on those recourses that already exists. We want to use fully the power and authority that already exists.

Senator FONG. Actually, what we are after now is to educate the people so they will know where to go?

Mrs. PETERSON. And to see if there are any gaps—if there are areas where we do not have sufficient authority to correct the difficulties that exist.

Senator FONG. Thank you.

Senator WILLIAMS. Thank you very much, Mrs. Peterson.

We now are honored to have George Larrick, Commissioner of the Food and Drug Administration, who is accompanied by Dr. Martin Dobelle, medical officer, Device Branch, Bureau of Medicine of the FDA, and Mr. Kinslow, I believe, is with you, Commissioner Larrick, and we certainly are surrounded by devices here.

**STATEMENT OF GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS; ACCOMPANIED BY DR. MARTIN DOBELLE, MEDICAL OFFICER, DEVICE BRANCH, BUREAU OF MEDICINE; AND MAURICE KINSLOW, STAFF ASSISTANT FOR LEGISLATION, FOOD AND DRUG ADMINISTRATION**

Mr. LARRICK. Thank you very much. It is particularly gratifying to a bureaucrat who is interested in the consumer welfare to see such legislative interest in this field and to see top administration interest in this field. In compliance with your request, Mr. Chairman, I will omit certain portions of my prepared statement and file a copy for the record.

Last year when we appeared before this committee we outlined very briefly the scope of our operations in the Food and Drug Administration.

We noted that our operations are designed to safeguard consumers and, therefore, all have a bearing on the health and welfare of elderly people. However, the aging folks are particularly susceptible to three types of quackery.

During the past year, since we met with the full committee, there has been significant progress in improving our ability to deal with cheats against the elderly in each of these three fields. However, lest the report we present to the committee paint an unduly optimistic picture of achievement, it is only fair to point out that we are also faced with some very pressing problems and there are limitations on what we can accomplish.

On January 24 of this year, a landmark decision was handed down by the U.S. district court in Trenton, N.J., in a contested seizure involving this product I have here. In this action some 900 packages of Vitasafe Capsules and over 3,700,000 pieces of printed material (labeling, as defined by the statute), designed to promote the sale of the products were seized. The Vitasafe formulas were mixtures of numerous ingredients promoted for the treatment of many health

conditions for which they are not effective. The label of this Vitasafe package bears the innocuous statements "Food Supplement—for Dietary Purposes Only," "Average Dosage for Adults: One CF capsule daily," and a statement of "Ingredients in Each Capsule", of which 16 of the 25 listed ingredients are marked "minimum daily requirement not yet established" or "need in human nutrition has not been established." This information is misinterpreted by accompanying circulars.

As you all see here, one attractive picture is entitled, "Important Message to Men and Women over 40."

The next picture goes on and says, "Our Fights Have Turned to Kisses."

The tone of the advertising addressed particularly to people past middle life follows that theme.

In testifying concerning the meaning of this material Dr. Godfrey M. Hochbaum, Chief of the Behavioral Science Section of our U.S. Public Health Service stated:

\* \* \* I believe that this kind of material would arouse the interest of many people who suffer from real or imaginary complaints, these vague variety of complaints such as tiredness, nervousness, real or imaginary, sexual impotence, marital problems, and so forth, because many of these people with little education who are very naive cannot identify the causes of their difficulties, and because they cannot \* \* \* they look for some magic formula, something that will change their lives and satisfy all their needs and remove their frustrations, this with the real hope that this would provide a solution to their problems. And everything in here is in the form that would appeal to exactly this kind of people, attract these kinds of readers.

In its ruling that the product violated the law the court ordered it destroyed. Our summary of the court's lengthy decision is that:

(1) The labeling representation that the capsules are an adequate and effective treatment of or preventive for a host of symptoms and conditions including aging, impaired digestion, night blindness, and impotence is false and misleading and represents a danger to health when a person having one or more of these listed symptoms resorts to the product as a cure and thereby fails to obtain competent medical help to correct his physical impairment.

(2) The implication that minute quantities of ingredients listed in the products labeling are of nutritional significance or enhance the products nutritional value is likewise false and misleading.

(3) The labeling suggestion that it is necessary to eat enormous quantities and varieties of foods to obtain equivalent vitamins and minerals is false and misleading.

The reference to this decision is civil action No. 875-60. I give the citation so that anyone who wishes to see the decision in its entirety can do so.

We consider this a very important up-to-date opinion regarding how far a manufacturer can go in making claims for vitamin and mineral products. The decision, we believe, points the way for future activities and lends much support to changes in the dietary food regulations such as those we proposed in 1962. It is especially significant in our evaluation of the numerous comments we received about the proposals.

We have continued to combat frauds by enforcement actions. With your permission, Mr. Chairman, I submit for the record a tabulation

showing the enforcement actions that have been terminated in the Federal courts during calendar year 1963 against devices and food supplements which have particular appeal to the aged. (See p. 204.)

There were also a number of actions concluded against drug products during 1963. We will, if you wish, prepare a similar tabulation for drugs if the committee so desires. We will not take your time to discuss all of these actions, but believe a brief summary is interesting.

Over the past 25 years the Electronic Instrument Co., Inc., and L. L. Roby Manufacturing Co., both of Tiffin, Ohio, engaged in the manufacture and widespread promotion of expensive but completely worthless devices, such as the ones we have with us. These devices are over on our left here in the committee room.

These were offered for the diagnosis and treatment of virtually all diseases. These large and complex electrical contraptions were sold at prices up to \$1,200 each to fringe practitioners who used them on young and old alike, but particularly on old people.

A series of seizures beginning early in the 1950's seemed to have no effect on the manufacturer. Subsequently, however, in 1962, the Electronics Instrument Co., Inc., was put out of business by a permanent injunction issued by the U.S. district court at Toledo, Ohio, in a case brought under the pure food law.

In 1963 a similar injunction action was granted against Lester L. Roby, Sr., and Lester L. Roby, Jr., a father and son team operating under the names of L. L. Roby Manufacturing Co. and "International Electronics Research Society Inc." Although no bona fide research work was ever done, the latter impressive name was used as a vehicle to carry their promotions in pseudo-scientific medical terminology.

The elder Roby had been associated in the past with the Electronics Instrument Co. The 1963 injunction decree enjoined the Robys and their firms from further distribution for commercial purposes of the four major devices at the side of the room.

In those instances where trusting patients were suffering from serious degenerative diseases while relying upon such gadgets for diagnosis or treatment, one can readily visualize the tragic results. Mr. Kinslow can, if you wish, tell you more about these individual machines.

The Magnetron is another electrical device promoted for a number of chronic infirmities including arthritis, varicose veins, prostate trouble, and heart trouble. The device consists of a wooden cabinet with a transformer, a rheostat, condensers and electrodes, totally devoid of any medical value. Yet its promoter, Dr. Peter Pauls, of Lewiston, Idaho, sold many of them for \$197.50 each.

An example of misrepresentation of vitamin products promoted to elderly people is "Arlan's Geriatric Vitamins" shipped by the Lit Drug Co., of Newark, N.J. The name of the product unwarrantedly suggests and implies that it is of unusual value as a special dietary supplement for use by the elderly because their nutritional requirements are different from adults generally. Our examination of the tablets also showed that some failed to disintegrate and thus would not permit adequate assimilation of the tablet nutrients.

The 1963 Congress program explored why people are vulnerable to medical quackery and featured methods of trying to combat it through health education and the media of public communications. Executives from radio, television, newspapers, magazines, book publishers, and advertising agencies participated in a panel which discussed means of curtailing medical quackery and promoting the dissemination of sound health education to the public. We believe this meeting will stimulate greater emphasis on health education as a means of dealing with the problem.

When we discussed our educational activities before the full committee last year, we mentioned a pamphlet then in process which listed a number of common types of cheats and swindles in the health field to which our older citizens particularly fall prey. The booklet has now been completed and is entitled, "Your Money and Your Life." We have a copy we will leave with the committee.<sup>1</sup>

I will add that negotiations are now underway, in cooperation with the American Optometric Association, to issue this item in an "Easy Vision" edition for the aging with impaired sight. Further negotiations are underway with the Division of the Blind, Library of Congress, to put out "Your Money and Your Life" and other FDA material as talking books for the sightless.

This exploration of pioneering techniques is part of recently increased FDA activities in bringing sound consumer education to the aging. A specialist in informational materials for the aging coordinates our programs in this field. Part of FDA's participation in Senior Citizens Month in 1963 included the issuance of three consumer memorandums especially addressed to the aging. These three have been among the most popular consumer memos we have ever issued. We plan to issue three more consumer memorandums for the aging in May 1964, which will be part of a larger informational kit.

In his consumer message, as Mrs. Peterson just remarked, President Johnson recommended amendment of the Federal Food, Drug, and Cosmetic Act to require that all therapeutic, diagnostic, and prosthetic devices be proved both safe and effective before they may be marketed.

Senator Lister Hill has introduced S. 2580 and Congressman Oren Harris has introduced H.R. 6788, which would carry out the President's recommendation on devices as well as achieving other consumer protection improvements. The proposed device amendment is of particular significance to older consumers because, as we noted earlier, they are most frequently the victims of those who promote quack devices.

The new device clearance system would operate in much the same manner as the new drug procedure now works. The sponsor of a new device would be required to furnish for the Government's evaluation and approval sound scientific evidence that the device is both safe and effective for its recommended uses before it can be marketed.

This would enable the Government to give the consumer the protection he deserves by requiring uncleared devices to come off the market promptly. Under present law a device may be sold with impunity until the Government is able to accumulate evidence to prove in court that the device is unsafe or will not do what is claimed in its labeling.

<sup>1</sup> For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402. Price 10 cents.



Not only is this proposal significant because the aging are victimized by quack devices but also because there are many medical devices used extensively by surgeons and other medical specialists in treating older people. These include artificial hip joints, pins and nails used in repairing fractured bones.

There is now no requirement that these devices be manufactured in such a way as to insure that they are safe or effective when used in the operating room. To illustrate the problems this causes we have with us some medical devices which have had to be removed from elderly patients because they were unsafe or ineffective or both.

(Transcript text continued on p. 182.)

PREPARED STATEMENT BY GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS

Mr. Chairman, it is a pleasure to appear before this committee to discuss the activities of the Food and Drug Administration aimed at protecting our senior citizens, including enforcement actions, and shortcomings in our present authority to deal with problems in this area. Last year when we appeared before the full committee we outlined briefly the scope of our operations. We noted that all of our activities are designed to safeguard consumers and therefore all have a bearing on the health and well-being of elderly people. However, the aging are particularly susceptible to three types of quackery.

The first type involves worthless therapeutic or diagnostic devices which are represented as preventing, curing, or diagnosing ailments to which we are all subject as we advance in years. The second type involves vitamins and nutritional supplements which are unscrupulously misrepresented as being of special value to the aged. The third is medical quackery which includes drug products that are ineffective in treating chronic or degenerative diseases but which are promoted by extravagant claims.

During the past year since we met with the full committee there has been significant progress in improving our ability to deal with cheats against the elderly in each of these areas. However, lest the report we present to the committee paint an unduly optimistic picture of achievement it is only fair to point out that we are faced with some very pressing problems and there are limitations on what we can accomplish.

On January 24, 1964, a landmark decision was handed down by the U.S. district court in Trenton, N.J., in a contested seizure involving this product I have here. In this action some 900 packages of Vitasafe Capsules and over 3,700,000 pieces of printed material (labeling) designed to promote the sale of the products were seized. The Vistasafe formulas were mixtures of numerous ingredients promoted for the treatment of many health conditions for which they are not effective. The label of this Vistasafe package bears the innocuous statements "Food Supplement—For Dietary Purposes Only," "Average Dosage for Adults: One CF capsule daily," and a statement of "Ingredients in Each Capsule," of which 16 of the 25 listed ingredients are marked "minimum daily requirement not yet established" or "need in human nutrition has not been established." This information is misinterpreted by accompanying advertising circulars. This picture bearing the caption "Important Message to Men and Women Over 40" depicts an obviously healthy, happy married couple. Another picture shows a couple in fond embrace and is captioned "Our Fights Have Turned to Kisses." A number of others dealing with apparently solved marital problems are similarly portrayed.

In testifying concerning the meaning of this material Dr. Godfrey H. Hochbaum, Chief of the Behavioral Science Section of the Public Health Service stated.

"\* \* \* I believe that this kind of material would arouse the interest of many people who suffer from real or imaginary complaints, these vague variety of complaints such as tiredness, nervousness, real or imaginary, sexual impotence, marital problems, and so forth, because many of these people with little education who are very naive cannot identify the causes of their difficulties, and because they cannot \* \* \* they look for some magic formula, something that will change their lives and satisfy all their needs and remove their frustrations, so they turn to something like this with the real hope that this would provide a solution to their problems. And everything in here is in the form that would appeal to exactly this kind of people, attract these kinds of readers."

In its ruling that the product violated the law the court ordered it destroyed. Our summary of the court's lengthy decision is that—

(1) The labeling representation that the capsules are an adequate and effective treatment of or preventive for a host of symptoms and conditions including aging, impaired digestion, night blindness, and impotence is false and misleading and represents a danger to health when a person having one or more of the listed symptoms resorts to the product as a cure and thereby fails to obtain competent medical help to correct his physical illness.

(2) The implication that minute quantities of ingredients listed in the product's labeling are of nutritional significance or enhance the product's nutritional value is false and misleading.

(3) The labeling suggestion that it is necessary to eat enormous quantities and varieties of foods to obtain equivalent vitamins and minerals is false and misleading.

The reference to this decision is civil action No. 875-60, U.S. district court, district of New Jersey, opinion dated January 24, 1964. We consider this a very important up-to-date opinion regarding how far a manufacturer can go in making claims for vitamin and mineral products. The decision points the way for future activities and lends much support to changes in the dietary food regulations such as those we proposed in 1962. It is especially significant in our evaluation of the numerous comments we received about the proposals.

The new requirement in the Kefauver-Harris Drug Amendments of 1962 about the truthful advertising of prescription drugs will be of significant value to elderly people as well as others. The beneficial effects of this portion of the new amendments increasingly will be felt as increases in staff, money, and facilities are available for our Bureau of Medicine and enforcement staff to deal with the heavy workload stemming from these provisions.

Another major advance brought about by the Kefauver-Harris amendments is that new drugs must now be proved effective as well as safe before they may be marketed. Further, drugs allowed on the market before the amendments solely on a showing of safety will under the terms of the amendment become subject to the effectiveness requirement on October 10, 1964. We recently published proposed regulations implementing this requirement.

We have continued to combat frauds by enforcement actions. With your permission, Mr. Chairman, I submit for the record a tabulation showing the enforcement actions that have been terminated in the Federal courts during calendar year 1963 against devices and food supplements which have particular appeal to the aged. There were also a number of actions concluded against drug products during 1963. We will prepare a similar tabulation for drugs if the committee so desires. In summary there were 23 seizures of food supplements and 24 seizures of therapeutic devices; 4 prosecutions of firms that promoted foods illegally and 2 injunction actions to restrain unwarranted promotion of therapeutic devices and foods. We will not take your time to discuss each of these actions but I do think you will be interested in a brief comment on a few of them.

Over the past 25 years the Electronic Instrument Co., Inc., and L. L. Roby Manufacturing Co., both of Tiffin, Ohio, engaged in the manufacture and widespread promotion of expensive but completely worthless devices, such as the ones we have with us. These devices were offered for the diagnosis and treatment of virtually all diseases. These large and complex electrical contraptions were sold at prices up to \$1,200 each to fringe practitioners who used them on young and old alike.

A series of seizures beginning early in the 1950's seemed to have no effect on the manufacturer. Subsequently, however, in 1962 the Electronics Instrument Co., Inc., was put out of business by a permanent injunction issued by the U.S. district court at Toledo, Ohio.

In 1963 a similar injunction action was granted against Lester L. Roby, Sr., and Lester L. Roby, Jr., a father-and-son team operating under the names of L. L. Roby Manufacturing Co. and "International Electronics Research Society, Inc." Although no bona fide research work was ever done, the latter impressive name was used as a vehicle to carry their promotions in pseudoscientific medical terminology. The elder Roby had been associated in the past with the Electronics Instrument Co. The 1963 injunction decree enjoined the Robys and their firms from further distribution for commercial purposes of the four major devices before you, which had been sold as the "Electronic Magnetic Model G," "Radioclast Model 40," "Auto-Electronic Radioclast Model 20," and the "Electronic Analysis Instrument Model F." They were also further enjoined from making false claims about a fifth device known as the "Electro-Sine Galvanic Model 200" (figs. 1, 2, and 3).

FIGURE 1.—Electronic analysis, model F.

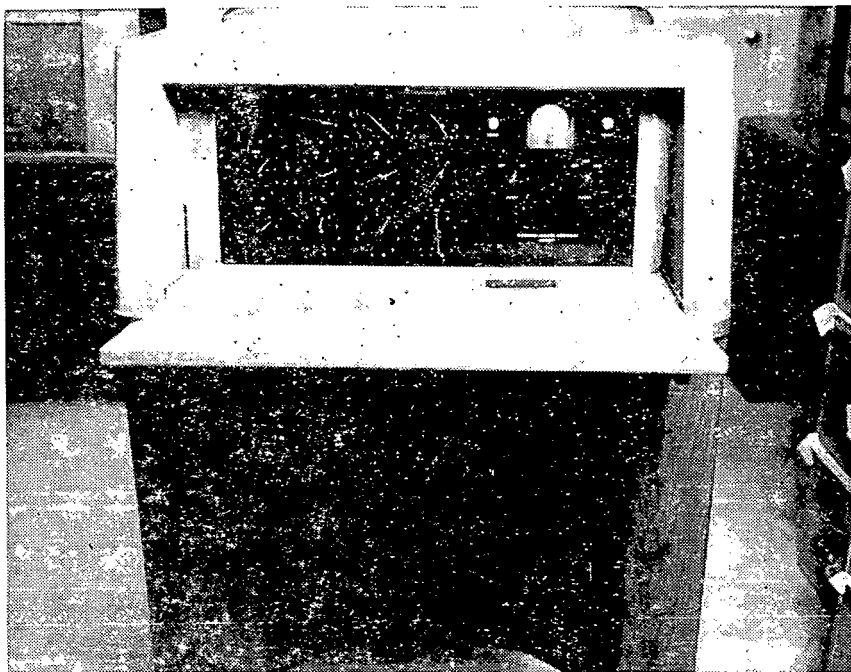


FIGURE 2.—Electronic magnetic, model G.

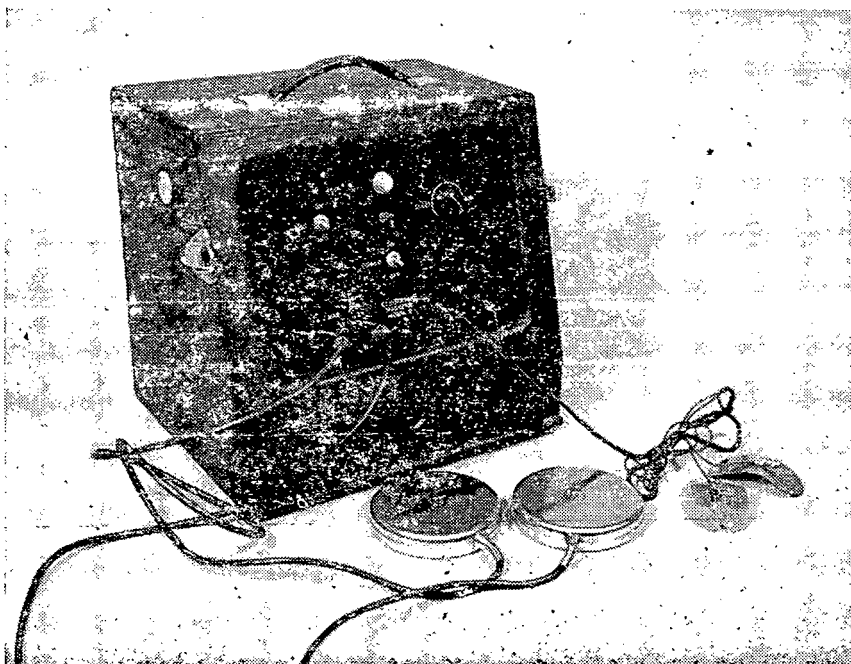
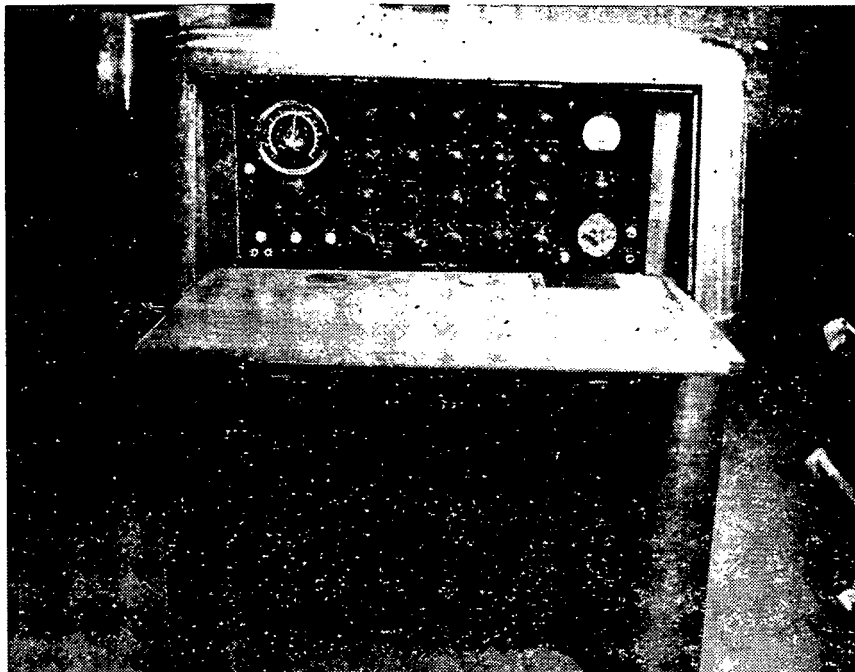


FIGURE 3.—Radioclast, model 40.



In those instances where trusting patients were suffering from serious degenerative diseases while relying upon such gadgets for diagnosis or treatment, one can readily visualize the tragic results.

The magnetron is another electrical device promoted for a number of chronic infirmities including arthritis, varicose veins, prostate trouble, and heart trouble. The device consists of a wooden cabinet with a transformer, rheostate, condensers, and electrodes, totally devoid of any medical value. Yet its promoter, Dr. Peter Pauls, D.O., of Lewiston, Idaho, sold many of them for \$197.50 each.

As a result of proceedings brought because of the shipment of this device in 1962 to two men over 70, the manufacturer discontinued interstate business but has set up two separate assembly plants from which distribution is limited to the States of production. We learned of this subterfuge in 1963.

A final example of a misbranded device intended for use by the elderly seized during 1963 is the leg rejuvenator. This is basically an elevated foot rest, which was distributed with false and misleading claims for easing heart strain, giving a lift to your heart, improving blood circulation, and reducing leg swelling. On August 5, 1963, a default decree was entered by the U.S. district court, district of Massachusetts providing for destruction of the device.

An example of misrepresentation of vitamin products promoted to elderly people is "Arlan's Geriatric Vitamins" shipped by Lit Drug Co., Newark, N.J. The name of the product unwarrantedly suggests and implies that it is of unusual value for special dietary supplementation by the elderly because their nutritional requirements are different from adults generally. Our examination of the tablets also showed that some failed to disintegrate and thus would not permit adequate assimilation of the tablet nutrients.

During 1963 we seized some 20,000 of these tablets on charges that they were adulterated and misbranded under the act. On September 12, 1963, a consent decree of condemnation and destruction was entered by the U.S. district court at Detroit and the tablets were destroyed.

In addition to these enforcement activities the FDA has engaged in other projects during the past year which strengthen programs that protect the elderly. In October 1963, FDA cosponsored with the American Medical Association the Second National Congress on Medical Quackery. The first congress in 1961,

which we discussed last year, emphasized the nature and extent of the problem. The 1963 congress program explored why people are vulnerable to medical quackery and featured methods of combating it through health education and the media of public communications. Executives from radio, television, newspapers, magazines, book publishers, and advertising agencies participated in a panel which discussed means of curtailing medical quackery and promoting the dissemination of sound health knowledge to the public. We believe this meeting will stimulate greater emphasis on health education as a means of dealing with this problem.

This exploration of pioneering techniques is part of recent increased FDA activity in bringing sound consumer education to the aging. A specialist in informational materials for the aging coordinates our programs in this field. Part of FDA's participation in Senior Citizens Month in 1963 included the issuance of three consumer memorandums especially addressed to the aging. These three have been the most popular consumer memorandums we have ever issued. We plan to issue three more consumer memorandums for the aging in May 1964, which will be part of an informational kit.

In his consumer message, President Johnson recommended amendment of the Federal Food, Drug, and Cosmetic Act to require that all therapeutic, diagnostic, and prosthetic devices be proved both safe and effective before they may be marketed. Senator Lister Hill has introduced S. 2580 and Congressman Oren Harris has introduced H.R. 6788 which would carry out the President's recommendation on devices as well as achieving other consumer protection improvements. The proposed device amendment is of particular significance to older consumers because, as we noted earlier, they are frequently the victims of those who promote quack devices. The new device clearance system would operate in much the same manner as the new drug procedure now works. The sponsor of a new device would be required to furnish for the Government's evaluation and approval scientific evidence that the device is both safe and effective for its recommended uses before it could be marketed. This would enable the Government to give the consumer the protection he deserves by requiring uncleared devices to come off the market promptly. Under present law a device may be sold with impunity until the Government is able to accumulate evidence to prove in court that the device is unsafe or will not do what is claimed in its labeling.

Not only is this proposal significant because the aging are victimized by quack devices but also because there are many medical devices used extensively by surgeons and other medical specialists in treating older people. These include artificial hip joints, and pins and nails used in repairing fractured bones. There is now no requirement that these devices be manufactured in such a way as to insure that they are safe or effective when used in the operating room. To illustrate the problems this causes we have with us some medical devices which have had to be removed from elderly patients because they were unsafe or ineffective or both.

This is a hip prosthesis which had to be removed from an aged patient because it broke due to faulty design plus a defect in manufacture. In addition, the stainless steel used is not the type which will remain inert in the body and ultimately sets up a reaction which causes severe infection (fig. 4).

Here is another prosthesis of the same type which had to be removed because of tissue reaction resulting from inferior material which ultimately rusted within the body.

We also have a similar device made of another material which destroyed the hip joint in an elderly woman within about 4 months after it had been inserted. The material is not biologically inert but had not been tested by the manufacturer to determine this before its introduction to the market and widespread use. Consequently, electrolysis causing severe infection resulted.

Here are 23 artificial eyes that were removed from predominately elderly patients because material defects, poor quality material, or poor design caused severe tissue reaction resulting in serious infections (see fig. 5).

And finally, Mr. Chairman, we have here eight different types of hip pins received just 1 week ago which have been removed from elderly patients within the past 2 years by a single surgeon because they are made of improper metal which is not biologically inert and resulted in severe infection, abscess formation, pain, and ultimately necessitating additional major surgery for the removal. The same surgeon also included four different defective bone screws which caused the same complications. This represents a total of 24 cases where

FIGURE 4.—Defective hip and bone prosthesis.

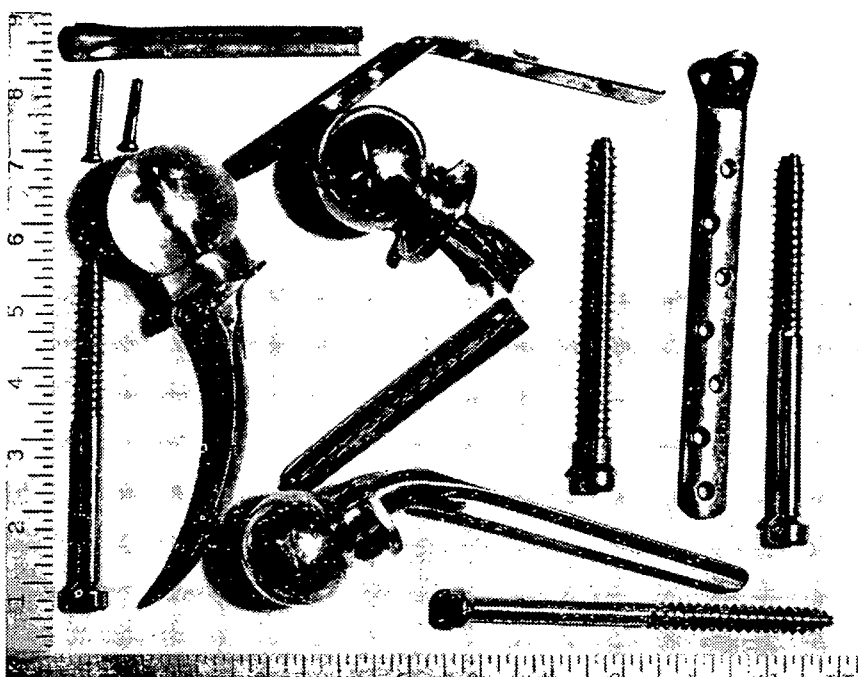
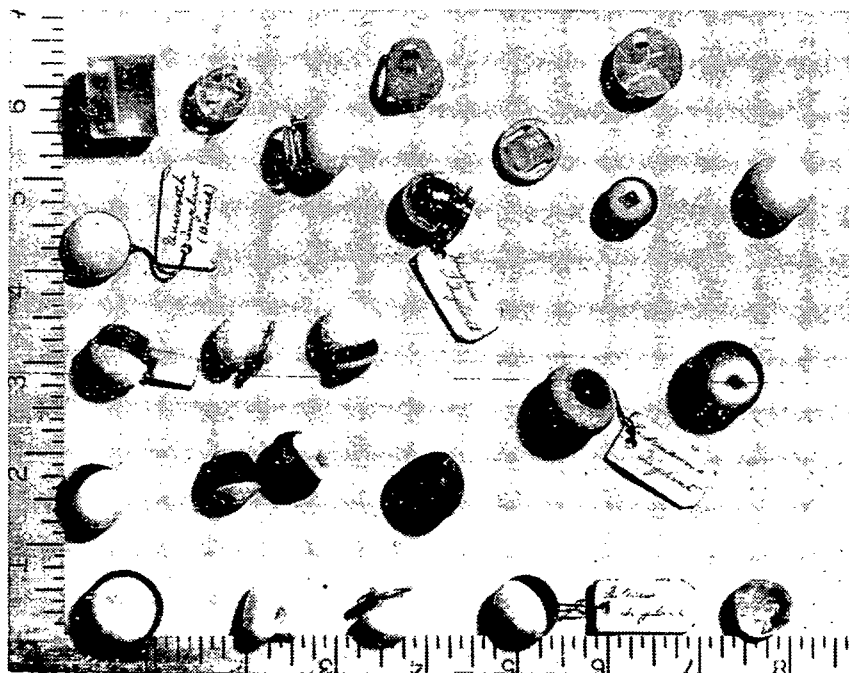


FIGURE 5.—Artificial eyes shown by Dr. Dobelle.



needless pain and suffering, reoperation, prolonged hospitalization, and expense occurred because defective devices were used in treating aged persons.

I believe this illustrates the need for the passage of the pending legislation.

Mr. LARRICK. As the chairman announced, I have with me this morning, Dr. Dobelle, who is a very distinguished orthopedic surgeon in his own right, a member of all of the specialized societies that skilled surgeons belong to, and whom we are proud to have as a member of the Food and Drug Administration team. I am going to ask him to briefly tell you about some of these devices.

Senator NEUBERGER (presiding). Dr. Dobelle, we are pleased to have you.

Senator KEATING. That didn't all come out of one person, did it?

Dr. DOBELLE. No, sir.

#### STATEMENT OF DR. MARTIN DOBELLE, MEDICAL OFFICER, DEVICE BRANCH, BUREAU OF MEDICINE, FDA

Dr. DOBELLE. All of these devices have been surgically applied to predominantly elderly patients to hold together a broken hipbone during nature's period of healing.

These prostheses were used because the bone had so greatly shattered that an attempt to jigsaw the pieces of bone together would not be good surgical judgment as a poor end result would be expected. Yet, in every instance reopenings had to be performed for their removal and in many of the instances a third and fourth operation for reconstruction followed.

This hip prosthesis was manufactured without the benefit of engineering or biological research. One has to but weigh it in his hands to appreciate the excessive weight of the head and neck of the device as compared with the frail weight of the shaft.

This created a tremendous shearing force with a weight imbalance at the point where the device broke. To add further insult to the metal, a manufacturing defect was present when sold for use as a prosthetic implant as evidenced by this smooth area and along with it, the type of stainless steel used was not biologically inert.

We have this area here which was an obvious defect at the time it was sold as such.

Here is a similar device, prosthesis, which caused a chemical reaction between the type of stainless steel used and the body fluids resulting in a loosening and an infection.

Here is another similar device which caused a chemical reaction because of the material which was presumed to be biologically inert, proved to be biologically active and destroyed the patient's hip socket in less than 6 months.

Senator KEATING. What does that mean, biologically inert? Can you make it simpler?

Dr. DOBELLE. Yes, sir.

Senator KEATING. These big terms scare me. I want to know what is wrong with me, and I don't want one of these long biological terms. There is the story of the man who went in to the doctor and asked for a simple term to describe what was wrong with him. The doctor looked him over and he said, "You are lazy." He said, "Well, you better give me another term so I can tell my wife." [Laughter.]

Dr. DOBELLE. Actually for a simpler definition, it would mean that something which was placed within the body that would not react with any of the body fluids or body tissues would be biologically inert, whereas substances placed within the body which are biologically active set up a chemical electrolysis, an ionization between the body fluid and the foreign body which was introduced.

Senator KEATING. I see.

Senator FONG. Are you saying, Doctor, that these things are bought by the individual without a prescription from his doctor?

Dr. DOBELLE. No, these are purchased by a physician, usually a hospital, from a manufacturer and the physician, the surgeon in turn, introduces it into the patient's body by operation.

Senator FONG. It is the fault of the physician then?

Dr. DOBELLE. No, the fault would be the manufacturer. The physician would have no knowledge of what this material was made of other than what it was purported to be when purchased.

Senator NEUBERGER. In other words, this is a perfectly suitable device if it is manufactured properly?

Dr. DOBELLE. That is correct, Senator.

Mr. LARRICK. These are legitimate surgical procedures where the surgeon is let down to the same extent that he would be if he bought a suture to sew up a wound and the string would break after it had been in there a short time. These are defective devices that frustrated the will of the competent surgeon who used them.

Senator KEATING. But these devices, even if not defective, because of their failure to be biologically inert—

Dr. DOBELLE. No, sir; they are biologically inert.

Mr. LARRICK. No; they are not.

Senator KEATING. These are not. For that reason, even if the devices did not have any defect in them, they still should not be used?

Mr. LARRICK. That is right; but in our terminology we include that in the category of a defect.

Senator KEATING. I see; yes.

Dr. DOBELLE. This group of some 20 hip nails, one bone plate, and these screws were received last Tuesday. They were sent to me by one orthopedic surgeon who removed all of them from elderly patients over a period of less than 2 years. These were used not as replacements, but to hold the fracture together. While they appear similar, there are eight different designs.

All, however, set up chemical rusting reaction in the body followed by infection, thus necessitating their removal.

The same situation existed in this bone plate and these screws, one of which was broken. Along with these devices sent to me by this one surgeon, he included a letter, and I quote from the letter.

I have one complete set of jewett nails, screws, and excrescences which have since come off, all in fact, in a towel, and I will send these under separate cover when I locate a suitable mailing container.

And this came in last Tuesday.

Senator KEATING. Would you hold up one of those screws?

Dr. DOBELLE. You see, they are a little bit different in design. There are eight different types.



Senator KEATING. Those are inserted the same way as a normal screw?

Dr. DOBELLE. That is right.

Mr. LARRICK. Senator Keating, would you care to have some of them?

Senator KEATING. I should say not.

Senator FONG. Are there many manufacturers of these screws in the Nation?

Dr. DOBELLE. Oh, yes.

Senator KEATING. They are not all bad, are they?

Dr. DOBELLE. We hope not, sir.

Senator FONG. And a doctor would buy these screws without having them checked out?

Dr. DOBELLE. Well, a doctor can hardly be aware of what this material is made of. When he looks at this, or when it is given to him at the time of surgery, he assumes that it is a biologically inert stainless steel, but we have a number of different types of stainless steel, and many stainless steels are biologically active and very much so.

On the other hand, we have some, and very few, which are not, but the ones that are biologically inert are extremely difficult to machine, whereas the less suitable type of steel you can put it on a lathe and it cuts like butter. The better type requires special cutting tools and they are rather expensive to do.

Senator FONG. Then you would like a law now to have the Food and Drug Administration to give approval for the use of these screws and other devices before they are used, is that correct?

Mr. LARRICK. That is right.

Senator WILLIAMS. Do you ask authority for these devices similar to that you now have where drugs are concerned?

Mr. LARRICK. We are asking the same type of control over therapeutic devices that the Congress has placed over medicine.

Senator FONG. The same as the Magnetron and the foot rest?

Mr. LARRICK. These are devices, too, which do not have, in our judgment, adequate controls.

Senator FONG. How do you differentiate a machine like that from any other machine that has nothing to do with health?

Mr. LARRICK. By definition, an article intended for the cure, mitigation or prevention of disease would be a therapeutic device. One which did not fall in that category would not come under the proposed statute.

Senator FONG. So anything that would come under that category you would like to have submitted to you before they are used?

Mr. LARRICK. Exactly, Senator Fong.

Dr. DOBELLE. Here, I have 23 different types of artificial eyes which I have collected during the past 9 months. All were removed because of material defect, poor quality control, or poor design which caused severe tissue reaction resulting in serious infection.

Senator KEATING. Would you hold those up a little so I could see them better?

Thank you.



DR. DOBELLE SHOWING FAULTY DEVICES

Dr. DOBELLE. Unfortunately, after these are removed from the socket of these elderly people, the infection has caused so much tissue damage to the base of the so-called socket that it is almost impossible to fit them with another type of artificial eye.

Senator KEATING. Does that lend itself to examination which would indicate that those are defective eyes and that they are going to cause this tissue damage? If you have looked them over, can you tell that?

Dr. DOBELLE. We know, during our investigation in the past 9 months, that, for example, this particular clear piece of plastic is technically known as methacrylate, methyl methacrylate. This is a common and very fine plastic, and this is probably, under ordinary circumstances, the very best and most inert type of material we have.

But unfortunately, during its manufacture it was not properly prepared chemically, so that frequently methacrylic acid, a particular acid during the hardening process, remains, and once this is instilled, the methacrylic acid is continually diffusing and extremely irritating.

Senator KEATING. Is that anything you would discover if you were to examine it in advance?

Dr. DOBELLE. Yes, very definitely.

Senator KEATING. Was it common to all of the eyes put out by this company, or was it just a single instance?

Dr. DOBELLE. No, these are all different manufacturers, there is not one company in this, they are all definitely made by different manufacturers.

Senator KEATING. But, I mean, the acid, which was in that eye. It might have been a particular instance.

Dr. DOBELLE. No, sir. I would have to explain something to you. The so-called polymer of this chemical is sold commercially and the company which manufactures this particular chemical is now the only one in the country, Rhome & Haas. Dupont also has made it, but they have discontinued it. When they sell this they sell it as a commercial product.

This is taken into a laboratory and this is polymerized (hardened), and during the polymerization process wherein a chemical known as hydroquinone is used, this hardens. The better type of laboratory would normally take some 36 consecutive hours to get all of the methacrylic acid out of this particular chemical before it was allowed to harden, but none of the manufacturers were aware of this until very recently when we became aware of this particular finding.

This was done in Boston by a very fine polymer research group.

Senator KEATING. Would you hold up that box again? A lot of those are big. You are holding a little one in your hand. What are those great big things? Are they eyes, too?

Dr. DOBELLE. Yes, sir; this is an eye.

Senator KEATING. What do they do with that little one? I don't understand.

Dr. DOBELLE. Well, eyes vary in sizes, and bases.

Senator KEATING. I never saw an eye as little as that.

Dr. DOBELLE. Yes, sir, there are eyes that small. Here is one made of metal, completely.

Senator KEATING. Metal?

Dr. DOBELLE. Metal. All metal.

Senator KEATING. Does the part that appears to be the pupil, is that metal?

Dr. DOBELLE. No, that would be covered. This is covered, with a coloring and with a piece of glass-like material, usually plastic.

Senator WILLIAMS. You have gathered these over the last 9 months?

Dr. DOBELLE. That is correct, sir.

Senator WILLIAMS. Is this a new area of inquiry for the FDA?

Dr. DOBELLE. It is, sir.

Senator WILLIAMS. What brought you into it?

Dr. DOBELLE. My interest was due to contact lenses. I became very interested as to why some patients could wear contact lenses and others could not. I have several nephews, one an ophthalmologist and one an optometrist. It was brought to my attention that some people psychologically rejected contact lenses because it produces a lot of irritation on a normal eye, when they place this contact lens.

Consequently, we investigated this thing through the Massachusetts Eye and Ear Infirmary, which is a very famous place in Boston, and came up with the amazing finding that the methacrylic acid which emanates from these contact lenses is one of the greatest causes of the irritation and inability for patients to wear contact lenses.

Senator WILLIAMS. If you had the responsibility to test the efficacy of therapeutic devices, would you have been brought into examination of the faulty area long before under that authority?

Dr. DOBELLE. Oh, yes.

Senator WILLIAMS. You are really volunteering here in a sense, in studying and giving out information on these things.

Dr. DOBELLE. My purpose is for the improvement of devices. We have gone to the American Optical Co. We have been in contact with Bausch & Lomb, and all the well-known optical lens manufacturers, for example, to learn of their problems because of the lenses which are in safety glasses, for example, or the color additives which are put into lenses and color additives which are put into contact lenses. Ladies, for example, like to have blue eyes some evening, and consequently, they can get a contact lens that will give them a blue eye.

Senator KEATING. Do they wear different contact lenses for different occasions?

Dr. DOBELLE. Yes, sir; they do. Now these color additives, too, are irritating, but they are put in without any ideas by the manufacturers that they can cause some serious damage.

Senator KEATING. They do not interfere with the sight in any way, those color additives?

Dr. DOBELLE. Yes, sir. As a matter of fact, we have brought to our attention through a laboratory and we know of eight authenticated cases of blindness caused by wearing contact lenses which produced a fungus infection of the eye which no antibiotic can touch.

Senator KEATING. You mean normal contact lenses, without the color added?

Dr. DOBELLE. Normal contact lenses.

Senator KEATING. You are going to scare every girl with contact lenses in the room.

Dr. DOBELLE. I hope I scare the manufacturers, sir.

Senator FONG. Would I be correct, if you had such a law you are asking for now, you would still make mistakes?

Dr. DOBELLE. I am asking for no law.

Senator FONG. You are asking you be given the power to pass on these devices, indeed, the use of these products before they are put in use, is that correct?

Dr. DOBELLE. That is correct.

Senator FONG. Even with such a law, you would not know what would be the harmful effects to an eye like that which you showed us?

Dr. DOBELLE. But the manufacturer would have to prove that these are safe and efficacious and biologically inert.

Mr. LARRICK. May I say that the objective of the law that we are seeking would be to take the combined knowledge and experience of the most skilled professional people in these various areas, plus the knowledge and experience of the best manufacturers in these areas, and use that combined experience to make standards for some of these products? This, of course, would not eliminate all human error. Nor would it deal with the practice of medicine. But it would lessen very substantially the likelihood that either through carelessness or ignorance, materials go into these devices which cause them to be defective and result in great difficulty.

Senator FONG. Of course, if you gave such an approval for the use of such product, you would be constantly watching it, would you not?

Mr. LARRICK. And we would give some approvals we would have to take back later, because we would learn things we did not know of at first.

Senator FONG. If these were not given to you in the first place, you would not have any knowledge.

Mr. LARRICK. It would reduce the burden of proof.

Senator NEUBERGER. Also, would there not be a sort of incentive for each of these eye manufacturers to be sure that its product was going to meet the requirements? Now if nobody is going to police it, there is no standard, but the very fact—

Mr. LARRICK. Senator, I think that effect would be very great. There is no question but that the incentive would do more perhaps than the actual enforcement of the law after it was passed.

Senator NEUBERGER. I was thinking of this animal standing here. It reminds me of a little refrigerator. Is there any possible machine where they do have to show its efficacy, I mean outside of health, before it is approved? If that were a refrigerator and a woman bought it on good faith for \$350, she would soon know if it functioned, would she not?

Mr. LARRICK. Yes. If your automobile is defective, the District of Columbia will not let you have a license for it.

Senator NEUBERGER. But in most any other machine, not referring to health, refrigerator, automobile, you, the consumer, can determine whether it is defective or not. But in a so-called health machine, you do not know, do you?

Mr. LARRICK. No; you have to rely on the claims.

Senator NEUBERGER. You are buying a pig in a poke, in other words?

Mr. LARRICK. That is right.

Senator FONG. You have no objections now from the medical fraternity relative to what you are trying to do, do you?

Dr. DOBELLE. No, sir; as far as I know.

Mr. LARRICK. I think it is only fair to say, Senator Fong, that I do not know just what the position of the American Medical Association would be on the basic philosophy of Government control in this area. I am very sure that they agree with the objectives we are trying to seek. Whether they would agree with our method is something that they should speak for themselves.

Senator WILLIAMS. Is Mr. Throckmorton in the room at this time?

Mr. THROCKMORTON. Yes, sir.

Senator WILLIAMS. Mr. Throckmorton is from the AMA and will probably address himself to Senator Fong's inquiry, will you not, sir, later when you are involved?

Mr. THROCKMORTON. Yes, sir; we can do that during my testimony.

Senator WILLIAMS. Yes.

Mr. LARRICK. That concludes our presentation.

Senator WILLIAMS. Following Senator Neuberger's inquiry, if you buy a refrigerator that is not efficacious, that means it does not work, you can go to court and you can get your money back. You can sue. How about these devices? Are the courts receiving a multitude of cases of people who get hoodwinked by these devices?

Mr. LARRICK. There are occasional cases in the courts, but the great fault is that people who are victimized by this type of chicanery are just not in the position to go to the expense and trouble to hire the expert witnesses to carry through a case of that sort.

To carry through one of these cases by the Government is a terrifically expensive deal. We have to have expert physicists to take those machines all apart and measure every circuit. We have to have very

skilled physicians who will go on the witness stand and testify that the device will not do any good. That just is not practical for the average person to do as a matter of course for a civil suit.

Senator KEATING. If you would yield on that point. I assume these machines do not do actual harm to a person—

Mr. LARRICK. There have been some that do, but the harm, Senator is delay. If you have a progressive degenerative disease and you forgo competent medical care, it is an indirect harm.

Senator KEATING. That Magnetron would not actually give you some new disease, so that your only damages in a legal action would probably be the amount you paid for it?

Mr. LARRICK. Generally that is right. However, some of them have very defective electrical circuits and my colleague points out that in this particular one, a condenser breakdown in the circuit could lead to very serious shock. But ordinarily, you are quite right.

Senator KEATING. That is an additional reason why it is not practical for these poor people who are cheated to bring an action, because unless it has actually resulted in some direct degenerative condition, their damages would probably be assessed at the amount they had paid for the device.

Mr. LARRICK. That is exactly right.

Senator KEATING. They could probably not recover in an action for the degenerative effects that had come from not going to a competent doctor and receiving proper treatment.

Mr. LARRICK. I would defer to your judgment as a skilled lawyer in that field, sir.

Senator KEATING. That is the way it appears to me.

Senator FONG. Do I understand, Mr. Larrick, that as far as the general laws of misrepresentation are concerned, they will be able to deal with misrepresentation and fraud, but the practicality of trying to show that a thing is fraudulent is very difficult, is that correct?

Mr. LARRICK. You are quite right, Senator.

Senator FONG. Therefore, you are asking for them to present these things to you first for your approval.

Mr. LARRICK. We think that in the health field, the burden of proof should be upon the proponent of the product or the article.

Senator FONG. It is not that we do not have present laws now to deal with quackery, fraud and misrepresentation.

Mr. LARRICK. Right.

Senator WILLIAMS. You have gathered these on your own initiative; these were not presented to you as a matter of requirement on the part of the manufacturer.

Mr. LARRICK. We bought them, paid for them, tested them and went into Federal court to have them condemned.

Senator WILLIAMS. But they did not have to be presented to you before.

Mr. LARRICK. No, sir. Many people were hurt and injured before we caught up with these devices.

Senator WILLIAMS. How does that Magnetron work? Can you demonstrate that, Mr. Kinslow?

Mr. KINSLOW. Yes, sir.

Senator WILLIAMS. What is this for, by the way?

Mr. KINSLOW. Mr. Chairman, this particular device was promoted for self-treatment, advertised through newspapers, and so forth, and sold to an individual to use in his own home. The labeling accompanying the article gives case reports, purported to be testimonials, involving rheumatoid arthritis, arthritis, and prostate gland trouble, varicose veins, diabetes, failing heart, and tumor. Those are the conditions that this device supposedly would treat.

The instructions indicate that you take off your shoe, put your foot on this pad here, take this electrode in your hand, this is a little difficult for me to do with this upon the table, but I will use my other hand, and you turn the device on.

You will notice that when I take my hand off of here the light brightens. You cannot tell this, but I am getting a little shock out of it. It is just enough to make the unsuspecting, naive, or desperate person believe that he is getting some advantage from it.

The instructions for use indicate that you start using it for a minute, and increase up to 30 minutes a day, but you should not expect results in less than a few months, and possibly after you have used it for a year, you will have much better results.

It is completely worthless.

Senator KEATING. You probably have to get new batteries in a year.

Mr. KINSLOW. It is not battery operated. You plug it into the electrical circuit, and that is one of the problems with this particular device. As Commissioner Larrick explained earlier, many of them, these Rube Goldberg-type devices over here, for example, don't do anything. They cannot hurt you and they cannot help you.

This Magnetron, however, has a homemade piece of electrical equipment in it, which if it broke down could result in the user getting a fatal electric shock.

Senator WILLIAMS. What was the price of the Magnetron? How much did you pay for that?

Mr. KINSLOW. \$197.50.

Senator WILLIAMS. Is that as it appeared, as it was? Did you do anything to this?

Mr. KINSLOW. We put the sign on top of it for the purpose of exhibiting it here today.

Senator KEATING. Is that the one that they were still selling within a State?

Mr. KINSLOW. Yes, sir. This device is still available within intrastate commerce in at least two States in the United States. However, it is not being distributed interstate now. This is an attempt to circumvent the Federal Food, Drug, and Cosmetic Act.

Senator WILLIAMS. How many States have, for these devices, an efficacy test as a matter of law?

Mr. LARRICK. The kind that we are seeking?

Senator WILLIAMS. Yes.

Mr. LARRICK. None.

Senator WILLIAMS. California has developed a law.

Mr. LARRICK. I am corrected. California apparently does have one.

Senator NEUBERGER. Mr. Chairman, along that line, the chairman and some members of this committee held a hearing in California and we were impressed by the laws they have about cancer cures. Yet the

deputy district attorney testified there that it was still difficult to get after these things and he recommended in his testimony to us that consideration be given to the possibility of establishing within the Department of Health, Education, and Welfare, a unit that would be charged with the responsibility of coordinating and taking action on medical quackery under the direction of a qualified specialist in legal medicine.

This seemed to me a good idea. It was not that he thought we ought to create a new bureau, but to make the work, the splendid work, that your agency is doing, more effective.

Mr. LARRICK. I think that is a splendid suggestion. Actually, the year before last, when we went before the Appropriation Committee, we got \$300,000 to be used to hire an outside public consultant group to make a comprehensive study of the relationship between the State and Federal laws in these broad areas, including foods, drugs, and therapeutic devices. We hired the Public Administration Service of Chicago, and they are presently making a very comprehensive study and will come up with recommendations of that sort, plus suggesting means of coordinating, preventing overlapping and improving relationships between the Federal and the State Government in the whole area of consumer protection in our field.

Senator NEUBERGER. Somehow, it seems to me we need some psychiatric studies in this area, too. There must be some reason that people are so gullible, because not all of them are illiterate or uneducated to buy this.

I think one of you men used the word desperate, and that probably has something to do with it.

Could it also be—you do not have to answer this as a question, it is rhetorical—could it be that the cost of medical care for the aged is so expensive that people think that rather than going to a doctor, who they ignorantly fear will charge them too much, think, “maybe I can do it at home?”

I wonder if this is not in the background. As I say, you do not have to comment. This is my opinion. But there must be other reasons because I was impressed at the California hearing of a very intelligent woman who was a sufferer of arthritis. She is a well-known public figure in California, and she admitted that doctors had been doing no good for her and she bought one of these devices with her eyes wide open, knowing that it probably couldn't do anything, but she was desperate to do so.

So, there is a reason, I suppose, and I believe that even if you told people it wouldn't do them any good, they might still buy it.

Mr. LARRICK. It depends on whether they believe you when you tell them it won't do any good.

Senator NEUBERGER. That is right. It is a pitiful thing that makes people do it.

Senator WILLIAMS. I think that is a very worthy point.

Senator YARBOROUGH. Mr. Chairman.

Senator WILLIAMS. Senator Yarbrough.

Senator YARBOROUGH. Mr. Larrick, on the metal pins and instruments which you have there which were taken from persons, the bodies of persons where they had previously been placed in an operation. Now, I assume that these operations were by surgeons, duly licensed



surgeons. These were not quackery operations, the placing of these pins in human bodies?

Dr. DOBELLE. Every one of these were operated on and introduced by an orthopedic surgeon, and every one of these were removed by an orthopedic surgeon.

Senator YARBOROUGH. Now, what protection does the surgeon have in introducing these pins into the human body? What protection has the surgeon got to know that the metals in these pins are the kind that have been made biologically inert and that they will not be hostile to human tissue?

Dr. DOBELLE. Actually, he has no protection whatsoever. Unfortunately we have a gaining tide of malpractice suits, but counsel and attorneys in general now are aware of the fact that the defective device, even though the physician is a prime target, actually is the fault and the responsibility of the manufacturer.

Senator YARBOROUGH. You mean for the malpractice suit, the doctor takes one of these pins made from metals that are not tolerated by the human body and human tissue, a competent surgeon introduces one of these pins into the body, to pin a broken hip, it is hostile, and the surgeon gets a suit for malpractice. There is no law or rule or regulation about the manufacture of these devices, these pins, these bolts, these metal braces that are put in the human body. There is no protection for the surgeon there except his judgment of the manufacturer; is that right?

Dr. DOBELLE. That is correct, sir. If I were doing an elderly lady, which happened to me about a year and a half ago, before I came to Food and Drug—

Senator YARBOROUGH. While you were in active practice?

Dr. DOBELLE. While I was in actual surgical practice, while I was putting in the last screw, the screw broke, and the anesthetist told me that this patient isn't doing too well—they are usually elderly patients—I took the screw head out, I did not go in to get the rest of the screw. We closed to save the patient's life. Then it is beholden upon me to go to the family and explain the situation and explain what happened. If you are convincing enough to the family, as a rule they will not be suing you for malpractice. If you could explain the situation to them. But unfortunately, all people are not like that, and many people, many persons in the younger members of families are always looking to see where they can get some money and this is an elderly lady who is going to die anyway. So they are going to sue for malpractice, and this becomes very time consuming, very aggravating to the physician—

Senator YARBOROUGH. Well, doctor, I am not so certain that all the people want to sue. In my experience as a lawyer I have seen very, very few suits for malpractice. I have seen many families who felt aggrieved, but they just felt like getting well or something. It was not the doctor's fault. In my section of the country malpractice suits are fairly rare.

Mr. LARRICK. Senator Yarbrough, the Food and Drug Administration's interest is to protect the patient. If that would stop some of those byproducts, that would be fine, but that is not our objective.

Senator YARBOROUGH. The point I was making here, the surgeon, it seems to me that the surgeon who operates in good faith needs some protection to know that these pins, these bolts, these things he has introduced into the human body have met certain standards of tolerance in the human body, certain tests of strength, and many other standards.

What was that thing that looked like a hammer or gavel that you put in your briefcase?

Dr. DOBELLE. This is exactly the same prosthesis as this one, which unfortunately was not made of the proper type of metal. It is the identical counterpart of that.

Senator YARBOROUGH. Where is that used?

Dr. DOBELLE. This actually is used wherein you have the head of the bone, of the femur, the thigh bone, shattered, and the neck is shattered beyond the point where you could possibly put it together operatively, and you know that it is not going to heal. So consequently, it is removed. The bone is removed.

Senator YARBOROUGH. You cut off the head of the femur?

Dr. DOBELLE. That is right. The shaft of the prosthesis is slipped down into the shaft of the femur, and this prosthetic help articulates with the hip socket.

Senator YARBOROUGH. And this successfully works?

Dr. DOBELLE. Very successfully.

Senator YARBOROUGH. You put a new ball on the hip bone that makes that—you put a metal ball over the top of the hip bone?

Dr. DOBELLE. That is correct. In our efforts we have devised heads or balls so that it would accommodate different sized sockets.

Senator YARBOROUGH. And this one you hold in your hand, you say, was made of improper metal?

Dr. DOBELLE. Yes, sir.

Senator YARBOROUGH. What happened when that was introduced?

Dr. DOBELLE. You get an ionization. You get an electrolysis between the body tissue and the metal itself. This sets up an infection, and the prosthesis becomes loose, and becomes very painful, and the patient cannot walk, and subsequently you have to remove it and evacuate the contents of the foreign material. You have to wait for quite a long period of time until complete healing has taken place, until you make an effort to do some other form of reconstruction operation.

Senator YARBOROUGH. Doctor, actually, in medical training you do not take training in metallurgy and chemistry and all these metals; do you get training in that?

Dr. DOBELLE. No; this is a training I had to learn myself.

Senator YARBOROUGH. You have to get that postgraduate?

Dr. DOBELLE. I have never known it. I have been an orthopedic surgeon close to 30 years. I never knew anything about metals particularly, and the Diamond Ordnance Fuse Laboratories in Washington, where I went for several days, gave me a very fine course in metallurgy. There were two fine metallurgical engineers, and this is where I learned something about the metals.

Senator YARBOROUGH. Doctor, were any of these devices here or pins or substitutes for bones manufactured recently? Is this due to the development and testing? Are these old pins, hip pins—

Dr. DOBELLE. These are within the past few years. But in recent years, in the last year or so, the manufacturers have a committee which

has gotten together, the F-4 committee, who are doing some heroic work in trying to set some real standards. But these are all recent.

Senator YARBOROUGH. These are all of recent manufacture?

Dr. DOBELLE. Some as recently as 2 or 3 months ago.

Senator YARBOROUGH. This is not something that is 20 years ago?

Dr. DOBELLE. No.

Senator YARBOROUGH. This is very recent usage?

Dr. DOBELLE. Yes, sir.

Senator KEATING. Would you yield?

Are they put out by what you would consider reputable manufacturers?

Dr. DOBELLE. Yes, sir; some of these unfortunately are. I do not think the manufacturer sometimes is quite aware of what might have taken place because they do not subject these to proper biological research. I am sure this one was put out by a very reputable concern, and it is completely rusted inside, completely rusted here. You have dulling along the very areas to show where these excrescences have been cleaned over. Unfortunately the surgeon was overzealous in sending these to me, so he had them all cleaned up and polished.

Senator YARBOROUGH. Mr. Chairman, I move the photographs of the artificial eyes, the photographs of these hip pins and prostheses, the photographs of these be placed in the record to illustrate and illuminate Dr. Larrick's testimony.

Senator WILLIAMS. If there is no objection, and if that is mechanically possible.

Senator YARBOROUGH. If the photographers will just take a picture, I don't mean an individual picture of each one.

Senator KEATING. You have had a lot of excellent photographers taking pictures here. How are you going to know which one to select?

Senator WILLIAMS. There is a problem here to select the Pulitzer Prize photograph.

Senator YARBOROUGH. We should not have the testimony without some photograph here. Its effect is inadequate. Just an ordinary photograph. We are not looking for expert photography.

Senator WILLIAMS. I think it is an excellent, wise suggestion.

Senator YARBOROUGH. Mr. Chairman, there are a number of photographers here. I see some expert ones. Just put a picture in there. I think if we could get a view of that magnetron over there—

Senator WILLIAMS. If the Senator would yield, the Food and Drug Administration's photographer can supply us with these.

Mr. LARRICK. Anything you want us to supply you with, we will be happy to do so.

Senator YARBOROUGH. Mr. Chairman, I want to ask the witness before I finish: What is that device over there that looks like a big cabinet model television set and has on top, radio class, model 20?

Mr. KINSLOW. Senator Yarborough, this device is the Electronic Analysis Instrument Model F. That is the name given to this device by the firm that manufactured and distributed it in interstate commerce.

Senator YARBOROUGH. It doesn't render any entertainment but it looks like a big Magnavox television set. What was that sold for?

Mr. KINSLOW. The device is purported to measure electrical emanations coming from the body and enable the practitioner using it to thereby diagnose diseased areas of the body of the patient whom he is touching with something of this sort (referring to metal electrode) or something of this sort (referring to metal electrode). There are jacks over here where these electrodes can be plugged into the device.

Senator YARBOROUGH. Now, you say the person treating, you mean this was solely to be used not by the patients themselves, but by the practitioner of the healing art?

Mr. KINSLOW. That is correct, Senator.

Senator YARBOROUGH. What practitioners use them, generally?

Mr. KINSLOW. They are generally used by fringe practitioners.

Senator YARBOROUGH. The next device, the radio class, model 20.

Mr. KINSLOW. The Radioclast models 20 and 40 are dual purpose devices. They cannot only diagnose but they can also treat. One half of the "keyboard" here, if you will, is used for diagnosis and the other half used in treating the patient. You can get diagnosed and treated very quickly, very ineffectively.

Mr. LARRICK. And very expensively.

Senator YARBOROUGH. It is a complete service. It diagnoses and treats all in one operation?

Mr. KINSLOW. That is right.

Senator YARBOROUGH. What is that Electronic Magnetic, model G?

Mr. KINSLOW. This is a portable "therapeutic" device. As a matter of history, these four devices were all shipped by the same manufacturer. This Radioclast model 40 was the granddaddy of all of them. It has been in use for many, many years, almost as long as I have been alive.

Senator YARBOROUGH. Are these still being manufactured and sold and used?

Mr. KINSLOW. Commissioner Larrick in his statement pointed out that in 1963 a permanent injunction was obtained in Federal court against the manufacturer of these devices enjoining him from further distribution in interstate commerce for commercial purposes.

Now, I am not aware as to whether or not the manufacturer is violating this injunction. If he is shipping them, he is violating an injunction for which he is subject to Federal prosecution.

Senator YARBOROUGH. According to your statement, if he manufactured and sold them in his own State, he would not be?

Mr. KINSLOW. We would have then the same situation we have with the magnetron.

Mr. LARRICK. We have investigated and he is not shipping in interstate commerce.

Senator YARBOROUGH. But he is manufacturing?

Mr. LARRICK. I don't think he is.

Senator WILLIAMS. Have any manufacturers that you have enjoined varied the device?

Mr. LARRICK. That happens quite frequently. Sometimes they even change corporate names. Therefore, if we can bring a criminal action we try to enjoin people as well as corporations, so that if it later becomes necessary we can bring a second offense against the person. In some of these cases we seized the devices.

Senator KEATING. In this action, did he claim this was effective? Did they produce medical testimony saying that people had been cured by this?

Mr. LARRICK. Yes. There was testimony to support his view. In one case we had last year there was very, very extensive testimony. The court concluded the device was utterly worthless, but they are not easy cases to win.

Senator FONG. Mr. Larrick, I ask you one more question. You are asking that the Congress give you the authority to approve these devices before they have been used?

Mr. LARRICK. Exactly.

Senator FONG. Have you ever asked the Congress for such a law before?

Mr. LARRICK. Yes, sir.

Senator FONG. When was that?

Mr. LARRICK. In June 1962 we asked for it in reporting on H.R. 11582.

There has been great improvement in the pure food and drug laws. There have been many, many forward steps. There have been very substantial increases in our facilities. I think the Congress has done very well in this field, but this improvement is one of the residual things that we have been trying to get for a great many years which we have not as yet gotten.

Senator FONG. Do you feel there is a great urgency for this law now?

Mr. LARRICK. I feel there is great urgency.

Senator FONG. Greater than in 1962 when you asked for it?

Mr. LARRICK. The bureaucrat who believes very strongly in something always feels there is great urgency for it.

Senator WILLIAMS. A bill has been introduced.

Mr. LARRICK. Senator Hill has introduced a bill in the Senate, Congressman Oren Harris has introduced a companion bill in the House, at the recommendation of the President.

Senator WILLIAMS. And the Hill bill has been referred to the Labor and Public Welfare Committee?

Mr. LARRICK. Yes.

Senator KEATING. Are you sure of that?

Mr. LARRICK. I believe so.

Senator KEATING. The other bill was put out by the Judiciary Committee.

Mr. LARRICK. Senator Keating, this is the bill S. 2580, which was referred to the Committee on Labor and Public Welfare on March 2.

Senator WILLIAMS. I have a feeling your testimony today will stimulate—well, when it becomes timely to consider anything in committee I would feel that all that you have told us today would be very helpful to Senator Hill.

We could go on for a long time here, members of the committee.

It has been very helpful. I wonder, finally, we have other witnesses we want to get on before noon. I am sure there is no way to estimate dimension of the fraud here in terms of physical hardship, suffering, pain, and loss of lives, is there any monetary measure of the dimension you are talking about?

Mr. LARRICK. It is very large when you consider that one of these machines may be used by an unorthodox practitioner to treat many

patients. I would not hazard a guess. I will check with my staff and if they can come up with a figure that has some reliability, I will be happy to supply it. But it is very big.

(See attached statement submitted in response to Senator Williams' request.)

The following example illustrates the monetary measure of the fraud committed when patients are treated by an unorthodox practitioner using a worthless device.

The Micro-Dynamometer is such a device. It was claimed to be capable of diagnosing all kinds of disease by measuring the minute electrical currents generated when metal attachments were applied to the skin of the patient. FDA scientists found that all it measured was the amount of perspiration present on the skin and that disease made no change in the readings on the device.

Last year FDA rounded up nearly 1,200 of these devices, most of which were being used by licensed practitioners. They sold for \$875 each, a total of over \$1 million. The cost to patients—at \$5 to \$10 per treatment—could easily have been from \$25 to \$50 million. But this would be only part of the real cost. As the court of appeals put it: "A device whose labeling claims it to be an aid in diagnosing as many diseases as this one, when in fact it is not, is unsafe for use no matter who uses it."

Unfortunately, there is reason to believe that many are still in use despite the fact that the courts have outlawed these devices no matter who is using them, or for what they are being used.

Senator WILLIAMS. We would be appreciative of that and I am sure we all have the same feeling that you have been extremely helpful this morning.

Mr. LARRICK. Thank you very much.

(Further pictures and a statement referred to by Mr. Larrick follow:)

(Text continues on p. 216.)

FIGURE 6.—Leg elevator.

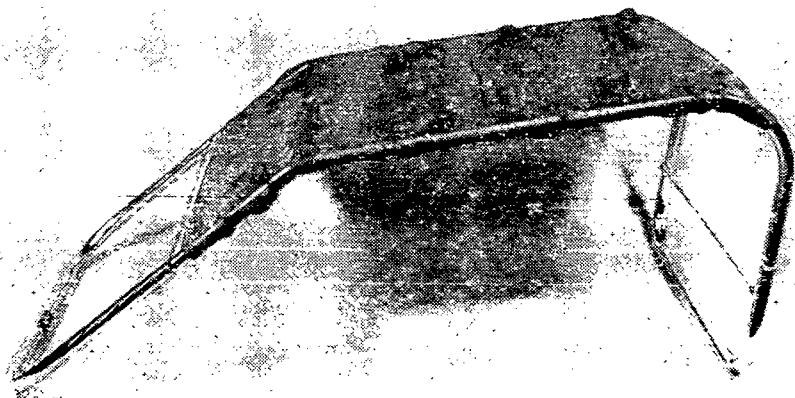


FIGURE 7.—Radioclast, model 20.

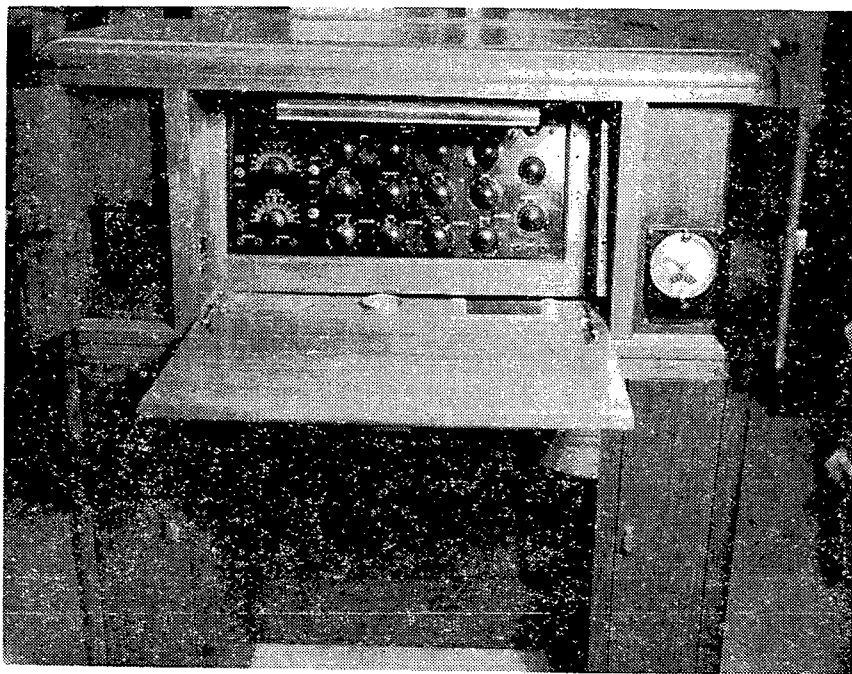
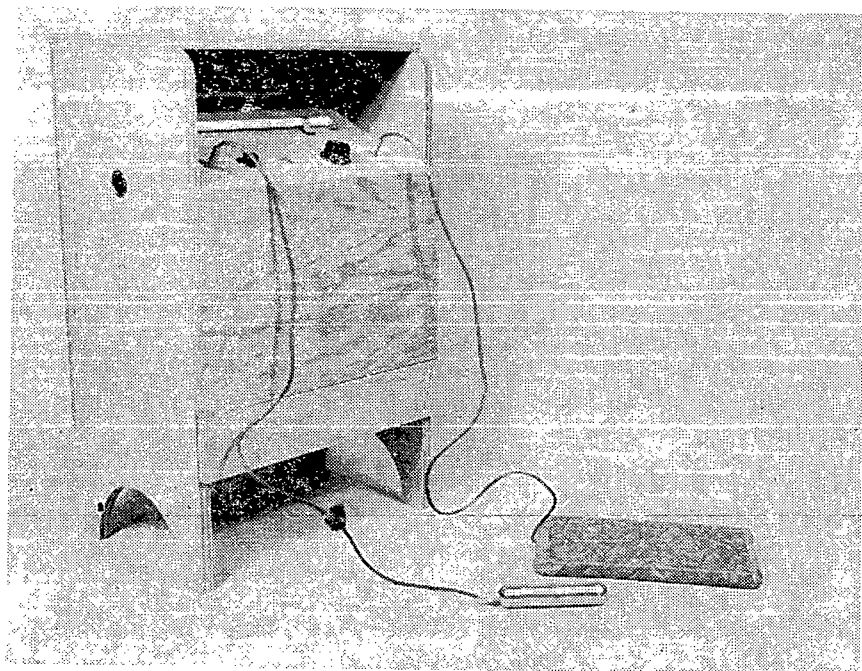


FIGURE 8.—Magnetron.



## FDA REPORTS OF MEDICAL QUACKERY—HOW GOVERNMENT PROTECTS THE CONSUMER

(By Geo. P. Larrick, Commissioner of Food and Drugs, U.S. Department of Health, Education, and Welfare)<sup>1</sup>

What do we mean by the term "quackery?"

In the dictionary a "quack" is defined as a pretender to medical skill, and the word "charlatan" is often given as a synonym. In popular terms the quack is considered to be a medical swindler.

But the collective word "quackery" is a broad term. It includes a wide variety of misinformation concerning health which is misleading to the public even though there may be no deliberate intent to mislead. So today what we are talking about is information versus misinformation in the health field, which can affect the consumer's pocketbook as well as his personal health and safety.

Who decides what is quackery? There has been a great deal of controversy about that. What was accepted medical practice 100 years ago, or 50 years ago, to a large extent may be quackery today. And in a few instances, the folklore of bygone times has later been found to have a scientific basis. But there is something new in this picture—the fact that science is now capable of distinguishing, with considerable certainty, the effective from the ineffective. Our laws, based upon medical knowledge, distinguish between what is legal and what is illegal. The fact that quackery can be put to the test, scientifically and legally, is the basic fact underlying this conference. Our mutual interest is how to expedite these determinations, and to take effective action against quackery both by law enforcement and by education.

There is no doubt that quackery is a major health problem. At the First National Congress on Quackery 2 years ago it was estimated that it cost the American public a billion dollars a year. This, of course, was an estimate. It includes the consequences of unnecessary and worthless treatments and products of every description and the misinformation utilized to promote such things. There are no statistics to tell the cost of quackery in money, injuries, and human life.

Far more impressive than any statistics are the experiences of people who have been victimized by quackery. Recently I learned of the case histories of several people who were users of an unproven cancer remedy. One woman patient who had cancer of the breast paid approximately \$8,000 for this drug. She had three operations between 1959 and 1963 and died of cancer in June 1963.

A 35-year-old woman who used the drug intermittently has paid a total of \$5,000. Her treatment dates from 1952, when she had surgery, and she had another operation in 1961.

These are typical of the expenditures people do make for unproven and ineffective remedies when they are motivated by the fear of cancer. They are not exceptional.

A more unusual case was one recently called to our attention by a Member of Congress. The person involved was a victim of a nervous ailment. During one year he paid \$28,600 for treatments with a machine represented as being capable of performing psychoanalysis and treatment of mental conditions, as well as other diseases. For similar treatments a college student paid \$2,600 out of his educational fund to improve his capabilities as a student.

The medical "con man" who is a big-time operator can bilk the public of millions. In December the Federal court at Indianapolis sentenced a man (Roy DeWelles) who is estimated to have taken in \$3 million with a machine to give enemas. It was supposed to "detoxify the colon" and cure everything. He got 10 years in prison for mail fraud.

The biggest money is made by the promoters who appeal to a mass market. Not long ago we stopped the sale of a product called Acnotabs. It was being advertised to teenagers and their parents as a sure cure for pimples. It sold for \$5.95 per bottle, and nearly 4 million of the tablets were seized in one lot. This action stopped a high-powered sales campaign that would have cost our teenagers millions of dollars.

Recently in New York the grand jury indicted the promoters of a worthless reducing remedy called Regimen. The advertising featured testimonials by people who had actually lost weight—not because they were taking Regimen

<sup>1</sup> For delivery at the 2nd Regional Conference on Health Quackery, Mar. 13, 1964, Atlanta, Ga.



but because they were on starvation diets. Over the last 6 years the weight conscious public has spent \$10 million for this product.

There is no way to measure accurately the cost of misbranding and misinformation in the health field. But the cost would be far more were it not for the protection of our Federal, State, and local laws.

There are three major kinds of health frauds which violate the Federal Food, Drug, and Cosmetic Act:

First—quackery in the promotion of so-called therapeutic devices.

Second—quackery in the marketing of food supplements and so-called health foods.

Third—false claims for drugs and cosmetics.

I want to give you some up-to-date illustrations of each of these. Quackery is not something that happened in the past. It is going on all the time. Old frauds reappear in the new disguises and new ones are being invented. There is a tendency to depict quackery in the trappings of the oldtime medicine man with his curly moustache and a silk hat. He does not look that way any more. Instead we see a man in a white coat with a professional-looking office who is probably a licensed practitioner and who has a machine or treatment that is so new and different that the medical profession is against it. He says they are afraid it will put them out of business.

Such a machine was the Micro-Dynameter—a device that was claimed to be capable of diagnosing all kinds of disease by measuring the minute electrical currents generated when metal attachments were applied to the skin of the patient.

The FDA scientists found that all it measured was the amount of perspiration present on the skin. It worked the same on dead people as on living persons. Disease made no change in the readings but washing the skin with alcohol or acetone did make a change.

Last year FDA rounded up nearly 1,200 of these devices, most of which were being used by licensed practitioners. They sold for \$875 each, a total of over \$1 million. The cost to patients—at \$5 to \$10 per treatment—could easily have been from \$25 to \$50 million. But this would be only part of the real cost. As the court of appeals put it—"A device whose labeling claims it is to be an aid in diagnosing as many diseases as this one, when in fact it is not, is unsafe for use no matter who uses it."

Nationwide publicity helped greatly in stopping the use of these devices. Our press release pointed out that people were being swindled by being treated for diseases they did not have or—much worse—being led to neglect getting proper treatment for diseases they did have. This is quackery at its worst.

We have not found all of the Micro-Dynameters. We have reason to believe that many are still in use. I want to point out that the courts have outlawed these devices no matter who is using them, or what for. We would like to have the vigilant help of State and local authorities in locating users of the Micro-Dynameter and all other fake medical devices. We will help the local people to take action or we will take action under the Federal law, whichever seems best.

#### NUTRITIONAL QUACKERY

By far the most widespread—and costly—form of quackery today is in the area of food faddism, dieting, and nutrition. It was here in Atlanta 2 years ago that we began court action against one of the biggest misbranding operations ever encountered by the Food and Drug Administration. A U.S. marshal seized \$3,800 worth of Nutri-Bio food supplement from an Atlanta sales agent who had been recommending it for such conditions as alcoholism, arthritis, cancer, stomach ulcers, and other serious ailments.

This started a series of actions with far-reaching consequences. Investigation disclosed that Nutri-Bio was being promoted by means of one of the largest collections of pseudoscientific health literature ever assembled. A second seizure in Washington, D.C., included more than 100 different leaflets, books, booklets, reprints, manuals, recordings, filmstrips sales kits, recruiting kits, etc.

Directly and indirectly, Nutri-Bio was being recommended through this literature as the answer to practically all health problems—anemia, arthritis, cancer, diabetes, frigidity, heart trouble, infections, nervousness, and so on. Then on the positive side it promised health, beauty, athletic ability, radiant living, and the capacity to stay young and vital. It was even recommended as a cure for juvenile delinquency.

The Nutri-Bio promotion was a classic example of food faddism gone wild. It would take several pages to list all the false claims and representations. Mushroom promotion methods had built it up to the point where more than 75,000 full and part-time sales agents were selling Nutri-Bio at \$24 per package for a 6-month supply for one person. The agents had to buy the sales literature as well as the products. Lured by the prospect of quick riches from the pyramid of chain letter plain of distribution, many invested their life savings. For \$10,000, for instance, you could start business as a "General" and get maximum commissions on all sales by your subagents. The pyramid collapsed when the distributors realized that the District of Columbia case was a challenge of the basic sales promotion materials and that they would be violating the law if they used them in their sales presentations. Nutri-Bio agents in the Chicago area alone turned in for destruction about 50 tons of this literature. We invite you to compare this with the efforts of Government and voluntary health agencies to disseminate reliable nutrition information.

Now I would like to call attention to a significant court decision handed down only a few weeks ago. In this case the Government had seized a quantity of "Vitasafe" brand vitamin and mineral capsules, accompanied by nearly 4 million pieces of sales literature. These products were sold by mail order. They are much like Nutri-Bio and many others in regard to the formulas, the sales claims, and the other false and misleading information used to delude the public into thinking they must buy and use such products in order to have adequate nutrition and protect their health. I am sure you will recognize these fallacious theories when I tell you how they were dealt with at the trial and in the court decision.

First, there was the idea that the nutritional needs of men and women are different. They had the "M" formula and the "W" formula and they used the sex angle in the sales promotion. For example, one piece of copy showed a husband and wife with the husband asleep on the couch and the headline: "I'm worried—My husband's idea of a good time—Sleeping all day Sunday."

Another one: "Our fights have turned to kisses."

At the trial of an eminent psychologist testified as to how this kind of sales appeal would be interpreted by the readers, especially those in the low income bracket who read the pulp-type of love story magazines. He pointed out how people identify themselves with the people they read about and said this kind of material "would arouse the interest of many people who suffer from real or imaginary complaints \* \* \* marital problems and so forth because many of these people with little education who are very naive cannot identify the real causes of their difficulties."

Nutrition experts testified that there is no significant difference in the nutritional requirements of the sexes and the court ruled that the products were misbranded because the labeling had incorrectly represented and implied that the formula "M" and formula "W" capsules were designed to satisfy the special needs of men and women, which representations were untrue.

Another sales angle we should all recognize is the "multiple ingredient" gimmick. It is common to find vitamin products with 50 to 100 substances listed on the label. In the *Vitasafe* case the nutrition experts showed that the ingredients were either (1) not needed because the ordinary diet supplies amounts greatly in excess of those needed for good nutrition, or (2) the ingredients were present in such small quantities as to have no nutritional significance, or (3) they had no nutritional value whatever. In the latter category were such items as rutin, lemon bioflavonoid, monopotassium glutamate, sulfur, choline bitartrate, inositol, and royal jelly. The court quoted a nutritionist who testified that all these ingredients are "irrelevant since they are absolutely insufficient to correct or tend to correct any possible deficiency."

Another nutrition expert testified that a vitamin capsule would provide nothing that is needed for the consumer if he is an average American eating average meals. "Only if his diet were unusual and restricted, like an elderly person surviving on a little more than tea and toast, would the consumer materially benefit from a *Vitasafe* capsule."

We are all familiar with the argument that everybody suffers from some kind of vitamin or mineral deficiency because nutritional factors are allegedly missing from our food supply. In the *Vitasafe* decision the court called particular attention to evidence regarding the incidence of deficiency disease in this country. As this witness put it: "When all the cases of vitamin deficiency reported in the United States in a single year are added up they do not reach the figure of 20,000, and therefore the clinically ascertainable incidence as manifested by published reports is much less than 1 percent."

Still another familiar vitamin sales gimmick is the one in which a large assortment of foods is pictured, with copy pointing out that each capsule or tablet contains as much vitamin B as a pound of liver, as much vitamin A as 6 quarts of milk, as much vitamin C as 2 pounds of carrots, and so on.

This has been interpreted by some purchasers as meaning that one tablet or capsule is equivalent nutritionally to these quantities of food. To others it is implied that one would have to eat an enormous quantity and variety of food in order to obtain the vitamins and minerals in one little capsule. In the *Vitasafe* case the court held this too was false and misleading because the foods referred to provide many times the amounts of nutrients, as well as additional nutrients, than those supplied in one *Vitasafe* capsule.

Finally, this important decision dealt with a long list of symptoms and diseases said to be prevented or remedied by taking the capsules. The court held that the listing of these symptoms itself constituted misbranding because the product was not an adequate and effective treatment for such conditions.

#### MEDICAL QUACKERY

Now I would like to speak of the third major area of modern quackery—the area of drugs and cosmetics. You will recall what I said earlier about the cost of quackery, especially when people are motivated by fear, as in the case of cancer. Many of the worst medical swindles have been worthless cancer cures. There was the Koch treatment, which consisted of distilled water, and the Hoxsey treatment, which was an extract of common herbs and weeds. Both were supposed to contain some mysterious property which would cure cancer, and both were promoted as great scientific advances in the treatment of cancer, which the medical profession and the Government were trying to suppress. Thousands of people paid millions of dollars for these fake medicines.

The Government went to court twice against the Koch treatment, and both times the jury failed to reach a verdict. Dr. Koch then went to South America, and he has never returned.

It took 10 years of litigation, including three trips to the Supreme Court of the United States, to stop the distribution of the Hoxsey treatment. In 1962 Congress passed the Kefauver-Harris Amendment to the Federal Food, Drug, and Cosmetic Act. This law requires the sponsor of a new drug to prove that it is effective as well as safe before he can distribute it commercially. Making predictions about quackery may be risky, but in my opinion we will never see the mushrooming of another big cancer swindle like the Hoxsey treatment or the Koch treatment in this country.

Of course, we still have some unfinished business in this area. For example, on February 17 the U.S. district court at Pittsburgh issued a preliminary injunction stopping the distribution of a drug called *Mucorhycin*. It was sold on a nationwide basis, by mail order.

*Mucorhycin* was devised by Philip Drosnes, a former tire salesman, and Lillian Lazenby, a former cafeteria worker. The product is made of wheat, salt, yeast and water, which is mixed in a pan and allowed to ferment until a mold is produced. The drug is an extract from this mold. This so-called cancer cure has been distributed by mail to both laymen and health practitioners. Prices have ranged from \$6.75 to \$10 per half ounce, a 1-week supply. It was claimed to dissolve tumors and recommended as a general tonic and panacea for all kinds of diseases and conditions.

During the court hearing, the defendants claimed that more than 5,000 cancer patients have been treated by 500 doctors with *Mucorhycin* in the United States and seven foreign countries. To demonstrate the effectiveness of the product, they cited two cases of alleged "cancer cures."

The defense contended that *Mucorhycin* was sold as a food dietary supplement and that there is no evidence that the product is harmful or caused injury to anyone.

Judge Rosenberg ruled that *Mucorhycin* is not a food. He said that product is a drug since it "was dispensed and used in the treatment, cure, prevention, and mitigation of disease." He stated that the "real test is how the product is sold."

The defendants maintained that there is no evidence that *Mucorhycin* has harmed or injured anyone. But Judge Rosenberg ruled that *Mucorhycin*, as a hope-giving treatment, could cause "irreparable injury to the public" by inducing patients to delay competent medical treatment until they are beyond help.

The Government also charged that Mucorhycin is manufactured under non-sterile conditions by nonqualified personnel and by a process that has no control system, all of which does not conform to good manufacturing practice.

In addition, the Government charged that the drug has never been registered and is misbranded in that it purports to be an antibiotic; that it is distributed and prescribed by healers who are not licensed to prescribe drugs and that Mucorhycin is not recognized among qualified scientific experts as an effective treatment for disease.

Is it possible to eliminate quackery? That is a very fundamental question for this conference.

My answer is that we can eliminate it to the extent that we are willing to work for its elimination. The patent medicine quackery typical of a half century ago has virtually disappeared. No longer do we have a host of fake remedies for tuberculosis, diabetes, and dozens of other diseases and conditions. The new and stronger provisions of the law will to a large extent prevent the marketing of irrational and ineffective drugs. We anticipate further changes in the law which will help greatly to eliminate quackery in the medical device field. The exaggerated claims for vitamins and so-called "health foods" will also become rare if we devote enough effort to debunking them. The *Vitasafe* case shows how they can be debunked in the courtroom.

But going to court to stop quackery is something like locking the barn after the horse has been stolen. Our long-range objective must be to eliminate the causes of quackery.

As I see it, there are four major ways to attack the problem of quackery:

The first is to improve the quality and quantity of medical care available in this country. Second-rate unorthodox medical care is what we do not want. There is too much of it now.

Next is research to find effective means for prevention and treatment. When insulin was discovered, a great many fake remedies for diabetes disappeared from the market. But diabetes quackery did not disappear. It was greatly reduced, but not eliminated.

Progress is made by eliminating what is unworthy, as well as finding what is better; and there are many situations where we cannot afford to wait for the discovery that may solve a medical problem. So our third way to eliminate quackery is through stronger laws and law enforcement. Through this approach we can keep fake products from getting on the market, as well as take them off the market. But remember—adequate enforcement requires strong, scientifically trained organizations.

Our fourth approach is through education. Here is a tremendous job for everyone who is interested in the public health and welfare. The well-informed consumer is much less likely to make unwise choices in health products and services than the person who lacks basic knowledge in these matters. The problem is how to impart such knowledge, and what knowledge to impart. Most of us just pick up what we know about such things—we get it through a lifetime of experience in raising a family. We get some of it through reading health articles—some good and some not so good. We absorb it through advertising and from TV and radio programs. How many of us have the opportunity to learn the basic facts about such things as anatomy, physiology, and nutrition? Such knowledge could save some of us a great deal of money as well as protecting health or even life itself.

The Food and Drug Administration has just issued a new booklet called "First Facts About Drugs." In it we have tried to put the kind of simple medical information that will help consumers to buy and use drugs safely and effectively. For instance:

Your body is a chemical factory. It manufactures powerful drugs such as hormones and enzymes. These regulate body processes, stimulate growth, and aid digestion.

Introducing other drugs into this chemical factory is a complex business which can have serious consequences.

When a drug is so powerful that it should be used only under a physician's supervision, the law requires that it be sold only by prescription.

Any drug may be poisonous if misused. Even aspirin causes about 100 deaths every year, mostly of small children.

Use over-the-counter drugs only for minor ailments that last a little while only. The pill taker who prescribes for himself for a continuing illness could be suffering from a serious disease. The over-the-counter drug he takes may re-

lieve his symptoms, but that's all it does. He may think he is getting better while the disease is growing and spreading.

Never become a steady user of any drug except at a physician's order.

We think that if more people could be "vaccinated" so to speak, with this kind of information they would make better use of drugs and it would help to prevent quackery.

President Kennedy in his historic message on consumer protection spoke of the "right to choose" and the "right to be informed" as basic rights of the consumer.

There is no true freedom of choice for those who are tricked and deluded, who are given misinformation, or denied the information that is needed for rational choice.

Our challenge today is to concern ourselves with the ways in which communication, health education, and law enforcement can be applied to help all our citizens make better choices in health matters.

#### RECENT ENFORCEMENT ACTIONS INVOLVING THERAPEUTIC DEVICES, JANUARY 1 TO DECEMBER 31, 1963

##### PRODUCTS SEIZED UNDER COURT ORDERS (CLOSED CASES)

**Product:** *Bioelectrometer electrophysical resistance instrument.*—A diagnostic device used in locating "subluxations" of the spinal column by measuring electrophysical resistance with attached electrodes. Device is contained in metal instrument cabinet containing a power supply and circuitry which provides voltage between a probe and a hand electrode. Current is measured by a microammeter on cabinet panel.

Possession: Kenneth C. Cook, D.C., San Francisco, Calif.

Charges: Misbranded while held for sale after shipment in interstate commerce. Failed to bear adequate directions for which it was represented in labeling and advertising; namely, in diagnosing and treating arthritis, asthma, bursitis, piles, headaches, constipation, backaches, gas, kidney, heart, or stomach disorders; dizziness; blood pressure; leg pains; migraine; frequent urination; gall-bladder pains; and other painful conditions.

Disposition: Default decree, January 3, 1963. Device released to the Food and Drug Administration for educational and exhibit purposes.

**Product:** *Tubin Ion-O-Matic air improver.*—A small, open-end container enclosing a high-voltage power supply, corona discharge ionizer, and a fan.

Shipper: Tubin Electronics, Los Angeles, Calif.

Charges: Misbranded—false and misleading claims. Literature accompanying this device claimed, among other things, that negative ions have a beneficial effect on sexual activity, vision, and emotional stability. The literature also suggested and represented that the device is adequate and effective as a treatment for relieving or overcoming hay fever, asthma, and other respiratory ailments; reducing high blood pressure caused by hypertension or nervous tension; exhilarating the mentally depressed; preventing mucous block in throat and nasal passages; reducing pain; and aiding in healing of wounds.

Disposition: Default decree of condemnation, January 4, 1963. Devices destroyed except for samples released to the Food and Drug Administration for educational and display purposes.

**Product:** *Halox therapeutic generator.*—A portable cabinet containing components capable of producing chlorine gas from table salt by means of electrolysis. The front panel of the Halox has two dials and three switches. One dial regulates gas flow and the other meters the flow of air. A rubber tube extends from the device providing an outlet for the gas. Included in the device are a fan, rheostat, transformer, salt water bottle, and carbon electrodes. Electric current ionizes the salt solution forming chlorine gas which is forced out through the inhalator tube by the fan. The chemical action also produces ozone which is inhaled by the patient along with the chlorine gas.

Shipper: Anthony Caporaso, Summit, N.J.

Charges: Misbranded—false and misleading claims and failure to bear adequate instructions for use. An accompanying booklet, "The Miracles of Father Aull," described as "the mysterious hermit of the mountains," represented the device as adequate and effective treatment for chronic sinusitis, arthritis, asthma, rheumatic fever, cancer, and to prolong life and expel all impurities from the human body; and that the device "is a system designed to balance body chemis-

try to eliminate the painful symptoms of toxic ills." Also misbranded because of inadequate directions for use in that under the law it is impossible to write "adequate" directions for use if the article is worthless or ineffective for its intended use. Tests determined that the chlorine gas generated by the device had a destructive effect on mucous membrane of animals.

Disposition: Default decree, January 17, 1963. Device and literature released to the Food and Drug Administration for exhibit and educational purposes.

**Product: Magnetic bracelets.**—A metal expansion bracelet consisting of eight enclosed magnets. Each magnet engraved with the word "Relax" and the design of playing-card clubs. The bracelet is gold colored on the outside and silver colored on the inside.

In possession of Rimar, Inc., San Juan, P.R.

Charges: Misbranded while held for sale after shipment in interstate commerce. False and misleading claims represented the device as adequate and effective treatment for providing longer and more active life, relieving arthritis, and inhibiting bacterial growth.

Disposition: Default decree, February 12, 1963. Merchandise destroyed.

**Product: Firmatone Electronic Wrinkle Remover.**—Battery-operated device with transistorized circuit to produce electrical impulses to be applied to the body through sponge applicators. Also included in package with literature was a bottle labeled: "Firmatone Contact Lotin—Contains allantoin wonderful skin food and fabulous moisturizer."

Shipper: GlamRon, Inc., Hollywood, Fla.

Charges: Misbranded—false and misleading labeling. Literature accompanying the device contains statements which represent and suggest that use of the article is effective for rejuvenating the face by eliminating poor skin texture, dry skin conditions, sagging facial contours, skin wrinkles, flabby facial muscles, facial puffiness due to poor circulation, and in general creates a healthier, more youthful appearance.

Disposition: Default decree, February 21, 1963. Device destroyed.

**Product: Facialift.**—Electronic facial exerciser device. An electronic unit powered by a single 9-volt battery utilizing a transistorized circuit to produce evenly spaced pulses causing muscular contraction.

Shipper: Facialift (Division of Willoslim, Inc.), Beverly Hills, Calif.

Charges: Misbranded—false and misleading therapeutic claims. Literature represented the device as effective treatment for improving skin texture, firming flabby muscles and sagging contours, improving circulation to flush out accumulated fatty deposits and body fluids, and other benefits.

Disposition: Consent decree, June 12, 1961. Misbranding literature destroyed, devices relabeled and released to claimant, February 27, 1963.

**Product: Beau-Monde Vibrators.**—Vibrator device with backrest, footrest, and headrest.

Dealer: Allied Liquidators, Los Angeles, Calif.

Charges: Misbranded while held for sale after shipment in interstate commerce by false and misleading claims. Accompanying literature represented the device as adequate and effective treatment for relieving arthritis, back discomfort, sinus conditions, and poor circulation.

Disposition: Consent decree, March 4, 1963. Devices relabeled in compliance with the Federal Food, Drug, and Cosmetic Act.

**Product: Auto-Electronic Radioclast (model 20, Series 800).**—A wood cabinet containing a combination of electrical circuits. The control panel contains pilot lights, line switch, heater switch, and a series of three dials intended for use in determining the identity of diseased organs. Three other dials purport to identify disease conditions present and additional dials for determining the intensity of these conditions. A rheostat controls amount of current to the device. An attached detector plate is used to locate the "maximum reaction" and thereby determine the "location" of the disease in the body. Also used as an "aid to determine spinal pressure."

Shipper: Electronic Instrument Co., Tiffin, Ohio.

Charges: Misbranded—inadequate directions for use. (Under the law it is impossible to write "adequate" directions for use if the article is worthless or ineffective for its intended use.)

Disposition: Default decree, March 21, 1963. Devices destroyed.

**Product: Whirlpool Geyser Bath.**—A plastic hose attachment to the exhaust end of a vacuum cleaner. The hose has an air regulator and vents which cause water to become turbulent when placed in a bathtub. The device is also sold with a blower attachment.

Shipper: Sholin Manufacturing Corp., Oconomowoc, Wis.

Charges: Misbranded—false and misleading claims. Literature accompanying devices claimed: "Ideal for relief of gout, arthritis, cuts and breaks, sprains, cerebral palsy, overweight, bruises, polio, rheumatism, indigestion, nerves, multiple sclerosis and sore muscles."

Disposition: Default decree March 25, 1963, devices destroyed by the U.S. marshal.

*Product: Relax-A-Matic automatic massage assembly unit.*—The unit consists of pulsating motors with attachments for mounting to bed springs, pillows, and a coin-operated electric timer.

Shipper: Relax-A-Matic, East Orange, N.J.

In possession of Eugene Halpern, New York, N.Y.

Charges: Misbranded when introduced into, and while in, and while held for sale after shipment in interstate commerce by false and misleading therapeutic claims. Printed material accompanying the device contained statements representing the device as effective treatment for varicose veins, rheumatic fever, heart disease, soreness, stiffness, back and sacroiliac pain, nervousness, and others in addition to keeping "veins and arteries free from deposits."

Disposition: Consent decree, April 16, 1963. Misbranding literature destroyed, devices relabeled in compliance and released to claimant.

*Product: Oxy-Gear Oxygen Inhalator Kit.*—Device consists of a portable metal cylinder designed to hold 145 liters of oxygen under 1,800 pounds pressure. Attachments include a mask, tubing, and release valve to permit gradual release of oxygen over 15-minute period.

Shipper: Oxy-Gear, Inc., Chicago, Ill.

Charges: Misbranded—false and misleading claims. Literature accompanying device contains statements which represent and suggest the device is adequate and effective treatment for relieving sudden cardiac and asthmatic attacks, shortness of breath, and lung conditions; and for overcoming effects of shock, smoke inhalation, migraine headaches, exhaustion, hangover, and driving fatigue.

Disposition: Court decree of condemnation April 16, 1963. Misbranding literature destroyed, devices relabeled in compliance, and released to claimant.

*Product: Rejuvenec.*—An electronic facial exercizer with transistorized circuit, battery-operated, electrical pulse generator, and electrode applicators enclosed in a plastic case. Also "Rejuvenec Lotion" and literature.

Shipper: Rejuvenec, Inc., Minneapolis, Minn.

In possession of Rejuvenec, Des Moines, Iowa.

Charges: Misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce by false and misleading claims. Literature suggests that device is effective in regaining and retaining a youthful face and throat by eliminating lines and wrinkles and by toning and firming facial tissue.

Disposition: Default decree, April 22, 1963. Seized devices released to the Food and Drug Administration for educational and exhibit purposes.

*Product: Filter Queen Vacuum Cleaner, Vibrator, Demolisher, and Attachments.*—Device is canister-type vacuum cleaner with attachments, including a portable vibrator unit attachment.

Shipper: Health-Mor, Inc., Chicago, Ill., and Cleveland, Ohio.

Dealer: Filter Queen, Inc., Denver, Colo.

Charges: Misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce by false and misleading claims. Carton label for the "Filter Queen Vibrator" attachment contained statements which represent and suggest that the devices are adequate and effective treatment for relieving muscular pain and discomfort from arthritis and rheumatism, aiding health, firming flesh, and reducing unwanted fat. Also misbranded in that labeling fails to bear adequate directions for improving health, and overcoming asthma, hay fever, arthritis, rheumatism, and sinus headache, the conditions and purposes for which the devices were offered in oral statements by a Filter Queen salesman.

Disposition: Consent decree, April 25, 1963. Misbranded literature destroyed and newly labeled boxes brought into compliance. Claimant permanently prohibited and enjoined from making therapeutic claims for devices.

*Product: Vac-U-Prep.*—A prosthetic device consisting of plastic tubes and suction cups which was to be used as medical therapy for male impotency.

Dealer: Sooner Prosthetics, Ada, Okla.

**Charges:** Misbranded while held for sale after shipment in interstate commerce by false and misleading claims in that literature accompanying the product contained statements which represent and suggest that use of the device is an adequate and effective treatment for senile impotence of a psychological nature, premature senility, lessened flow of blood due to circulatory difficulties, premature ejaculation, and marital sexual incompatability.

**Disposition:** Default decree, July 11, 1963. Devices and labeling destroyed.

**Product:** *Aqua-Laxer Hydro-Massage*.—A massage device consisting of a motor-driven air blower, a flexible hose, and a perforated plastic mat. The mat is placed on the bottom of a bathtub. The motor pumps air to the mat through the tube, causing a flow of air bubbles in bath water.

**Dealer:** Aqua-Laxer Distributing Co., Houston, Tex.

**Charges:** Misbranded while held for sale after shipment in interstate commerce, in that labeling, namely, the brochure entitled "You Are As Young As You Feel," accompanying the device, contained statements which represented and suggested that the article is adequate and effective treatment for poor circulation, muscle fatigue, arthritis, rheumatism, bursitis, neuritis, mental and physical tension, varicose veins, backache, nervous conditions, and sinus conditions; and that use of the device will improve health and vitality, prevent discomforts, tranquilize, cleanse the muscle tissues, make you feel younger, is like a fountain of youth, and for other purposes; which statements are false and misleading.

**Disposition:** Consent decree, July 18, 1963. Misbranding literature destroyed. Devices relabeled in compliance.

**Product:** *Comforette leg elevator*.—A device constructed of gold-colored tubular metal covered with colored plastic material constructed in such a fashion that it serves as a support for the legs, elevating them approximately 10 inches when the user is resting in a supine position.

**Shipper:** Hill Manufacturing Co., Santa Ana, Calif.

**Charges:** Misbranded, false and misleading claims. Labeling accompanying article contained statements which represent and suggest that the device is an adequate and effective treatment for heart conditions and nervous tension, and that it restores energy and improves circulation.

**Disposition:** Consent decree, August 2, 1963. Misbranding literature destroyed for purpose of bringing devices into compliance with the law.

**Product:** *Jacuzzi whirlpool bath*.—A portable unit used to swirl water in a tub.

**Dealer:** Fernarden Equipment Co., East Point, Ga.

**Charges:** Device was misbranded while held for sale after shipment in interstate commerce in that literature and labeling failed to bear adequate directions for use for traumatic sprains, strains, contusions, bursitis, bone injuries, circulatory disturbances, inflammation, edema, ulcers, pectoral sclerosis, peripheral nerve injury, neuritis, arthritis, and post poliomyelitis; conditions for which the article was offered for sale in oral statements by a salesman for the dealer during a home demonstration.

**Disposition:** Consent decree, September 20, 1963. Decree provided for release of articles to claimant for bringing into compliance with the law.

**Product:** *Auto-Electronic Radioclast, model 20*.—A wooden cabinet containing a combination of electronic circuits. The control panel contained pilot lights, line switch, heater switch, and a series of dials intended for use in determining the identity of diseased organs. Three other dials were supposed to identify the disease conditions present, and additional dials were supposed to determine the intensity of the disease. An attached detector plate purported to locate the point of maximum reaction and thus determine the location of the disease in the body. For use by a practitioner.

**Manufacturer:** Electronic Instrument Co., Tiffin, Ohio.

**Charges:** Failed to bear adequate directions for use. (Adequate directions cannot be written for a worthless device.)

**Disposition:** Condemned by court order October 9, 1963, and delivered to the Food and Drug Administration for educational use.

**Product:** *Magnetron*.—Device consists of a 6,000-volt transformer and two condensers in a wooden cabinet about 2 feet high, 15 inches wide, and 11 inches in length. The control panel includes a neon tube, electrode jacks, power switch, intensity control, and fuse holder. Electrodes and foot switch connect to device.

**Shipper:** Peter D. Pauls, D.O., Lewiston, Idaho.

**Charges:** Misbranded in that device failed to bear label containing name and place of business of manufacturer, packer, or distributor and labeling failed to bear adequate directions for use and such directions cannot be written since pro-



spective user may be subjected to hazardous electrical shock under any conditions of use due to faulty design of article and the device is regarded as worthless for any medical purpose. (A previous condemnation of this device (Oct. 19, 1962) established that labeling by the manufacturer represented the device as adequate and effective as a treatment for diabetes and tumors; varicose veins and rheumatoid arthritis; that use of the article would impart new strength, vim, vigor, and vitality to every part of the body which would result in better health; and that use of the article would cause hearts to grow stronger and prostate gland tumors to shrink, build up the blood, improve capillary circulation and nutrition causing local disease symptoms and conditions to disappear; and that the user, through use of the article, might regain and restore health, aid the body to become stronger and healthier, and cause disappearance of disease.)

Disposition: Default decree, November 13, 1963. Devices delivered to Food and Drug Administration for educational exhibit purposes.

*Product: Veltron electric chin massager and Veltron roller massager.*—These are vibrator devices. The chin massager is curved to fit under the chin and is equipped with a strap which is placed over the head. The roller massager is contained in a cylindrical plastic housing.

Shipper: S. L. McNair Corp., Anaheim, Calif.

Charges: Devices were misbranded by labeling and package insert which represented the devices as adequate and effective treatment to relieve tension, stimulate and increase circulation, and for firming sagging, flabby chin, and throat muscles and wrinkles.

Disposition: Default decree, November 14, 1963. Devices destroyed.

*Product: Safe-T-Sun health tan sunlamps.*—Device is an electrical lamp fixture containing a 275-watt ultraviolet lamp and holder for filters. Lamp is supported on tripod for floor use. (Professional model of lamp is labeled "Jayne Mansfield Health-Tan Sunlamps.")

Shipper: Celebrity Merchandisers, Inc., New York, N.Y.

Charges: Misbranded by false and misleading claims for tired back, stiff neck, arthritic-like pains, skin problems, aching muscles, and toning the skin; and that filter would permit unlimited use of lamp without burning.

Disposition: Consent decree of condemnation September 9, 1963. Devices brought into compliance by destruction of misbranding literature and other labeling December 4, 1963.

*Product: Micro-Dynamometer* (13 units seized in 5 actions).—The Micro-Dynamometer is a simple galvanometer for measuring electrical currents and potentials of small magnitude. The device is enclosed in an elaborate metal or wood cabinet, depending on the model. The control panel has a meter to measure the flow of current coming from two "probes" which are placed at various points on the body. The panel also has a number of dials which can be set at numbered or lettered positions.

Shipper: Ellis Research Laboratories, Inc., Chicago, Ill.

In possession of practitioners and their clinics or institutions over the country, and the manufacturer, Ellis Research Laboratories, Inc., Chicago, Ill.

Charges: Misbranded, false and misleading claims and inadequate directions for use when introduced into and while in interstate commerce. Labeling and literature contains statements representing the device as adequate and effective in diagnosis of most diseases including cancer, tuberculosis, rheumatism, nephritis, nerve impingements, etc. Literature and labeling contained inadequate directions for use in that under the law it is impossible to write "adequate" directions for use if the article is worthless or ineffective for its intended use.

Disposition: Default decrees. Devices, accessories, and literature destroyed or released to the Food and Drug Administration for educational and exhibit purposes.

*Product: Vibra-Matic health aid unit* (mattress and component parts).—Device is a mattress, electrical switch, motor, and metal frame for support of motor.

Shipper: Vibra-Matic Co., Wichita Falls, Tex.

Dealer: Union Mattress & Pillow Co., Denver, Colo.

Charges: Misbranded when introduced and while in interstate commerce and further misbranded while held for sale after shipment in interstate commerce in that labeling and literature represent and suggest that the article is adequate and effective as a general health aid and in the treatment and prevention of nervous, emotional and physical tensions, insomnia, tired muscles and joints, overstimulated muscles in active growing youngsters, fatigue, hypertension, poor circulation, many chronic ailments, pain caused by arthritis, rheumatism, backache, hemorrhoids, headaches, and other medical conditions.

Disposition: Consent decree, November 6, 1963. Devices brought into compliance with the law by relabeling.

*Product: Leg rejuvenator.*—A fabric-covered tubular metal frame to be used as an elevated footrest.

Shipper: Beacon Enterprises Inc., New York, N.Y.

Charges: Misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act with false and misleading claims for improving blood circulation, easing heart strain, to reduce leg swelling and for other health purposes.

Disposition: Default decree entered August 5, 1963, providing for destruction.

#### RECENT ENFORCEMENT ACTIONS IN FEDERAL COURTS INVOLVING THERAPEUTIC DEVICES, JANUARY 1-DECEMBER 31, 1963

##### INJUNCTIONS FILED

*Product: Radioclast model 40.*—Electronic magnetic model G electro sine galvanic model 200, auto electric radioclast model 20, series 800, and electronic analysis instrument model F (described under "Seizure" tabulation).

Shippers: L. L. Roby Manufacturing Corp., and the International Electronics Research Society, Inc., Tiffin, Ohio.

Action and charges: Injunction. All these devices falsely claimed to be adequate and effective for the therapeutic treatment of body areas of congestion, inflammation, and irritation; for aiding the body to eliminate areas of congestion, inflammation, and irritation; and for supplying stimulating energy to the body.

Disposition: Permanent consent decree of injunction issued May 27, 1963, prohibiting further distribution of these devices by the firms and codefendants Lester L. Roby and Lester L. Roby, Jr.

#### RECENT ENFORCEMENT ACTIONS IN FEDERAL COURTS INVOLVING FOOD SUPPLEMENTS, JANUARY 1 TO DECEMBER 31, 1963

##### PRODUCTS SEIZED UNDER COURT ORDERS (CLOSED CASES)

##### *Product: Nutri-Bio Food Supplement*

Shipper: Nutri-Bio Corp., Elk Grove Village, Ill.

Charges: Misbranded because the label, other printed material, and a film titled "Just To Be Sure," implies that this product is effective in promoting mental and physical health, radiant living, sociability, enthusiasm, liveliness, and other social graces and personality traits. Also implies that it is of special value as a dietary supplement and has therapeutic use because it contains numerous vitamins and minerals, and that everyone needs food supplements. This product further charged misbranded because its labeling does not bear adequate directions for use and treatment in the prevention of (among other things) arthritis, bursitis, psoriasis, measles, and bad teeth, the conditions and purposes for which it was offered in oral statements made by a Nutri-Bio sales agent to a customer.

Disposition: Condemned and destroyed, together with literature and film, January 18, 1963.

##### *Product: Jack LaLanne's Instant Breakfast*

- Dealer: LaLanne, Inc., Hollywood, Calif.

Charges: Misbranded in that its name and statements on its label and in accompanying literature imply that it contains an unusual quantity of protein for special dietary supplementation with a low amount of calories which, therefore, makes it of special value for weight reducing; that it satisfies the appetite and appeases hunger; that it furnishes in one can seven complete breakfasts, each significantly more nutritional than a breakfast consisting of 4 fluid ounces of fresh orange juice, two eggs, two slices of bacon, a cup of black coffee, one slice of whole wheat bread, and one pat of butter; all of which statements are contrary to fact.

This product is also charged misbranded in that it is represented as a food for special dietary use, yet its label fails to bear information concerning such properties as prescribed by law; nor does the label bear, as required by law, a

statement of the percent by weight of the artificial sweetener in this product, sodium cyclamate, and in juxtaposition with it the word "nonnutritive."

Disposition: Consent decree, January 29, 1963. Literature destroyed. Product brought into compliance by relabeling under FDA supervision, and released to claimant.

*Product: Visol-Vitamin Product*

Shipper: Rifer Laboratories, Inc., Santurce, P.R.

Charges: Misbranded in that its labeling bears statements which imply it is effective for strengthening vision and brain, for treatment and prevention of loss of eye brightness, and for infection of the mucosa, and dryness of skin, which statements are false and misleading.

Disposition: Default decree, February 14, 1963. Destroyed, March 5, 1963.

*Product: Larson's C.R.D., a dietary food supplement*

Shipper: The Fleetwood Co., Chicago, Ill.

Dealer: Walgreen Drug Store, Denver, Colo.

Charges: Misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce, in that its labeling implies this product is a reducing diet; that it is effective for removing pounds and inches of excess fat off big eaters in 8 hours, and they need diet for only one meal a day and eat normally otherwise, without counting calories; all of which statements are false and misleading. In addition, labeling fails to bear adequate directions for use of the product for all the conditions and purposes for which it is prescribed in the labeling.

Disposition: Consent decree, November 19, 1962. Shipment to be released to client for salvage by bringing into compliance with the law under supervision of FDA authorities. Salvage completed and merchandise released to claimant, February 26, 1963.

*Product: Yerba Mate*

Dealer: Turet Importers, Philadelphia, Pa.

Charges: Misbranded while held for sale after shipment in interstate commerce, in that its labeling, including folders and leaflets, contains statements which imply that it is an effective treatment for producing exhilaration and relief from fatigue, stomach acidity, indigestion, and constipation; that it is a heart tonic and diuretic; that it will excite the brain to increased mental activity and capacity; stimulate organs of nutrition; comfort the mind and dispel weariness, insomnia, cerebral erethism, headache, dyspepsia; will counteract depression of alcoholic debauching, gout, nerve disorders, and others; whereas all these statements are false and misleading.

Disposition: Consent decree August 15, 1962. Article destroyed March 14, 1963.

*Product: Vi-Ron-Ite Tonic*

(Label: A high-potency tonic of therapeutic strength \* \* \*. Each fluid ounce represents B<sub>1</sub> (thiamin) 10 milligrams D.R. \* \* \*. Provides a therapeutic tonic for iron, thiamin \* \* \*. Effective as an aid to normal energy metabolism \* \* \*.)

Shipper: C. M. Bundy Co., Cincinnati, Ohio.

Charges: Misbranded in that its labeling (which includes carton and bottle labels and leaflet in carton) contains statements which imply it is effective for treatment and prevention of anemia, rundown condition, and tiredness; to promote tissue growth, release body energy, slow down the aging process, retain blood vessel pliability, build muscle and nerve tissues, and promote normal energy metabolism. The statements also suggest that this product is of unusual significance as a special dietary supplement, and has therapeutic use because in one bottle it supplies as much essential iron as 40 pints of raw oysters, 9 pounds of beefsteak, 93 pounds of spinach, or 60 pounds of fish, all of which statements are contrary to fact.

Also charged to contain less than the declared amount of thiamin.

Disposition: Default decree March 11, 1963; product destroyed March 15, 1963.

*Product: Super Coronaid Tablets*

(Label: "A planned aid in the prevention and management of arthrosclerosis where the use of diets low in fats, cholesterol and calories are indicated and used.")

Shipper: Balanced Foods, Inc., New York, N.Y.

Dealer: Chamberlin Natural Foods, Orlando, Fla.

**Charges:** This product charged misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce, because its labeling, including leaflet, implies that it is an effective treatment in prevention and management of atherosclerosis, coronary heart attacks, and diseased arteries. Product labeling also suggests that its use may add years to your life, improve your health, reduce cholesterol in the arteries, save you from sudden heart attacks, and help keep your arteries flexible.

**Disposition:** Consent decree February 9, 1962. Article destroyed March 15, 1963.

*Products: Natural vitamin C "400" tablets with accrola superamino tablets*

**Distributor:** Universal Nutritions, Inc., New York, N.Y.

**Shipper:** Lust Health Foods, Inc., New York, N.Y.

**Charges:** Natural vitamin C "400" tablets: Misbranded in that its labeling contains statements which suggest that it is effective for the treatment and prevention of stiff joints, rheumatic pains, asthma, allergies, bleeding gums, hardening of the arteries, weak blood capillaries, slow wound healing, poor resistance to disease, lack of vitality, nutritional anemia, and for other purposes, all of which claims are false and misleading.

Superamino tablets: Misbranded in that its labeling implies that it is effective for treatment and prevention of great fatigue, loss of strength and pep, depression, and vague aches and pains; for promoting youthful strength, energy, firm, healthy tissues; for gland repair, enzyme and hormone production, resistance to disease, vigorous health, body building, to produce antibodies to fight disease, including infections, bacterial, and virus diseases; for blood, long life, bone cell and bone development, heart tissue growth and heart cycle action; and to maintain brain tissues in later life. Further charged misbranded by claims that the product is of significant value as a source of protein for special dietary supplementation, that the body needs all the essential amino acids in it every day and every meal, and that the nutritional protein requirements for people over 40 are different than those of adults generally; all of which statements are contrary to fact.

**Disposition:** Consent decree January 15, 1963; destroyed March 12, 1963.

*Product: Oro-Vita Food Supplement (vitamin and mineral tablets)*

**Dealer:** Oro-Vita Corp., Salt Lake City, Utah.

**Charges:** Misbranded while held for sale after shipment in interstate commerce, in that its labeling, sales manual, and other literature, claim that it contains a so-called tramin base represented as a unique, nutritional discovery consisting of elements from the land, the sea, and from what used to be the bottom of the sea, and that all of its trace elements interrelate and balance for near perfect function. Also charged misbranded in that its labeling implies that it is effective for the treatment and prevention of numerous diseases and afflictions of the body, including irritability, low vitality, stunted growth, soft bones, malformed teeth which decay easily, fragile bones in old people, senility, premature aging, neuritis, senile dementia, chronic sickness, digestive, nervous and mental ailments, damage to the liver, coronary heart attacks, strokes, diseases of the kidney, premature wrinkles, intelligence loss, migraine headaches, obesity, diabetes, cancer, leukemia, memory defects, severe agitation, and pernicious anemia. Charged further misbranded in that labeling suggests that this product will keep the blood neutral, assist in blood coagulation, develop and maintain health, happiness, and vigor, prolong the prime of life, help one live longer, increase the intelligence quotient, prolong female fertility, and aid vision; and in that its labeling literature implies that food supplies generally consumed by the public are inferior and do not contain adequate amounts of vitamins and minerals, that the multitude of ingredients contained in this product are vitamins and minerals; and that the need in infant nutrition for niacin, iodine, iron, and calcium has not been established; all of which statements are false and misleading.

**Disposition:** Consent decree May 20, 1960, provided for release of goods to claimant for relabeling and salvage to bring into compliance with the law. This was never accomplished, and product and literature were destroyed March 13, 1963.

*Product: Gold-N-Sweet safflower shortening*

**Shipper:** San-Val Distributing Co., Los Angeles, Calif.

**Charges:** Article misbranded in that the labeling implies it is effective in the prevention of arteriosclerosis, heart attacks, strokes, and for other purposes; further, in that the labeling claims it is a shortening made entirely from saf-

flower oil when it really consists of safflower oil and hydrogenated cottonseed oil. In addition, although this product is composed of two or more ingredients, the label fails to show the common name of each of these ingredients; and "all vegetable shortening" is not a common or usual identification for safflower oil and hydrogenated cottonseed oil.

Disposition: Decree of condemnation March 4, 1963, literature destroyed and product turned over to State institution March 20, 1963.

*Products: Vita-Glo Food Supplement, Nutra-Glo Food Supplement, Brewer's Yeast Tablets, and Dehydrated Cabbage Tablets*

Dealer: Century Foods Co., Varna, Ill.

Charges: Misbranded because their labeling claims are false and misleading.

Labeling of Vita-Glo Food Supplement, and Nutra-Glo Food Supplement implies that these products are effective for treatment of infections and improper functioning of all parts of the body, as well as for nervous disorders, anemias, and dental decay; and effective to promote growth and longevity. The labeling of the Brewer's Yeast Tablets implies that the product is effective for treatment of insomnia, liver disease, enlarged heart, and for other purposes.

The labeling of the Dehydrated Cabbage Tablets implies that the product is of significant value as a special dietary supplement, and also suggests it is effective in the treatment of ulcers.

Disposition: Default decree of condemnation. All products destroyed April 3, 1963.

*Products: A-E Plus Capsules, Speed A Vite Capsules, Vitamin A Capsules, Saffinol Capsules, A-D Vitamin Capsules, Admiral Sea Spray Salt, Halibut Liver Oil Capsules, and Soy Bean Lecithin Capsules*

Dealer: Barth Levitt Products, Long Island, New York, N.Y.

Charges: The products (bulk and repackaged articles) are charged misbranded while held for sale after shipment in interstate commerce, as follows:

*A-E Plus Capsules.* Misbranded because the labeling, including catalogs titled "Guide to Health," contains statements which imply that the product is effective in the treatment of infection of mucous membranes of eyes, nose, mouth, and throat; treatment and prevention of a wide range of ills; protection against adverse changes in the body; to promote growth, healthy eyes, and skin; that the germ oil and lecithin in the product will promote significantly the absorption of vitamins A and E; and that the lecithin in it will promote fat digestion and fat transport in the body, particularly for people over 40; which statements are false and misleading.

*Speed-A-Vite Capsules.*—Both the name and labeling statements imply that this product is effective for the treatment and prevention of infection of the mucous membranes of the eyes, nose, mouth, and throat; to promote growth and healthy eyes and skin; and that it is of unusual benefit because it contains acacia to absorb vitamin A into the blood more rapidly and to a greater extent, which statements are contrary to fact.

*Vitamin A Capsules.*—Because the labeling implies that the product is effective for treatment and prevention of infections of mucous membranes of eye, nose, mouth, and throat; and to promote growth and healthy eyes and skin; which statements are false and misleading.

*Saffinol Capsules.*—Because the labeling implies that the product is effective for dissolving fat, promoting fat transportation in the body, building the blood, and for the promoting of all functions of the body; which statements are false and misleading.

*A-D Vitamin Capsules and Halibut Liver Oil Capsules.*—Because the labeling of these two products implies that they are effective for treatment of mucous membranes of the eyes, nose, mouth, and throat; poor bone and tooth development in children; muscle weakness; tooth decay and bone disorders; for the promoting of growth, healthy eyes, and skin; and that these products will regulate the use of calcium and phosphorus; which statements are false and misleading.

*Admiral Sea Spray Salt.*—Because its labeling implies that this product is of unusual significance for special dietary use due to the presence of all the trace elements from the sea, that such trace elements are catalysts which unlock the benefits of food so that the body can utilize such food to best advantage, and that it will promote health; which statements are contrary to fact.

*Soybean Lecithin.*—Because the labeling implies that this product is effective for promoting fat digestion and fat transport in the body, particularly for people over 40; which statements are false and misleading. In addition, this product charged misbranded because it purports to be a food for special dietary use, and

its label fails to bear information prescribed by FDA regulations in order to inform purchasers fully as to its value for such use, since the label fails to bear, as required by regulations, the statement "The need for choline and inositol in human nutrition has not been established."

Disposition: Consent decree, March 29, 1963; destroyed April 18, 1963.

*Product: Vita 50 Capsules (Vitamin A capsules)*

Dealer: Taylor Laboratories, Jackson, Miss.

Charges: Misbranded while held for sale after shipment in interstate commerce in that labeling statements represented and suggested the article was adequate and effective as a treatment for dry skin, acne, and eczema, and provided resistance to infections, which statements were false and misleading since the article was not adequate and effective for such purposes.

Disposition: Default decree March 19, 1963; destroyed April 18, 1963.

*Product: Replenz (Enzyme aid, a vitamin and mineral preparation)*

Shipper: K. V. Pharmacal Co., St. Louis, Mo.

Dealer: Taylor Laboratories, Division of the Duman Milner Corp., Jackson, Miss.

Charges: Misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce in that labeling represented and suggested that the article was adequate and effective for aiding the digestive process, dyspepsia, food intolerance, belching, flatulence, "over 40 stomach trouble," stomach distress due to enzyme deficiency, gas, heartburn, lack of vitamins due to impaired intestinal absorption, and for other purposes, which statements were false and misleading since the article was not adequate and effective for such purposes.

Disposition: Default decree March 19, 1963; destroyed April 18, 1963.

*Products: Safflower Oil, Safflower Oil Capsules, Dia-Mel Dietetic Crackers, and "Calories Don't Count" (book)*

Dealer: Forks Township Pharmacy, Easton, Pa.

Charges: The articles (all lots) charged misbranded in that their labeling (placard and book accompanying them) imply that these products are effective for the control of body weight and for reducing and maintaining slimness, no matter how many thousands of calories are consumed a day. Labeling also suggested that these products will lower and control the level of blood cholesterol; can be used for the treatment and prevention of arteriosclerosis, heart disease, diabetes, and heartburn; increase resistance to colds and sinus trouble; increase sexual drive; and for other purposes; all of which claims are false and misleading.

Disposition: Condemnation and destruction; destroyed May 28, 1962.

*Product: Liver-Iron-Vitamins*

Shipper: Barry Laboratories, Detroit, Mich.

Charges: Misbranded because of claims that this product is effective in the treatment of all types of anemia which respond to liver and iron salts. In addition, labeling does not bear adequate directions for use in the treatment of such anemias, for which it is recommended.

Disposition: Order of condemnation; destroyed June 25, 1963.

*Products: Vit-Ra-Tox Colo-Clenz No. 19, Vit-Ra-Tox No. 21A, Veico "77", Veico No. 83 Wheat Germ Oil, Vit-Ra-Tox "16", Vit-Ra-Tox No. 22 Dietary Supplement, Veico No. 79A Intestinal Cleaner, Springreen No. 66 Natural Food Concentrate, Springreen No. 30 Natural Food Concentrate, Springreen No. 31 Natural Food Concentrate, Springreen No. 33 Natural Food Concentrate, and Vit-Ra-Tox No. 22 Dietary Supplement*

Shipper: V. E. Irons, Inc., Boston, Mass.

Dealer: Michael Sorokie, Irving Park Diet Center, Chicago, Ill.

Charges (illustrative, but not complete): Misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce, in that—  
Vit-Ra-Tox Colo-Clenz No. 19 and

Veico No. 79A Intestinal Cleaner: Labeling on these two items implies that constipation is the universal disease; that less than two or three bowel movements a day results in poisoning of the body; that lack of bulk in the diet causes abnormal digestive processes, foul body odors, poisoning, interference with absorption of nutrients, and promotes diseases; and that the use of these products will correct all these conditions; all of which statements are false and misleading.

Vit-Ra-Tox No. 21A: Labeling states that vitamin B<sup>12</sup> is not established to be needed in human nutrition, whereas the need for such substance has been established; labeling implies it is a completely balanced source of nutrition, and that it is an effective treatment for all conditions of ill health, except dangerous, acute conditions; which statements are false and misleading.

Veico "77": Labeling implies that it is for systemic detoxification and an intestinal purificant, which claims are false and misleading.

Veico No. 83 Wheat Germ Oil: Labeling fails to bear adequate directions for use required by law for the effective treatment, prevention, or cure of heart attacks, cholesterol deposits, arthritis, varicose veins, diabetes, and heart and circulatory ailments, for which conditions the article was intended to be used, as indicated by oral statements made by a saleswoman.

Vit-Ra-Tox "16": Labeling statements falsely and in misleading manner suggest it is effective for systemic detoxification and is an intestinal purificant.

Vit-Ra-Tox No. 22 Dietary Supplement: Labeling statements imply that vitamin B<sup>12</sup> is not established to be needed in human nutrition, whereas the need for such substance has been established. This product further misbranded in that the label implies that the bound form of the vitamin, or the vitamin complexes as occurring in plant tissue, have more nutrient value than that of the vitamin embodied in the complex and that these complexes are necessary elements of nutrition, which representations are false in that such complexes or bound forms are not necessary elements of nutrition in themselves, and have no more value in nutrition than do the vitamins embodied in those complexes.

Springgreen No. 66 Natural Food Concentrate

Springgreen No. 30 Natural Food Concentrate

Springgreen No. 31 Natural Food Concentrate

Springgreen No. 33 Natural Food Concentrate: Labeling of these four products, including order form headed "Springgreen," imply that the American diets are lacking in vital nutrients because many foods are deficient in their expected nutritional value due to depleted soils, refining processing, transportation, and cooking, and that the use of Springgreen is necessary to correct these deficiencies, which representations are false in that malnutrition is rare in this country, and completely adequate nutrition can be obtained through the use of a variety of properly selected common foods.

Disposition: Four consent decrees dated July 31, 1959, November 30, 1960, March 28, 1961, and June 18, 1963, ordered destruction of literature and all articles except Vit-Ra-Tox No. 19 Colo-Clenz and Veico No. 79, which articles were to be released to claimant under conditions specified in permanent injunction against similar violations. Eight of the products, with accompanying literature, were destroyed shortly after the July 31, 1959, court order. Another product was destroyed December 1, 1960; two more groups of products destroyed on March 30, 1961, and the literature on July 24, 1963. The two items ordered returned were released to claimant on June 25, 1963.

*Product: Nutri-Bio food supplement vitamins*

Shipper: Nutri-Bio Corp., Beverly Hills, Calif.

Dealer: Nutri-Bio of Ohio, Inc., Sandusky, Ohio.

Charges: Misbranded while held for sale after shipment in interstate commerce, in that the name of the article "Nutri-Bio \* \* \* dietary food supplement," is misleading as applied to a product whose composition varies from carton to carton; and because its label implies that the product is of significant value for special dietary supplementation because it contains unsaturated fatty acids, linoleic acid, linolenic acids, inositol, para-aminobenzoic acid, rutin, biotin, methionine, bioflavonoid complex, hesperiden complex, choline, alfalfa juice and powder concentrate, copper, manganese, magnesium, potassium, sulfur, chlorine, sodium, and montmorillonite (wonder clay). Also charged misbranded and adulterated in that it contains less vitamins C and B<sub>12</sub> than claimed on the label.

Disposition: Decree of condemnation, June 26, 1963; product destroyed, July 5, 1963.

*Product: Hemo-Glo tablets*

Label: Iron, B<sub>12</sub>, B-complex, vitamin C, bioflavonoids, liver, enzymes, and herbal extracts.

Shipper: Barrows Chemical Co., Inc., Long Island, New York, N.Y.

Dealer: Nu-Age Biorganic Products, Inc., Venetia, Pa.

Charges: This product (in bulk and repack) charged misbranded when introduced into, while in, and while held for sale after shipment in interstate com-

merce, in that the bulk and repack labels contain statements which imply that the product is of significant value as a special dietary supplement, and for treatment of iron deficiency anemia because it contains black cohosh, buchu leaves, comfrey root, strawberry leaves, mullein leaves, violet leaves, pipsissewa herb, juniper berries, licorice root, buckhorn bark, cellulolytic enzyme, amylolytic enzyme, lipolytic enzyme, prickly ash bark, inositol, choline, lecithin, dulse, burdock root, dandelion root, oregon grape root, yellow dock, gentian root, red clover blossom, hyssop, sarsaparilla root, watercress juice, alfalfa juice, rutin, lemon bioflavonoids, beef peptone, red bone marrow, and desiccated and defatted liver. Further charged adulterated and misbranded in that it contains only 67 percent of the amount of vitamin B<sub>1</sub>, 50 percent of the vitamin C, and 76 percent of the niacin claimed on the label.

Disposition: Consent decree, March 26, 1963; article destroyed, July 5, 1963.

*Product: Jettup B complex with B<sub>12</sub>*

Labeled ingredients: Riboflavin 5 mg.; whole liver desiccated 102.5 mg.; Brewer's yeast 102.5 mg.; niacinamide 50 mg.; thiamine hydrochloride 50 mg.; pyridoxine HCl, 1 mg.; vitamin B<sub>12</sub>, 1 mcgm.

Dealer: Goodrich-Wright, Inc., Dallas, Tex.

Charges: Product charged misbranded while held for sale after shipment, in that its name and labeling statements imply that it is effective for treatment of nervous tension, uncontrolled movements of the hands and legs, irritability, fast pulse, fatigue, loss of appetite, inability to sleep, swelling of the face and ankles, decrease in mental and physical efficiency, blurred vision, and irritation of the eyes, corners of the mouth, and nostrils, and that it is unusually fast acting in the treatment of disease, all of which statements are false and misleading.

Also charged misbranded and adulterated in that the product contains less than the declared amounts of ingredients listed on the label.

Disposition: Default decree of condemnation, August 5, 1963; article destroyed, August 8, 1963.

*Product: Geriatric vitamin tablets*

Shipper: Lit Drug Co., Newark, N.J.

Charges: Charged misbranded in that the name "Geriatric Vitamins" implies that the product has unusual value as a special diet additive for the elderly because the nutritional requirements of the elderly are different from those of adults generally, which implications are false and misleading, since they are contrary to fact. Also charged misbranded and adulterated because its label is false and misleading in its entirety for an article which fails to disintegrate, and the declared nutrients cannot be adequately assimilated.

Disposition: Order of condemnation; destroyed September 4, 1963.

*Product: Dexaphene tablets*

(Label: Phenyl propanolamine hydrochloride 25 mg.)

Shipper: Reese Chemical Co., Cleveland, Ohio.

Dealer: Best Drug Co., Atlanta, Ga.

Charges: Misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce in that labeling represented and suggested the article was adequate and effective for overcoming obesity through appetite control; for removing excess body weight, and depressing the appetite, resulting in less food intake, loss of weight, and longer life, which statements were false and misleading.

Disposition: Default decree August 27, 1963. Destroyed September 6, 1963.

*Product: Nutri-Bio food supplement*

Shipper: Nutri-Bio Corp., Beverly Hills, Calif.

Dealer: Thomas Gordon Railey, Jeffersonville, Ind.

Charges: Misbranded by false claims in labeling and promotional material that this product is effective for treatment of nervousness, loss of weight, dental caries, anemia, palpitation of the heart, pyorrhea, excessive bleeding from minor wounds, muscular spasm, osteoporosis; and to promote mental and physical health, happiness, sociability, enthusiasm, liveliness, vigor, alertness. Also charged misbranded because of false claims made in a sales talk by Thomas Gordon Railey that this product is effective for treatment of baldness, heart attack, serious heart condition, strokes, swollen knees and ankles, asthma, and allergies.

Disposition: Decree of condemnation October 9, 1963. Products destroyed October 25, 1963.



RECENT ENFORCEMENT ACTIONS IN FEDERAL COURTS INVOLVING FOOD SUPPLEMENTS,  
JANUARY 1, 1963-DECEMBER 31, 1963

## CRIMINAL PROSECUTIONS TERMINATED

*Product: Supro-Zyme tablets*

Defendants: Universal Nutritions, Inc., New York, N.Y., Supro-Zyme, Inc., and Emanuel Fred, president.

Charge: False and misleading claims and inadequate directions for use in treatment and prevention of tired blood anemia, vague aches and pains, pneumonia, intestinal infections, improper heart functions, and arthritis.

Disposition: Guilty plea. Universal Nutritions, Inc., fined \$3,000; Supro-Zyme, Inc., fined \$1,000; E. Fred sentenced to a 4-month suspended jail term and placed on 6-month probation, February 5, 1963.

*Product: Biotta juices (lacto-carrot, -celery, and -beet)*

Defendant: Dorwin B. Cook, trading as Cook's Finer Food, Seattle, Wash.

Charge: Misbranding juices by false and misleading claims for effectiveness in the treatment and prevention of fatigue, obstipation, chronic disturbances of the gastrointestinal tract, unspecific dermatoses, nervous and overstrained conditions, obesity, rheumatism, cardiac conditions, and cancer.

Disposition: Nolo contendere. Defendant fined \$300, May 13, 1963.

*Product: Mineralife capsules*

Defendants: Owen E. Brosam and Wallace C. Halsey, Logan, Utah.

Charge: Misbranding of worthless rock material with false and misleading claims for the treatment of cancer, heart trouble, shortness of breath, and tiredness, and that the capsules will restore youthfulness and promote relaxation and calmness.

Disposition: Guilty plea. Brosam placed on 2-year probation, May 21, 1963. Halsey reported missing on an airplane flight.

*Product: Various health tablets (Millrue, Soy Germ Oil, Phyl-In-Alfa)*

Defendant: Will H. Roberts, trading as Roberts Health Center, Evansville, Ind.

Charge: Misbranding drugs with false and misleading claims for effectiveness in the treatment of breast malignancies, colitis, ulcers, piles, tumors, asthma, cysts, arthritis, and inoperable cancer.

Disposition: Guilty plea. Roberts sentenced to 2 years, suspended, and placed on 2-year probation; fined \$650, May 27, 1963.

RECENT ENFORCEMENT ACTIONS IN FEDERAL COURTS INVOLVING FOOD SUPPLEMENTS,  
JANUARY 1-DECEMBER 31, 1963

## INJUNCTIONS FILED

*Product: Phenylpropanolamine hydrochloride (PPA)*

Shipper and dealer: Nysco Laboratories, Inc., Long Island City, N.Y., and Eugene J. Yoss.

Purpose of the injunction: To restrain the distribution of phenylpropanolamine, misbranded by false or misleading claims for effectiveness in depressing appetite and weight reduction, as an adjunct in the control of obesity, as a stimulant to increase physical and mental activity to burn up unwanted calories, and in maintenance of weight levels.

Disposition: Permanent injunction granted April 1, 1963; stay of injunction granted for 2 weeks April 17, 1963; injunction confirmed (court of appeals) June 7, 1963.

Senator YARBOROUGH. One other question, Mr. Chairman.

Dr. LARRICK, in your investigations, have you run into the treatment by radioactive earth, the sitter situation where you sell them to buy a block of radioactive earth, and it is supposed to cure—

Mr. LARRICK. We have had radioactive earth, combs, and pillows; we even had a service where they put chairs down in old abandoned uranium mines and charged so much an hour to sit there in the mine.

At the moment I think we have that one pretty well under control.

Senator YARBOROUGH. I guess you have seen or have pictures of long lines of people sitting with their feet in this earth?

Mr. LARRICK. Very correct, Senator Yarborough.

Thank you very much indeed, gentlemen.

Senator WILLIAMS. Thank you, gentlemen, very much.

Next, Jerry Walsh, special educational consultant to the Arthritis and Rheumatism Foundation, accompanied by other witnesses.

If Mr. Walsh will come forward and introduce his friends, we will proceed.

Mr. Walsh, you have been before this committee before. We welcome you back. Your office is in New York City, is it not?

**STATEMENT OF JERRY WALSH, SPECIAL EDUCATIONAL CONSULTANT TO THE ARTHRITIS AND RHEUMATISM FOUNDATION; ACCOMPANIED BY DR. JOHN CALABRO, DIRECTOR OF THE ARTHRITIS CLINICS OF SETON HALL AND JERSEY CITY MEDICAL CENTER; AND FRED WALCZYK, OF BALONNE, N.J.**

Mr. WALSH. The national headquarters of the Arthritis and Rheumatism Foundation is located in New York City, Senator.

As you say, I did appear before the Committee on Aging earlier. May I stand? I can get through this quicker and I know we are in a hurry, so I will stand, if you do not mind.

Senator KEATING. Let us not let him start without the announcement that he was named this year by the President's Committee on the Employment of the Handicapped as the "Handicapped American of the Year." We welcome you here.

Mr. WALSH. Thank you, Senator.

I have here some quack remedies. As the Senator said about the "radioactive" pads, they are supposed to be cures. These sell for \$65 a pair, this one for \$35. They are supposed to be radioactive material and contain nothing but sand in this one, and aluminum foil in the other.

First of all, before I get into our testimony today, I do want to point out a couple of things brought out by our previous speakers.

One is that I have a pair of these so-called prostheses. I have vitallium cups in both hips, and I had them inserted so that I could get some more motion because of the lack of motion from my rheumatoid arthritis. I hope that everyone who writes about this interesting speaker ahead of me will point out and take time to educate the patient. When we speak of prosthesis of the hips as I have, we have literally thousands of people with these manmade joints, particularly arthritics. So I hope they do specify what type of prosthesis it is. There may be questions in the minds of many, many patients who are walking today with these prostheses in their hip joints and they may question their doctor, so I think it is our responsibility to these patients and to the medical profession to continue the confidence between the patient and his physician.

Senator WILLIAMS. I am glad you raised that, because the medical theory is sound. It was the product that was questioned.

Mr. WALSH. Yes; I think the media have a responsibility to clearly define what this is, because confidence among the patients is the greatest attribute we have today, and we must not lose this in any way.

You speak of the radioclast machine over there and about the intelligence of the patient and we say how desperate they are.

As you know, Senator, I have had rheumatoid arthritis for 23 years. It struck me when I was 18 years of age, and I was in bed for 7½ years. Yet I, a supposedly intelligent patient, did fall prey to the charlatans, doorbell doctors, and misery merchants for more than \$3,000. I did go to a chiropractor in my hometown of Columbus, Ohio, and I did submit to the radioclast machine in diagnosing my case. It was the nurse or the receptionist to whom I gave the information that was extracted supposedly from the machine who actually was giving the answers because these machines are worthless in diagnosing a case. I know that also, you could send a specimen of urine or blood to these people and there is a place there they can insert it. Yet this is not even attached to the machine. These machines are used on some gullible arthritics.

As the Senator may or may not know, Mayor Kelly of Chicago in the thirties had faith that this tube cured his arthritis and he called it a miracle spike. He wore it on his lapel and not only said this cured him, but would cure people who had symptoms of arthritis if they would shake hands with him.

This was a prominent man. This was a man who was very successful, but this was a man whose arthritis condition probably went into remission, and attributed it to this.

This is how the charlatans are helped. Many patients submit testimonials because they feel that when their disease goes into remission it is due to whatever they are eating, wearing, taking, or using. Actually the disease goes into remission by itself.

Since the last hearing I have been able to travel for the Arthritis Foundation more than 121,000 miles into 129 cities. This problem of quackery, not only in arthritis but in other diseases as well, is prominent throughout the United States. It is getting larger every year. The interest that your committee has shown in spotlighting the charlatans is of immeasurable help in combating quackery. As the Arthritis Foundation says, the way to put the quacks out of business is to fight fraud with facts and to educate our patients and the public. We work with the Food and Drug Administration, with the American Medical Association, the Federal Trade Commission, the postal authorities, and all the regulatory agencies of Government.

We ask and urge the people who have arthritis—12 million Americans—men, women, and children—are in practically every block in the United States—to report these quacks in action, report supposed cures, when the doorbell doctor knocks at the door with these gadgets. These people could be informants and could do a tremendous service for their country, because, as I said, they represent 12 million victims of the quacks.

The loss in tax dollars of these arthritics unable to work is over \$200 million, so this is really a large problem.

As it says in my report—and I will not go into the report in the interest of time—there are reasons why arthritis sufferers fall for quackery. It tells what the lack of information means and how it

applies to this problem, and how the promoters reach the patient, and many other factual things that I have found during this tour. We are giving it to the committee for your use.

Another thing in this war on poverty that our good President has initiated. We have many people with arthritis who are bedfast and not able to work. During the 7½ years that I was in bed the Government not only lost the benefit of my income tax, but spent welfare dollars for a couple of years to help me out at a time when I needed it. Nor could this restore my dignity. I think it behooves the Nation, when we have 12 million people with a problem, to be aware of the expense we represent.

I see reports coming out of the Government—State, and Federal, and local—that do not even mention arthritis other than to say that it is a chronic disease. The reader has to assume that the figures for arthritis are included in the total chronic disease figure.

If we are to educate the people and the public to make them aware of the problem of arthritis, we have to use the term "arthritis" and "rheumatic diseases." We have to enlist the arthritic to help—and not only in quackery.

As you know, arthritis is a major concern of our senior citizens. They seem to fall prey most often to "glorified aspirin." A bottle here containing the equivalent of 16 aspirin costs \$5.95. A senior citizen on a pension who buys this is dangerously wasting his money and health. Aspirin does help in the treatment of arthritis, but this costs \$5.95 for a quarter's worth of aspirin.

(The following report was submitted by Mr. Walsh :)

(Text continues on p. 221.)

#### HIGHLIGHTS: REPORT ON ARTHRITIS QUACKERY IN THE UNITED STATES, 1964

The information on arthritis quackery which appears below is based on answers obtained to questions posed arthritis sufferers by Jerry J. Walsh, an arthritis victim personally cheated of thousands of dollars by promoters of so-called arthritis remedies and cures.

Mr. Walsh, special educational consultant for the Arthritis & Rheumatism Foundation, has journeyed 121,000 miles and visited 129 U.S. cities during the last year to alert fellow arthritis sufferers to the dangers of misrepresented remedies and nostrums on which they waste an estimated \$250 million a year. Recently named Handicapped American of the Year for 1964 by the President's Committee for Employment of the Handicapped, Mr. Walsh began his anti-quackery crusade after testifying at hearings on fraud and misrepresentation affecting the elderly conducted by the Senate Committee on Aging in 1963.

Mr. Walsh deplores the fact that arthritis victims frequently are ignored by many of the Government agencies—Federal, State, and local—which they as taxpayers help support. He cited recent important statistical health reports in which the category "arthritis" would have to be assumed to be included in overall statistics for the chronically ill. Other publications, Mr. Walsh says, make no mention at all of this serious disease which currently is crippling more than 12 million Americans. He feels that this reflects a general disinterested attitude toward the rheumatic diseases which needs to be corrected "for the sake of public health alone."

At the same time, Mr. Walsh acknowledged the many complex problems now confronting consumer protective agencies and called for expansion of their efforts through increased budgets.

Mr. Walsh maintains that special efforts should be made today to aid arthritis victims in the light of the President's recently declared war against poverty in which many millions of crippled arthritis victims are fighting alone and unaided—their resources depleted by the heavy expenses of long-term illness. Nearly \$200 million a year is spent by taxpayers in subsistence allowances to arthritics unable to support themselves.

In the first 3 weeks after his appearance before the Senate committee he received 4,137 letters. Most were from sufferers asking his aid in getting proper treatment. Many were from persons who offered him a "cure" or "lasting remedy." At the moment, he can count 231 such products (some of them the same) ranging in price from \$2 to more than \$200 which have been sent him. He has spoken personally to several thousand fellow sufferers and through the press, radio, and television media to several millions more. He has also helped local chapters of the foundation to set up their own product information programs and to work together with local media committees to check on proposed arthritis advertising.

Here are some of the answers as Walsh reported them from arthritis sufferers:

(1) WHY DO ARTHRITIS SUFFERERS FALL FOR QUACKERY?

(a) Constant pain (which seldom disappears completely): "Many sufferers actually carry news items about arthritis suicides to remind them not to give in."

(b) Fear of getting worse and of losing job: "Many people refuse to admit they have a rheumatic disease."

(c) Lack of information: "In which we can all share some of the blame—physicians, media people, and the foundation itself. We haven't reached everybody with the facts."

(d) The enterprise of the promoters of misrepresented remedies and treatments who see a good market for their wares.

(2) WHAT DOES "LACK OF INFORMATION" MEAN, AND HOW DOES IT APPLY TO THIS PROBLEM?

(a) In medicine: Up-to-date knowledge of how to treat arthritis is not sufficiently widespread. "In one southern city of more than 1 million that I visited, there were only two rheumatologists, and only one was in practice. Some doctors I talked to had never heard of self-help devices" (these are simple aids conceived by therapists to enable handicapped persons to dress, eat, groom, and reach things). "Some medical schools offer no arthritis training."

(b) Among media: "Many of newsmen who interviewed me had never heard that there were more than 60 forms of arthritis. They were often amazed that it is not just 'a disease of old age.' One interviewer said, 'You mean my brother-in-law falls for this stuff ('remedies' I had with me); he had never realized that arthritis sufferers are exploitable."

(c) Among patients: "Some had no idea whether steroids were 'good' or 'bad' (they are of value in certain cases but must be used carefully under a physician's direction). 'What diet should I go on to get rid of my arthritis' was a question I heard again and again" (no diet either causes or cures any form of arthritis). Often, when I asked sufferers why they had tried an advertised remedy, I got the reply: 'It was in the paper' (or on the air) and 'they' wouldn't let it in if it wasn't true. The picture of Americans as wise sophisticates is just not true in my experience."

(3) HOW DO THE PROMOTERS REACH THE PATIENT?

(a) Door-to-door salesmen: "Since so many people have arthritis, a 'door-bell doctor' can try homes at random and expect to find an arthritis sufferer in almost one family in every five. Many victims admitted falling for a pseudo-scientific pitch on everything from vitamin supplements to 'healing' machines. It is difficult to stop because the product may be innocently labeled and a law enforcement official must actually hear the salesman's claims to take him into court."

(b) Through the mail: "This type of solicitation is involved in the ARF study of advertised 'clinic' promotions. I have had many people tell me that once they answered an ad, they later received promotions from more than one outfit."

(c) The aggressiveness of the promoters: "Many of the products and devices I received, even after I had appeared in public warning against cures and remedies, were offered to me free if I would send a testimonial. The misery merchants counted on my feeling better for a few days sometime and giving the product the credit."

## (4) WHAT ARE THE BEST SELLERS IN ARTHRITIS REMEDIES AND CURES?

"It depends where you are, although some seem to have a universal appeal—such as alfalfa, copper bracelets, vibrators, and books claiming a new treatment method. However, geographically, the most popular are:

East coast: Hot, dry climate, glorified aspirin.

Midwest: Sea water, machines (mycrodynometer, etc.), immune milk.

South: Uranium mines, "uranium pads," home remedies and superstitions.

Mountain States: Food supplements, vitamins, liniments.

West coast: Machines (depolarary, atomotrone), Mexican herbs.

"Of course, most localities have their own native cure. But, big promoters take advantage of the old saying indicated by this regional breakdown that 'the grass is always greener on the other side'—selling sea water in the Midwest, and so forth."

## (5) ARE THERE DIFFERENT BUYING ATTITUDES AMONG SUFFERERS THAT PROMOTERS CATER TO?

"Older people seem to go for the patent medicines and the natural food pitch—probably because the old methods seem best to us as we get along in years. Younger sufferers often are people who say they can't take the time from their busy lives to take long, slow medical treatment. Influenced by the notions of breakthrough and medical miracles that we have come to expect, they want to take a shot or pill and be well at once. They almost seem to be saying 'Cure me quick, I'm on a parking meter.'"

## (6) WHAT IS THE APPEAL OF ADVERTISED ARTHRITIS CLINICS?

(a) "To many arthritis sufferers a clinic is a clinic: They do not distinguish between, say, the Mayo Clinic, which they have seen in news stories, and the so-called clinics they have become familiar with in advertisements."

(b) "The clinics know how to sell: They are friendly to prospective patients; they show you your X-rays; they explain your disease in simple causes. Many sufferers are flattered by the fact that they are given an opportunity to personally refer friends to the clinic."

(c) "There is often a stigma attached to going to a hospital clinic (many are for indigents) and many people are proud to be able to pay to go to an advertised clinic: The fact that most hospital clinics operate during working hours doesn't help, either. There should be more arthritis night clinics."

## (7) ARE THERE OTHER ARTHRITIS SUFFERERS INTERESTED IN JOINING THE FIGHT AGAINST QUACKERY?

"I am happy to have found some sufferers like myself who are campaigning in their communities against quackery by questioning, complaining, and exposing. I've suggested to our ARF chapters that many homebound arthritis sufferers be given a chance to participate in the program against quackery by monitoring TV and radio advertising, by writing for advertised products and turning their information over to the foundation and to enforcement agencies. I know that many victims of the charlatans want to help like the lady from Indiana who sent me a virilium tube, for which she had paid \$300, with a note telling me to show it to as many people as I could and tell them how ridiculous it was so they would be warned. 'Then,' she said, 'it may at last do some good. It never helped my poor mother.'"

Mr. WALSH. I brought along Dr. John Calabro, who is director of the arthritis clinics at Seton Hall College of Medicine, Jersey City, N.J., to give a physician's viewpoint on the problems of arthritis and quackery.

Senator WILLIAMS. Before you begin, you also have Mr. Fred Walczyk there. We welcome you. We appreciate your being here.

**STATEMENT OF DR. JOHN CALABRO, ASSOCIATE PROFESSOR OF  
MEDICINE AND DIRECTOR OF THE ARTHRITIS CLINICS OF SETON  
HALL AND JERSEY CITY MEDICAL CENTER, JERSEY CITY, N.J.**

Dr. CALABRO. Many physicians actually treating arthritis patients are unaware of the vast scope of the quackery problem; others excuse their disinterest by saying these promoters do not harm the patient and they actually give them some sort of psychological boost.

The aspect that disturbs me most is that while these remedies may not physically harm the patient, they indirectly injure him by postponing adequate treatment and arousing false hopes. Repetitious disappointment of aroused hopes for obtainable relief brings discouragement to the patient and makes him suspicious of all treatment—even that which can legitimately help. It is not by accident, that nearly 50 percent of those who believe they have rheumatism are not under medical supervision, and many of them are not under a doctor's care because they believe little can be done for them.

Every physician owes it to his patient to become aware of this multi-million-dollar exploitation and to cooperate actively with those attempting the often difficult task of protecting the arthritis sufferer.

I am pleased to report that physician arthritis teaching has enjoyed an enormous increase in the past 3 years, but we still have the problem of patient education, and remember, gentlemen, there are 12 million arthritis patients in this country alone.

In a study of 100 patients (60 percent of these were over the age of 45) in our own arthritis clinics, a clinic affiliated with a school of medicine, 60 percent continued to try such remedies as alfalfa seed, linaments, cod liver oil, sea brine, etc., even while under treatment.

The patients did not mention these experiments to the attending physician because they said they had not been asked directly by the doctor.

Twenty-eight percent reported incidents prior to treatment at the clinic in which they felt physicians were in too big a hurry, did not know anything about arthritis or said there was nothing that could be done about it.

These attitudes need to be changed and a responsibility of the physician in changing them is paramount.

I think on this slide you will see that the majority of these 100 patients utilized some form of nonscientific remedy in the form of vinegar and oil, kerosene and iodine baths, and so on.

I would like to introduce the testimony of two patients now under our care who spent years of effort, large sums of money, and untold hope of treatments which gave no relief but aggravated their serious conditions instead.

## STATEMENT OF LORRAINE ALLEN, KEARNEY, N.J.

Mrs. Allen, a 35-year-old housewife who has been a victim of rheumatoid arthritis for 8 years is unable to appear in person, because the effects of her disease require her to be hospitalized at the present time. I would like to read her testimony. [Reads:]

When the doctor told me I had arthritis, I cried. My sister had it after her third child was born, and though it cleared up after 6 months of gold injection treatment, she had terrible pain. I was afraid because gold did not work for me and cortisone only helped some.

At that time nobody told me about exercises and splints or heat to keep my joints straight. Sometimes I thought my arthritis would just go away. I'd have as long as a week when I could walk across the room as though there was nothing wrong with me, then my hands and feet and knees would swell and hurt so that I couldn't get up to try to walk.

I got pretty discouraged, so I went to this chiropractor who said he could get me well, but it would take a long time. He worked on my spine and he told me to cut down the cortisone. I did, but at the end of the year I was worse than ever.

He said that was the fault of the cortisone.

I was very depressed when I read an ad for the Ball Clinic which said they had helped thousands. I wrote and asked them for references and got the names of three people I could write to. The answers I got from these people said they had gotten good results so my husband and I borrowed the money and I went out for a 6-week period, which is what the Ball Clinic said I'd need.

It turned out to cost twice as much as they said it would.

The first thing they did was to make me come off the cortisone altogether, then they gave me spinal manipulations, colonic irrigations, radio wave, ultrasound treatments, massages and baths and put me on a no-meat diet. I had managed to walk into the clinic but at the end of the 6 weeks I was so sick and in such pain I could not leave. They told me I must stay for 2 more weeks, but even then they had to carry me out on a stretcher. Those last 2 weeks cost \$400. All together my stay cost almost \$900. It took us a long time to pay back the money we had borrowed.

Up to about 3 months ago I still got letters from the Ball Clinic urging me to go back; they also wrote that if I could get three other arthritics to go they would send me a check for \$5, or they would give me a lower rate when I came back.

After this experience I thought I would never try anything. I was afraid to go back to the doctor because he would ask me why I was off cortisone. For about a year I just stayed home and tried to take care of myself.

For 3 months I just sat in a chair. Finally our home broke up and I could not take care of my three children. The organization that helped find a place for them put me in touch with the Arthritis Foundation and sent me to the arthritis clinic at Seton Hall College of Medicine in Jersey City.

You will see the next slide will show our patient's hands, and this is the way we saw her a year ago. [Continues reading:]

Right now I still can't walk, but I have had an operation on one hip and I only hope that everything will turn out all right.

I would not want to tell anybody with arthritis what to do, but I feel if I had been able to find out what I now know early enough I'd never have gotten so bad. To me the important thing is to keep fighting because every time you let it go for a while it gets ahead of you. You can't help yourself then and it just cripples you up. I was careless about keeping splints on my hands and they got worse right away.

Treatment is a steady and, I have to admit, a sometimes depressing struggle but I wish I had back the 2½ years I spent trying other things or just giving up.

(See figs. 9, 10, 11.)



FIGURE 9.—Mrs. Allen undergoing examination.



FIGURE 10.—Rheumatoid arthritis of the hands.

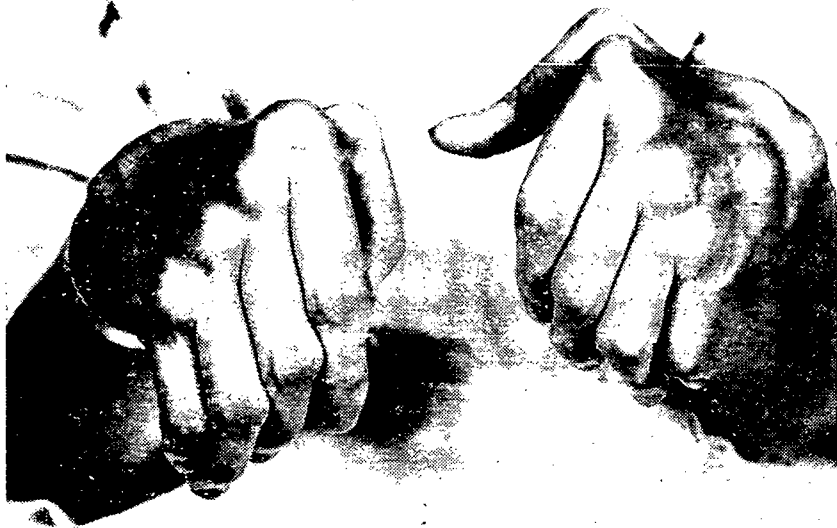


FIGURE 11.—X-ray of arthritic hands.



This is just one example of thousands in which lack of knowledge concerning arthritis and ineffective treatment has led to unbelievable deformities and discouragement.

We are fortunate today in having with us Mr. Fred Walczyk, a 40-year-old rheumatoid spondylitis sufferer from Bayonne, N.J., who will tell us how pain and fear of crippling had driven him to try several remedies which promised relief. In pursuit of one, "Liefcort," Mr.

Walczyk said he had traveled to Canada only to find his disease got worse afterwards.

The problem of Liefcort was brought out in great detail by Dr. Ronald Lamont-Havers medical director of the Arthritis and Rheumatism Foundation, in previous testimony to this group.

Today, Fred, the publisher of the Jersey Angler News and a Bayonne Times reporter will report on other items suggested to him by friends and unsolicited letters.

Thank you.

Senator WILLIAMS. Thank you, Dr. Calabro.

Mr. WALSH. Could we have a word from Mr. Walczyk, please?

Senator WILLIAMS. Yes, we had better switch the microphones over.

Mr. Walczyk.

#### STATEMENT OF FRED WALCZYK, OF BAYONNE, N.J.

Mr. WALCZYK. Senator, I have no prepared statement of any kind. However, I do have a stack of letters here that I have received since an article mentioning me appeared in one of the national magazines.

The letters are from well-meaning people who suggest various remedies. Before I tried Liefcort I tried about every other remedy there is, from some of these contraptions displayed here on through radium baths, and some of them may seem outrageous and silly.

Senator Neuberger asked, "Why do people fall prey to this sort of thing?" Well, usually arthritis strikes between the ages of 20 and 30, which are the most productive years, I think. A young fellow just coming up, he is just starting to get his head over the water and he is starting to produce and his income is becoming stable. Suddenly he is hit with a bomb, he is faced with an eternity, more or less, of an unproductive nature.

At first, if he is like me, he winds up with a nervous breakdown. He feels he is going to be a millstone on somebody's neck, and this is the worst of all. Any time he hears, from well meaning friends and relatives, that there is a cure someplace—though he knows in his heart that basically and medically it probably is not true—he is going to try it anyway, because he hopes it might be that one thing that might cure him.

From my experience none have cured me.

If I may, I would like to read one of the letters here that was sent to me. It is from Las Vegas, Nev.

It does suggest that I could be cured, and it goes on to say:

I bought the Saturday Evening Post this afternoon, I read the article by Ralph Lee Smith, "Hucksters of Hope for Arthritics."

I am sure if I give you the formula you and all the other people suffering from arthritis throughout the world will benefit by the one and only cure that nature has placed before each and every one of us, at the small price of \$1 per quart. I do not want one red cent from you, buy it yourself, I have cured three people who were on crutches in not over 45 days.

Now, I am no doctor, but I cured myself in less than 10 days in 1918, and never have any symptoms since I tried it. It is a little messy, but it cannot hurt anyone. It is gasoline and lubrication oil. One part gasoline and two parts oil, so it will not blister. Now rub it into the joints that are giving the most trouble, now don't get too impatient, rub and rub, but don't blister. If it seems to be a little too strong cut down on the gasoline.

[Laughter.]

Now, I am going to send to the editor of the Post the same information I am giving you. Now, if you can get around, please call on quite a few of the garages and ask the mechanics if they have ever had arthritis. If you find one in 10,000 I will buy you the best hat in Texas.

Now, Mr. Walczyk, use just commonsense. What would you do to a rusty hinge? You would lubricate it, would you not? Now, the marrow in the bones stopped so it is very necessary to start it moving throughout the bone structure of the body. You have got to start it moving now a little olive oil would not hurt to take internally.

Please try it and my heart goes out to all who suffer from any kind of ailment. Just a well wisher.

This is a typical letter I have received, and this is just a sampling of them.

Mr. WALSH. Mr. Walczyk, as a fellow arthritic I want to emphasize that this is neither humorous nor funny for people who have been cheated out of their precious dollars. We present these only to help in this exposé.

I want to thank the Senator. After the hearing last year, as you know, we made a film of our appearance which was widely circulated throughout the United States indeed, in each one of your States. It has helped greatly in this problem.

In conclusion, I just would say that a modest doubt is the beacon of the wise. If we can just get the modest doubt among arthritic Americans about "cure" claims we have done a commendable job. I thank you Senators for taking the time to hear about this problem.

We do represent 12 million people who are cheated out of \$250 million annually so we do need some help.

Senator WILLIAMS. Gentlemen, before you leave I wonder if the members of the committee have any observations?

Senator SMATHERS. First, I want to congratulate the subcommittee on the splendid work which it is doing in this field of exposing these types of frauds which are practiced on elderly people.

I might say this—when the people laughed about that letter that was read by Mr. Walczyk—my father has been totally incapacitated by reason of rheumatoid arthritis since 1937. As a matter of fact, the reason that I now come from Florida instead of the chairman's State, New Jersey, was because he was told to move from New Jersey to Florida to improve his arthritis. My father was a graduate lawyer and I have always considered him a pretty able man. I well remember as a young man when he went to Canada and went through the course up there. When he was told to wear coins in the bottoms of his shoes, which he was told would drain off some kind of poison which was working through his system, he did.

I recall as a young boy when we raised bees for the express purpose of getting bees and putting them in a quart jar and he would stick his hand into it to let the bees sting him, because he was told that it would somehow have some curative, therapeutic effect on him.

I remember in high school when he would ask me to drive him to a fellow who had a "fever," a big cylinder, and they would put him in there. I have seen them run the heat up to 180° F., and right before my eyes fever blisters would break right out on his lips.

As you say, these people are in such great pain, such great difficulty, they will try anything; and I don't know whether he finally outgrew it, or what, but in any event when cortisone came along, he was the first man to ever actually try it. They used him as sort of a guinea

pig, and it upset his heart action for a while, but later on they got the doses worked out and while he is still crippled and has to use two canes today to get about, nonetheless, I would say for the hopefulness that is in it that he no longer suffers any great pain, and he is 85 years old. But this is a very serious thing and certainly these people hurt so badly that they will try anything, and it is up to this committee and other committees, and the AMA to be certain that they do not become victims of quacks and frauds which is so easy for them to do in their desire to get rid of this horrible pain.

I thank you, Mr. Chairman.

Senator WILLIAMS. Thank you, Mr. Chairman of the full committee.

Mr. WALSH. Since the committee has been presented with the foundation's analysis of advertised clinic promotional material, the Ball Clinic has gone out of business as of December 31. This has helped tremendously. As you know, too, State congresses on medical quackery are springing up throughout the United States. We have consumer protection. I think we also need more patient protection.

Thank you for your time, Senators.

Senator WILLIAMS. Senator Yarborough.

Senator YARBOROUGH. Mr. Walsh, what is the book with the red paper jacket on it?

Mr. WALSH. Well, this was a bestseller for a couple of years, Dan Dale Alexander's, "Arthritis and Common Sense," in which he reports cod liver oil and orange juice is a cure.

Senator YARBOROUGH. This book that you hold in your hand that was in bookstores all over the country?

Senator KEATING. It was a bestseller.

Mr. WALSH. Yes, sir. Numbers of our patients who went into natural remission also gave testimony that this cured their arthritis. We do not have a cure for arthritis and there is no known cure, but it can be controlled if the doctors, through modern medicine, get the patient early enough. Seven out of ten can be spared the pain and suffering that goes with arthritis. This is why it is important.

This one, of course, is Dr. Jarvis' book, "Arthritis and Folk Medicine," where he says that honey and vinegar are a cure.

Senator KEATING. I take that, honey and vinegar. I don't have arthritis but I think it helps.

Mr. WALSH. It is good for many other things, Senator. I would like to note that when we stand up here and try to expose some of these things, we take on a tremendous responsibility. In fact, right now our national medical director will be appearing in court to fight these charlatans. We have only a small staff, so they can tie us up in litigation and check our program in this way. This is why we need more and more help.

Senator WILLIAMS. Maybe that honey and vinegar helps to grow a full head of hair.

Senator KEATING. It is like vitamins. Maybe it is not, but anyway I imagined it is, and I take it every day and it is not bad.

Mr. WALSH. Many of these things will cure diseases that we have not even diagnosed as yet.

Senator KEATING. That is what is wrong with me, I think. [Laughter.]

Senator WILLIAMS. Tell me, are there any best selling books that give the fact and true hope through proper care?

Mr. WALSH. Yes; Dr. John Bland, up in Vermont, has a book on arthritis which is factual, but more and more is needed. Also there is a lack of Federal regulation of advertising of so-called arthritis treatment facilities—spas and the like. Many of our patients think that a clinic, Mayo Clinic, the Ball Clinic, any clinic is the same, so we have to educate them. We need stronger and more uniform State laws on health fraud and misrepresentation and possible curbs of mail solicitation of arthritic sufferers by the promoters. They put the arthritis sufferer on a sucker list because arthritis doesn't kill, it only makes you wish you were dead.

I hope Senator Neuberger as a woman will start doing some housecleaning on some of these antiquated laws.

Thank you very much.

Senator WILLIAMS. Thank you. You have been, again, most helpful. We hope that we can follow through.

Senator YARBOROUGH. While we are waiting for the next witness, I would like to ask, Mr. Chairman, if asafetida is still indicated in the treatment. It used to be favored for meningitis and—

Dr. CALABRO. I am not familiar with it, but I remember being faintly reminded of it when I was in medical school.

Senator YARBOROUGH. One of my colleagues stated you are too young to remember that most popular remedy that was favored for many years. It was worn in a plug around your neck that was supposed to give immunity to communicable disease. It had a very strong odor and it may have been of some protective value, because it kept the friends away from you.

Senator WILLIAMS. Thank you, again.

Gentlemen, Mr. Robert Throckmorton, general counsel of the American Medical Association, and I believe Mr. Oliver Field, director of investigation, is with Mr. Throckmorton.

Will you introduce your friends, Mr. Throckmorton, please?

**STATEMENT OF ROBERT B. THROCKMORTON, GENERAL COUNSEL, AMERICAN MEDICAL ASSOCIATION; ACCOMPANIED BY OLIVER FIELD, AMERICAN MEDICAL ASSOCIATION, DIRECTOR OF INVESTIGATION; AND PAUL DONELAN, ATTORNEY, DEPARTMENT OF LEGISLATION**

Mr. THROCKMORTON. On my right is Mr. Oliver Field, who is director of department of investigation. On my left is Mr. Paul Donegan, an attorney in our department on legislation.

Senator WILLIAMS. We welcome you here. Proceed the way you wish.

(Discussion off the record.)

Senator WILLIAMS. We will receive your full statement and if you could give us the highlights, feeling that probably we would want some time for questioning.

(The statement referred to follows:)

**STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION, BY ROBERT B. THROCKMORTON**

Mr. Chairman and members of the subcommittee, I am Robert B. Throckmorton, of Chicago, Ill. I am the general counsel for the American Medical Association, a position I have held since July 1, 1963. Prior to that time, I was engaged in the practice of law in Des Moines, Iowa, and was counsel to the

Iowa State Medical Society. With me today are Mr. Oliver F. Field, director of the AMA Department of Investigation, and Mr. Paul R. M. Donelan, of the AMA Department of Legislation. The department of investigation, part of the general counsel's office, has the primary responsibility at the AMA in our program of combating quackery.

Representatives of the AMA appeared before the Special Committee on Aging concerning frauds and quackery affecting older citizens on January 15, 1963. At that time, we discussed many of the specific practices and activities of various types of quacks. Today, I will not discuss in my statement such examples of quackery, but will report on the activities of the AMA in combating quackery, with particular emphasis on those activities that have taken place since we last appeared before this committee. I shall also present our suggestions as to the areas of this problem that require special emphasis and attention. As we previously pointed out to the committee, it is virtually impossible to segregate the problems of quackery involving the elderly from the other age groups of our society. Therefore, our statements and our programs basically apply to all age groups, including the elderly. We will, of course, be happy to answer any questions that the committee may have on such specific problems.

One of our primary purposes, announced at the time of the founding of the AMA in 1847, was the combating of quackery in all its forms. Since that time, the AMA has had an unceasing interest in this problem and has continuously devoted its efforts to the eradication of this menace. Time does not allow me to detail all the efforts of the AMA over the years, but I think our record is a good one. However, a great deal remains to be done before we can say that this is a problem of our society that is under reasonable control.

I would like to clarify the role and responsibilities of the American Medical Association in this area. The constitution of the AMA states that the objects of the association are to promote the science and art of medicine and the betterment of public health. Pursuant to that purpose, in the area of quackery, we have the dual responsibility of keeping medicine's house in order; that is, stamping out any such practices among doctors of medicine, and we have our responsibility to the public to deal with quackery outside of medicine. Our responsibilities in each of these areas can be broken down into (1) enforcement, and (2) education. In discussing the work of the AMA against quackery, I will distinguish between our efforts directed to physicians and those directed to the general public.

First, I would like to discuss some of the continuing activities at the AMA in relation to quackery.

Our department of investigation has been in existence since 1907. It devotes a great deal of its efforts to the collection and dissemination of information on medical quackery, cultism, faddism, and other aspects of pseudomedicine. This information is made available not only to the medical profession, but also to the public, Government agencies, voluntary health agencies, writers, and others. We believe that the files of the department of investigation are the most complete and extensive in the United States on the many facets of quackery. Since we last testified before this committee, the staff of this department has been increased, and, I am pleased to say, we will add additional personnel in the next few months in order to accomplish the department's expanding efforts to fulfill its mission.

In addition to the department of investigation, there are many other departments, councils, and committees of the AMA which focus their attention on this problem. For example, our council on foods and nutrition is very active in combating food faddism and nutrition quackery. It has prepared an informational kit designed to assist other organizations in initiating campaigns against nutrition quackery. Over 13,000 of these kits have been distributed. It has produced a film entitled "The Medicine Man," which exposes the techniques of the quack health lecturer. This film has been shown over 14,000 times, including more than 1,000 telecasts. Over 1 million copies of the pamphlet, "Merchants of Menace," have been distributed. This pamphlet exposes the modern day medicine man and the doorstep diagnostician. The council has six copies of an exhibit entitled "Nutrition Nonsense." It deals with diet delusions and food fads. This exhibit has been shown over 300 times at various public meetings and conventions.

The AMA Department of Community Health and Health Education conducts an extensive program of conveying valid health information to the public. Its question and answer service, handling thousands of inquiries on various health subjects, is a valuable means of conveying accurate health information to the

public. Many of these inquiries result from the misinformation and propaganda of the quack. This year the sixth annual meeting of the AMA and the American Student Health Association will devote its program to the subject of quackery. This is part of the overall program of this department in conveying accurate health information to school age children.

The AMA Communications Division is active in educating both the public and the medical profession on the problems and claims of quackery. *Today's Health*, a magazine directed at the lay public, regularly runs articles exposing false claims on various health matters. This publication is read by approximately 2½ million people each month. At our previous appearance before the special committee, we gave you several examples of such articles. The AMA News, a biweekly newspaper going to all physicians and many others, carries a number of articles on this subject.

Recently AMA produced two television spots on quackery, each of which was distributed to over 300 television stations. Our president, Dr. Edward R. Annis, has appeared on several national television programs and before many civic and other groups discussing quackery. The communications division has prepared a basic fact sheet on medical quackery. A copy is attached to this statement for the information of the committee. I think it is interesting to note that this fact sheet lists 34 major areas in which the quack operates. Also attached to this statement for your information is an article by Dr. Annis which appeared in *Parade* magazine. This article sets forth some of our basic thoughts on this problem and discusses many of the specific areas involved.

In addition to these activities of the AMA, I would like to mention some of the specific actions we have undertaken since we last appeared before the special committee in January 1963.

(1) On October 25-26, 1963, the AMA, in conjunction with the U.S. Food and Drug Administration, sponsored the Second National Congress on Medical Quackery. This meeting was attended by 725 persons, many of whom are the leaders of the various organizations most active in combating quackery. Not only does a meeting such as this give us an opportunity to exchange authoritative information on quackery, but it had the intended result of receiving a great deal of national publicity through the various communications media, thereby further educating and alerting the general public to this problem.

(2) We also held a private session at that time between representatives of the Food and Drug Administration, the Federal Trade Commission, the U.S. Post Office, several State medical licensure boards, the AMA, and others to discuss several specific problems in this area, and to lay the ground work for better coordination of efforts among the various groups represented.

(3) Following the First National Congress on Medical Quackery in 1961, a number of quackery conferences were held at the State and local level. Since the AMA last appeared before this committee, State quackery conferences have been held in Texas, Wisconsin, and Missouri. In 1964, State medical associations have scheduled such conferences in Georgia, Louisiana, Mississippi, and Iowa.

(4) On February 10 of this year, the AMA sponsored a meeting of the legal counsel and officers of the State boards of medical examiners. These boards are the bodies which have the responsibility for the licensure of physicians, and they often have responsibility in connection with the licensure of nonmedical health practitioners. A good part of the program of that meeting was devoted to the question of quackery. I am pleased to report that the theme of this meeting, which was that of increased cooperation and coordination between the AMA and the State boards in the field of medical discipline and quackery control, met with such an enthusiastic response that a similar meeting has already been scheduled for next year.

(5) On April 16-18, the AMA will conduct a legal conference for medical society representatives. This is a meeting of the attorneys, executive secretaries, and other representatives of the State and local medical associations. This meeting will present a program concerned with combating quackery, and another session will be devoted to the problem of discipline within the medical profession itself. Again, the early response to the announcement of this program indicates that tangible results may be anticipated in the nature of stepped-up disciplinary and antiquackery programs by State and county medical societies.

(6) Just recently, the AMA met with the National Health Council concerning the desires of the members of that organization for greater effort and coordination in the work of combating quackery. The National Health Council is



an organization of more than 50 of the leading voluntary health associations, national medical associations and similar groups. Many of its members, such as the American Cancer Society, the Arthritis and Rheumatism Foundation, the American Heart Association and the AMA, are active in investigating and exposing quackery. Several governmental agencies, such as the U.S. Public Health Service, are advisory members of the Council.

The National Health Council believes that there is a need for more formalized and regular meetings of those groups which are active in the quackery field; that educational programs on quackery should be developed for implementation by the local units of these national organizations; and that the communications media need more authoritative advice and information on quackery from the members of the Health Council. The Council requested the AMA to take leadership in these matters. The AMA has agreed to schedule a meeting in May of the several organizations most active in combating quackery. You will be interested to know that the Food and Drug Administration, the Federal Trade Commission and the Post Office will be invited to send representatives to this organizational conference. From this meeting there should develop a regular committee which will coordinate the activities of these various groups and which will act as a source of exchange of information on their work. We agreed to survey the many organizations that have an interest in this field prior to such a meeting, and to determine the extent of their present activities against quackery and their plans and desires for the future.

(7) Finally, and perhaps most importantly, the board of trustees of the AMA, in November 1963, authorized the appointment of an AMA Committee on Quackery. This will be the first time that the AMA has had a specific committee to deal with this problem. It is composed of five eminent physicians from around the country who are knowledgeable and authoritative in this field. Such a committee will provide guidance to the work of the AMA staff and add prestige and impetus to our present efforts.

Most of the work that I have mentioned is directed against the quack outside of medicine. The AMA is not blind, however, to the fact that some physicians and some of its members can be justifiably tagged with a quack label. The AMA believes that it has a serious duty to the public and the profession to police its own ranks in this regard. Only a small percentage of actions by physicians which could subject them to medical discipline could properly be labeled medical quackery. Nevertheless, if a physician is guilty of quackery, this constitutes a violation of medical ethics and subjects him to medical disciplinary procedures.

Another important fact, as far as physicians are concerned, is that not all physicians belong to medical societies and associations. The medical association has authority to discipline only its members. If a physician engaged in quackery is not a member of his county, State, or national medical society, then the State medical licensure board has the only authority to proceed against him. In some States, the medical licensure board does not have authority to take disciplinary action and existing procedures make it either impossible or extremely difficult to take action against physicians who are guilty of quackery. The medical associations and the State licensure boards are determined to seek remedial legislation to permit or facilitate appropriate action against quacks and unethical practitioners where this is indicated.

When we last testified before this committee, Senator Williams inquired about disciplinary procedures of the medical profession, and we provided some information on this subject. In addition to the information previously submitted, we call to your attention the excellent work of an ad hoc medical disciplinary committee appointed by the AMA. This committee made an extensive study, lasting some 2½ years, and submitted its report in 1961. You will be interested in the conclusions and recommendations of that committee. A statement of these is attached to this statement.

You will note that recommendations are made for the improvement of medical discipline by the medical schools, the State boards of medical examiners, the State and local medical associations, and the AMA. The work and report of this committee have definitely caused greater interest and activity in medical discipline in all segments of medicine, and its recommendations are being implemented by the various groups to which they were directed. Such implementation automatically enhances the ability of medicine to discipline the physician-quack. I can assure this committee of the dedication of the AMA to doing all things necessary to work toward the elimination of this problem within the medical profession.

Although we have made some point of our interest in disciplinary procedures, we do not want to leave the erroneous impression that quackery by physicians is a major problem. The files of our department of investigation disclose only a handful of the 278,000 physicians in this country as having engaged in quackery. In some of these cases the evidence is insufficient. In others there is a reasonable doubt whether the physician is practicing unscientific medicine or whether he has developed something new which may ultimately be accepted by science. In others, the State and county medical societies, or boards of medical examiners, are unable to act because of inadequate State laws. However, we will do our part and are increasing our efforts to work toward the elimination of quackery in any form by members of the medical profession.

Our files do disclose a far greater volume of quackery by nonphysicians than by physicians. Many quacks are licensed as practitioners of healing arts other than medicine. Many others, of course, have no license of any kind.

Your committee has been helpful in stimulating us to increase our efforts to keep medicine's house in order. If other branches of the healing arts are similarly stimulated to take appropriate action in this field, there will be very tangible progress made in curing the overall problem.

We have reason to feel that a very substantial volume of quackery and unauthorized practice is committed by the so-called drugless healers and that this is detrimental to the public health, to say the least. Chiropractic is said to have approximately 25,000 practitioners. It claims to be the second largest healing arts group in the country. Chiropractic must be labeled a cult practice because it is not supported by any reliable scientific or demonstrated knowledge. This in itself, is sufficient to constitute these practitioners as quacks in the eyes of members of the scientific community.

Even forgoing this point, however, it is abundantly clear that many chiropractors engage in practices which exceed the scope of their licensure and competence, which often include deceptive and misleading advertising and which frequently constitute quackery in its worst form by any conceivable standards of measurement. For example, the case of *Correll v. Goodfellow*, decided by the Supreme Court of Iowa on January 14, 1964, discloses an incident that is simply appalling. The 70-year-old plaintiff went to the defendant chiropractor for a sore back. She purchased a series of 12 treatments in order to save \$6 from single treatment prices. Shortly after the treatment began, she turned her ankle. The chiropractor offered to treat her ankle with an ultrasonic machine, which he was not authorized to use under Iowa law. The elderly plaintiff told him, "I am diabetic, you wouldn't dare use that on my foot." Defendant assured her, "That won't bother you at all. You don't have that much diabetes." As a result of three such treatments, it became necessary to remove the back part of the injured heel and Mrs. Correll suffered permanent disability of her foot and ankle.

Another illustration, of the type of practice by chiropractors I am referring to, came to my attention last Friday when the American Medical Association received an unsolicited letter seeking information concerning a chiropractor. The writer requested, "Please do not mention our names if you do any investigating." I shall, of course, respect this request.

This letter, in short, discloses that the chiropractor treated the spouse of the writer for "worms, shattered nerves, poison oak (which he claimed settled in the stomach) and for an aluminium allergy." He also treated an elderly member of the family for gallstones "that don't show up on X-rays" and reportedly stated that this elderly person "would have had leukemia if he hadn't started treating him when he did." Incidentally, the one office call that the spouse had resulted in a bill in the neighborhood of \$100. A copy of the bill is attached, and it indicates that the cost of the "treatment" was only \$5. However, X-rays and vitamins boosted the bill by more than \$90, and our correspondent admitted to being "stunned" by a bill of this magnitude "for one office call."

We know these are not isolated examples.

We do not believe, of course, that quackery will ever totally disappear from the face of the earth, human nature being what it is. Nevertheless, we think that much more can be done to control this problem and to protect our citizens from this insidious evil. I shall briefly discuss the two areas of activities that I previously mentioned—enforcement and education.

There is a need for effective enforcement of laws, at the local, State, and Federal levels. The statute books are full of laws forbidding the practice of

medicine without a license, making it illegal for other practitioners to exceed the scope of their authorized practice, condemning the fraudulent purveying of worthless drugs and devices, prohibiting false and misleading claims, etc. Nevertheless, these laws in many instances are not effectively enforced.

The AMA supports the principle of sufficient funds and personnel for Federal agencies to carry out their responsibilities in connection with quackery. The AMA would like to take this opportunity to commend the Food and Drug Administration, the Federal Trade Commission, the Post Office, and other Federal agencies on their work against the quack and their cooperation with voluntary organizations such as the AMA.

Enforcement of State laws is difficult and expensive. Nonetheless, not only laws against quackery but those which prohibit the unauthorized practice of medicine, or those which limit other practitioner to a narrow field of activity, must be enforced if the public is to be protected.

Even greater than the need for effective law enforcement is the need to educate the public as to the methods and misrepresentations of the quack and the true facts of human health. The quack operates in an area of ignorance, and, of course, there is much ignorance among the public today as to the many complex aspects of medical science. The ultimate weapon against the quack and his pseudo-science is truth. If the true medical and scientific facts of life can be conveyed to our citizens, then the quack and his frauds would disappear. This, obviously, is a large order.

I have outlined some of the many educational activities of the AMA against quackery. There are, of course, numerous other groups, both governmental and private, engaged in such public education. However, there are many areas to be covered—we mention 34 major ones in the attached fact statement—and the truth on these subjects must be repeated continuously to the public, as with any effective educational effort. Millions of people must be repeatedly reached with medical truth until they are in a position of their own knowledge to recognize quackery in its many forms.

I hope I have demonstrated to this committee the dedication of the AMA to fighting quacks and the evils of quackery. We stand ready to assist this committee and the Congress in this struggle.

On behalf of the American Medical Association, I thank you for this opportunity to present these comments.

#### CONCLUSIONS AND RECOMMENDATIONS IN THE REPORT OF THE MEDICAL DISCIPLINARY COMMITTEE TO THE BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION, JUNE 1961

The medical disciplinary committee, through the various activities outlined in the preceding sections, sought to find out if satisfactory disciplinary mechanisms exist and if they are being effectively used. The results of the study show that, by and large, adequate medical disciplinary mechanisms do exist and that they are used. The frequency and effectiveness of their use, however, are less impressive. There has been a failure, in some areas, to act promptly, impartially, and objectively when the necessity arises.

Based on the belief that there is room for improvement in the discharge of medicine's disciplinary obligations and the realization that disciplinary mechanisms must be constantly reviewed and improved, the committee recommends the following:

##### MEDICAL SCHOOLS

It is the opinion of the committee that medical schools have not provided adequate instruction in the field of medical ethics. It is recommended, therefore, that greater efforts be made to acquaint the medical student and the young medical practitioner with ethical and proper socioeconomic principles during the period of his schooling.

It is suggested specifically that—

(a) Each medical school develop and present a required course in ethics and socioeconomic principles; and

(b) Medical schools cooperate with State boards of medical examiners and State medical associations to insure that students become acquainted with practical problems of ethics and socioeconomic principles and their proper solutions.

## STATE BOARDS OF MEDICAL EXAMINERS

Your committee believes that there is a need for closer and more effective liaison and cooperation between State boards of medical examiners, medical schools, and medical associations. It further believes that certain procedural changes are worthy of consideration by the State boards. It is the recommendation of the committee, therefore, that—

(a) Each State board of medical examiners include in all examinations for license questions on ethics and proper socioeconomic practices;

(b) Each State board of medical examiners cooperate with medical schools to the end that medical students may be acquainted with ethical and proper socioeconomic principles during their period of formal schooling;

(c) Each State board of medical examiners check the files and records of the American Medical Association, the Federation of State Medical Boards, and, if possible, every other State board of medical examiners before issuing any applicant a license to practice medicine;

(d) Each State board of medical examiners, in cooperation with the State medical association, review the disciplinary provisions of the State's medical practice act and recommend whatever amendments are necessary to insure that they are effective in the light of current social and scientific progress;

(e) The Federation of State Medical Boards appoint a committee to draft model rules of procedure in disciplinary cases and urge their adoption by State boards and that the American Medical Association make available to the federation on request staff assistance to aid in this activity;

(f) State boards of medical examiners seriously consider the advisability and necessity of making discipline their primary responsibility;

(g) Each State board of medical examiners make an annual report of its disciplinary activities to the Governor of its State, sending copies of such report to the State medical association, to the American Medical Association, and to the Federation of State Medical Boards;

(h) State boards of medical examiners be urged to obtain competent legal assistance as they develop disciplinary mechanisms, recommendations, and procedures, and that they consult with such counsel at all stages of board proceedings to prevent errors which may result in litigation; and

(i) A mechanism be established to provide an effective method of collecting and distributing, through a central source, information on disciplinary procedures as well as on licensing and disciplinary actions taken by all of the individual State medical boards.

## MEDICAL ASSOCIATIONS

Your committee believes that State medical associations have not been as effective as they could be in the area of medical discipline because of the practice of limiting their concern to matters that are appealed to them from the local level. Some defects in basic mechanisms and considerable apathy at the county and State level in taking action against offenders have contributed to the situation which exists.

It is the recommendation of your committee, therefore, that—

(a) State medical associations become actively concerned with the disciplinary programs of county medical societies and develop a greater interest in and knowledge of the activities of their component societies in the discharge of disciplinary obligations;

(b) State medical associations review their disciplinary programs critically and at once to the end that changes in disciplinary mechanisms at State or local level may be made as necessary;

(c) State medical associations develop indoctrination programs for use by their component societies to acquaint new members with ethical principles and acceptable socioeconomic practices;

(d) State medical associations continue to encourage the widest development and use of grievance committees and urge that their component societies make the services of such grievance committees more widely available;

(e) State medical associations increase their concern and activities with respect to complaints of overcharging, medical advertising, and solicitation of patients, abuse of prepayment and insurance mechanisms, as well as all other conduct inimical to the best interest of the public and the profession;

(f) State and county medical societies utilize grievance committees as "grand juries" to initiate action against an offender so as to obviate the necessity of

making an individual member of a medical society complain against a fellow member;

(g) State medical associations amend their bylaws to provide that the State association may take necessary disciplinary action when it believes that serious violations of ethical principles have occurred without necessary corrective action being taken first at local level or when the State association believes that serious charges brought against an individual are not being given proper or prompt consideration by the disciplinary committee of the county medical society concerned;

(h) Each State medical association and all doctors within the State give increased support to the State board of medical examiners as it seeks to obtain proper appropriations for the conduct of its affairs and that the State medical association and its membership be concerned with the selection of qualified and dedicated members for its State board of medical examiners;

(i) Each State medical association develop and administer review and utilization committees in accord with the suggestions made in section V of this report; and

(j) County medical societies review their bylaw provisions relating to disciplinary procedures and revise them as necessary, using the suggested bylaws set forth in appendix 4 of the committee's report as a model.

#### AMERICAN MEDICAL ASSOCIATION

Your committee believes that the American Medical Association should become more aggressive and active in supplying advice and assistance to State boards of medical examiners and State and county medical societies in all aspects of medical discipline. It is recommended, therefore, that—

(a) The executive vice president be requested to provide this assistance, on request, through the proper department of the association;

(b) The American Medical Association, in cooperation with the Federation of State Medical Boards, the Council of State Governments, and other interested groups draft a model medical practice act;

(c) The American Medical Association encourage and urge each State medical association to report annually to the American Medical Association all major disciplinary actions taken within its jurisdiction during the preceding calendar year;

(d) The American Medical Association encourage and urge the Federation of State Medical Boards to cooperate with it in developing a means whereby each State board will report promptly all major disciplinary actions taken by it to the American Medical Association;

(e) The American Medical Association distribute annually to all senior medical students in the United States copies of the "Principles of Medical Ethics and Opinions and Reports of the Judicial Council";

(f) The American Medical Association prepare a syllabus or lecture guide on the subjects of medical ethics, medical practice acts, and proper socioeconomic conduct for the use of physicians called upon to give lectures on these subjects in medical schools, hospitals, or before medical societies;

(g) The bylaws of the American Medical Association be changed to confer original jurisdiction on the association to suspend or revoke the AMA membership of a physician guilty of a violation of the principles of medical ethics or the ethical policy of the American Medical Association regardless of whether action has been taken against him at local level;

(h) The American Medical Association request that adequate lectures on ethics and proper socioeconomic practices be given in all hospitals approved for internship or residency training; and

(i) The American Medical Association instruct its representatives to the Joint Commission on Accreditation of Hospitals to urge the joint commission to adopt, as a requirement for accreditation, the giving of adequate lectures on ethics and proper socioeconomic practices each year within the hospital.

Finally, your committee recommends that American medicine at the National, State, and local level maintain an active, aggressive, and continuing interest in medical disciplinary matters so that, by a demonstration of good faith, medicine will be permitted to continue to discipline its own members when necessary.

#### NOTE TO SCIENCE WRITERS AND EDITORS

As a source of background information on the subject of quackery, attached is an article prepared recently for publication in a national magazine by Edward R. Annis, M.D., President of the American Medical Association.

QUACKERY, BY EDWARD R. ANNIS, M.D., PRESIDENT, THE AMERICAN MEDICAL ASSOCIATION

As long as there are human beings there will be human nature—and shysters to take advantage of the fact.

Each year our gullibility to health frauds costs us at least a billion dollars. Furthermore, the gimmicks, devices, formulas, and fads of quacks accumulate faster than they can be caught in the spotlight of notoriety by Government agencies, medicine, and volunteer health organizations.

Indeed, quackery has become so commonplace that some forms have gained general acceptance. And no wonder. Quacks have been refining their technique since the beginning of time.

One of the earliest known prescriptions was a hair grower, compounded especially for Queen Ses of Egypt in about 3400 B.C. It consisted of dog toes, date refuse, and asses' hoofs. This concoction had the same effect as present-day hair restorers—none.

No one can claim immunity from a quack. At one time or another science itself has fallen victim to hucksterism. But when the mechanics of quackery are understood, the often dangerous, always expensive merchants of deceit can usually be avoided.

Quackery is perpetrated in many ways—lectures, books, mail-order circulars, and is even peddled house to house. Its forms are as varied as unscrupulous but fertile imaginations can make them.

Perhaps one of the best clues to spotting a quack comes from an understanding of the history of the word. "Quack," as it is used today, is an abbreviation for the earlier form "quacksalver." Using the cry of the duck to denote ignorant chatter and boasting, the word "salver"—to save or heal—was added. Thus quacksalver came to mean one who makes noisy pretensions to a medical skill for profit and prestige.

Nutrition—what we eat or don't eat—has become the most lucrative field for the quack. Annually Americans fall victim to \$500 million worth of dietary nonsense in form of "health" foods, food supplements, weight-reducing gimmicks and literature, fads, and cults. This is more than the American public spends on medical education each year.

Nearly another half billion goes for self-medication of self-diagnosed ailments. There is probably a nostrum for every symptom, whether real or imagined. Yet, with a few notable exceptions, tonics, elixers, potions, and pills available without prescription have little or no medical value. On the other hand, some do have the ability to mask symptoms of serious conditions that ought to be called to a physician's attention.

For most people, an occasional meal of kelp or dose of pep tonic is not an overt menace to their health—no matter how much it belabors commonsense and pocketbook.

It is a different matter when a person is seriously ill. Then the ministrations of a huckster can steal life itself. For while the quack plies his "miracles," the victim is lured away from the very help he so desperately seeks.

A cancer victim doses himself with sea water, purchased from a "specialist" at \$3 a pint, and wastes that precious margin of time when surgery or radiation might have saved him. Another man comes down with peritonitis while a wave machine, with less energy output than an ancient crystal set, directs harmonics at the ulcer in his stomach.

Such practices go beyond the nonsensical. They become vicious schemes, often tantamount to murder.

In an effort to expose such abuses, along with medical cultism, health frauds, and drug and nutritional absurdities, the American Medical Association and the Food and Drug Administration convened their Second National Conference on Medical Quackery this week in Washington.

Why, in a country as well educated as America, is such a conference necessary? Why would a woman give up insulin and face death in the belief that she had cured her diabetes by taking a \$5 bottle of dirty water infused with broom-straw? Why would a man crippled by arthritis pay by the hour to sit in an abandoned uranium mine?

Part of the answer to all this is the understandable resentment against dependency on a drug. Life sustained only by the ingredients of a hypodermic needle lacks a certain comfort and assurance craved by beings.

Another part of the answer comes from a former athlete whose promising baseball career was ended by agonizing, incurable, rheumatoid arthritis. Early this

year he told a Senate committee investigating quackery: "I can guarantee you that when you are on a bed of pain you will try almost anything." He certainly had, including miracle foods such as alfalfa tea and seaweed, and miracle gadgets, such as vibrators. The results—absolutely nothing—the cost—\$3,000.

The sweet talk of a charlatan, the promise of a miracle after medicine has honestly admitted it can do little or nothing, can't help but be alluring to a desperately ill person. And, when there is documentary proof of cures, the offerings of a quack can be overpowering.

Quacks invariably have reams of testimonials from those who have been saved. Many of these, of course, are varnished lies. Others are the actual convictions of patients in the hands of quacks.

Medicine is well aware of the fact that a patient's feelings often have nothing to do with reality. At least one-third of all symptoms seen by physicians are figments of the patients' imagination. And just as disease can be imagined, so can cures be imagined.

Research has shown time and time again that an injection of sterile salt water or the swallowing of a sugar pill will ease pain as readily as a drug in some people. Because they believe they have taken a painkiller, they imagine they feel relief.

So, when the fears and tensions of a cancer victim are eased by the promise he is getting better, then he well may feel better for a time—long enough at least to sign a testimonial for a quack.

Ironically, our modern age has given quackery a big boost. True, the market for wolf elixirs smuggled from the sacred tombs of ancient Egypt wouldn't be as great today as it was a century ago. But dolled up in new finery of scientific jargon, the same old cure anything pitch of the 18th-century hawker gets wide acceptance.

The wonders of electronics, the atomic age, the legitimate breakthroughs in medicine have impressed the public that science can do astounding things with some mighty strange materials. Mold is refined into penicillin; radiation, with its clinging aura of mystery, destroys cancer; high-pitched sound waves perform delicate ear surgery.

People today are generally aware of these developments. And it is from a launching pad of such fantastic reality that the quack skyrockets his fantastic deceit.

He capsulates dirt, calls it uranium, and claims it will cure 50 diseases his forebears in the art of fakery never heard of. He devises a machine that produces a mysterious new force, unknown to science but capable of righting any ailment. He uncovers the natural law of life and guarantees you'll live a century and a half if only you'll purchase his nostrums, eat his food, and live at his clinic.

Even taking into account the persuasiveness of the quack, his stock in trade, and the susceptibility of people overly concerned with their health, the limits of human gullibility defy understanding. It can only be gaged by the outrageousness to which people have fallen victim.

Until caught by postal inspectors, a 5-foot-2 mail-order slicker reaped a rich harvest with a device he advertised would make short people taller. It stretched them on a rack something like those used in medieval dungeons.

Another man sold electric blankets as a cure for cancer. He charged \$185 each, and when his victims died, he repurchased the blankets from the bereaved kin for \$5 or \$10. These he resold to other cancer victims at the new price.

One quack even convinced some cancer patients they should inhale bacteriophage—the same type of germs found in sewage, intestinal tracts, and pus. These, he claimed, would destroy the organism that caused cancer.

Medicine, unfortunately, is particularly vulnerable to shysterism. For one thing, everyone is at least somewhat aware of his health and hopes to keep it. For another, medicine is not an exact science. Its understanding is not complete nor does it have a specific answer for every ailment. Within these gaps the quack operates.

If, for instance, we had a cure for arthritis, quacks would have to vacate the field. There no longer would be room for phonyism. This, by the way, would save victims of arthritis \$250 million annually—the amount now spent on misrepresented cures.

In addition to a wealth of victims, the quack also finds a high degree of immunity from the law by hewing close to the line of medicine. When science can't say what causes or cures a disease, then it becomes extremely difficult to prove the fraud of a quack's treatment—especially when it is all made to sound

so plausible and when thoroughly conned victims will testify as to their cures.

Years were spent by Government prosecutors before they succeeded in closing Hoxsey cancer clinics. Yet the Hoxsey method never did have any sound scientific basis. The Hoxsey wonder drug, in fact, may have stimulated rather than cured cancer, according to a pronouncement of Government scientists.

The legal battle against others reaping fortunes from unproven panaceas for incurable diseases have not been so successful.

In 1919 a highly educated man—a physician, professor and chemist—claimed to have discovered a substance he named “glyoxylyde.” Just one injection of glyoxylyde, he said, would impart such a glow of health that the body would manufacture its own remedies against disease, including leprosy, cancer, and tuberculosis, which at that time would not respond to drugs.

Twice he was brought to trial; twice expert chemists testified that glyoxylyde couldn't be distinguished from distilled water, and twice he was set free. Jurors couldn't decide from the reams of testimony what was science and what was soothsaying.

Not that you can blame juries. The truth about glyoxylyde became so befuddled that its “benefits” can be found enumerated in such an influential tome as the *Congressional Record*.

The dupes of quacks can't be segregated by economic conditions, education, or any other category. Quacks have taken in physicians and medical editors as well as housewives and world renowned personalities.

Elder statesman and royalty have been among those trooping to the clinic doors of a Swiss physician who imparts longevity with injections of mashed cells from the unborn offspring of freshly slaughtered sheep.

Just why such injections should prevent aging, the good doctor has never found time to explain to the rest of us. At any rate, while his technique might be new, his concept isn't.

Back in the twenties a Kansas “doctor” was “rejuvenating” old men by giving them transplants of goat gonads. He'd probably still be doing it, except he was run out of the country, together with his yachts, four automobiles, and airplane. Besides, he discovered that hawking a mixture of blue dye and hydrochloric acid was just as lucrative and easier besides. It didn't entail the mess of an operation.

More alarming than the individuals among the quacks, however, are the whole “professions” that have sprung up in the shadow of medicine.

Anyone can set up an alleged health clinic. Truckdrivers, insurance salesmen and even ex-convicts have been found running them.

Nor is “private practice” out of the reach of the determined. A diploma for wall display can be had in various fields. Some of these supposed testimonials to a practioner's skill can even be had without a high school education.

But, whether a schooled scientist with a quirk in his nature or a door-to-door salesman peddling “nature's remedy,” quacks have much in common.

The department of investigation of the American Medical Association—a clearinghouse for information about quacks and their methods for more than 50 years—lists six simple rules in spotting one.

If he uses a special or “secret” machine or formula he claims can cure disease.

If he guarantees a quick cure.

If he advertises or uses case histories and testimonials to promote his cure.

If he clamors constantly for medical investigation and recognition.

If he claims medical men are persecuting him or are afraid of his competition.

If he tells you that surgery or X-rays or drugs will cause more harm than good.

In addition, the quack often wants payment in advance, for he'll tell you the expense of miracles comes high. In the “interest of humanity,” however, he's open to bargain, and will “sell below cost” a charm bracelet of “exotic” metals, that relieves pain, or an electronic gadget that looks like a horse collar and is supposed to magnetize the iron in the blood, thus curing all ills.

The phenomena of the quack in the healthiest Nation on earth is indeed difficult to comprehend. We're not the only pushovers in the world, it's true, but we do spend the most at it.

The real wonder is that our health is so good, considering the quack abuses we can inflict on ourselves. But even more to the point, our health would rise in inverse proportion to the decline of self-diagnosis and self-medication.



At the same time, the Nation's bill for health care would be noticeably reduced if Americans would stop squandering millions of dollars on medical and nutritional hokum.

Good health can't be found in a salesman's bag or a pitchman's persuasions.

Nor is it expensive, until something goes drastically wrong.

It requires only good eating habits, but not overeating; sufficient exercise, but sufficient rest too, and enough indulgence to give life its zing, but without falling addict to abuses.

#### MEDICAL QUACKERY

Quackery is the practice of deceit. It persists with a fervor perhaps equalled only by the sincere quest for more effective cures for more and more diseases.

Through faddism, fraud, deception, and delusion, the unknowing are led to seek nonexistent shortcuts to health. Knowing only what they're told by a "pitchman," millions each year attempt self-medication for self-diagnosed symptoms. Others, some with confirmed illnesses, are beguiled with assurance of a quick cure—even for incurable diseases. Medicine can't always give such assurances. The quack, unhindered by ethics or concern, can.

#### WHY IS MEDICAL SCIENCE SO CONCERNED WITH QUACKS AND THEIR WARES?

Quackery can negate the good that medicine can do. It can steal precious time—that early period of a disease when prompt, efficient treatment can often mark the difference between life and death. The cancer patient who infuses himself with expensively bottled sea water is in reality only withholding from himself surgery, chemotherapy, or radiation which might arrest the disease.

Quackery also can mask disease with telling effect. The nonprescription potion that soothes a persistent stomach upset may serve only to delay a trip to the doctor by a man with an unknown ulcer—a delay that often fosters serious consequences?

#### WHAT CAN BE DONE?

As with most serious medical problems, the solution is not simple. The prosecution of frauds perpetrated in the guise of medicine is extremely difficult. Just as the psychosomatic imagines disease, so can the gullible imagine cures, even when disease does exist.

Legislation alone cannot do the job, although it certainly can help as we have seen in the past few years. Before we can hope to make major progress toward the eradication of quackery, however, we must also impart to the public wider understanding of what quackery is and the means by which it flourishes.

#### BASIC FACTS

The word "quack" as it exists today is an abbreviation for the earlier form "quacksalver." The word "quack" has as its first meaning imitation of the cry of a duck. It thus came to mean ignorant chatter and boasting of medical skill and cure-alls. The word "salver" means to save or heal. Thus the original "quacksalver" early came to mean one who pretends to be a savior or healer and who makes noisy pretensions to a medical skill not based on real knowledge; a boaster of wonderful cure-all remedies. The present-day dictionary and legal definition of "quackery" is "boastful pretention to medical skill; an ignorant or dishonest practitioner professing skill or knowledge in any matter of which he knows little or nothing."

The major areas in which quacks operate, plus the advice of specialists in each of these fields, were compiled recently by the National Better Business Bureau. They are—

#### ALCOHOLISM

Advertised "cures," "remedies," or "treatments" for this disease are worthless. There are no "easy" or "secret" treatments for alcoholism nor any drugs conclusively demonstrated to permanently and safely remove or overcome addiction to alcohol or make it possible for the alcoholic to drink normally. Recovery from this disease is dependent upon the individual's sincere desire to stop drinking and his willingness to accept mental and spiritual help as through psychiatry, Alcoholics Anonymous, etc.

## ANEMIA

Anemia may involve pathologic conditions and there is no known product which may be truthfully advertised as a cure, remedy, or preventive of anemia. Pernicious anemia is a very serious condition. Self-treatment should never be attempted.

## ARTHRITIS AND RHEUMATISM

Although there are products of value in relieving temporary minor aches and pains associated with arthritis, no known drug, preparation, or device may be truthfully advertised to the public as a cure, remedy, or competent treatment. This is too complicated and serious a condition for self-treatment. There are numerous forms of arthritis, for which treatment vary greatly and only by early and thorough examination can the appropriate therapy be determined. The foregoing statements also apply to gout. Almost any condition producing aches and pain in the joints, nerves, and muscles may be called "rheumatism" by the public. The causes are legion, and although there are products of value in relieving temporary minor aches and pains associated with rheumatism, there is no single product that is a cure, remedy, or competent treatment for it.

## BALDNESS

There is no known drug, preparation, device, or method of treatment recognized as a cure, remedy, or competent treatment for baldness; nor as capable of growing or aiding in the promotion of the growth of hair, preventing baldness, or feeding or nourishing the hair or scalp.

Hair does not have "roots" like a plant and cannot be "fed" by any external application.

## BUST DEVELOPERS

There is no known preparation, system of exercise, or mechanical device which may be properly offered to the public to increase the size of the female breast. Estrogenic (hormone) preparations cannot be used with safety except under a physician's supervision, and then may produce satisfactory results in a minority of cases.

## CANCER

No known serum or drug will cure cancer. However, when treated in the early stages, cancer may be cured by competent surgery and, in selected cases, by the use of radium and X-ray if such treatment is given by a reputable physician. Some quacks use injections and diet methods which are thoroughly discredited, or escharotics, powders, and pastes which have been abandoned as useless, dangerous or apt to cause disfiguring scars, especially in the case of external or skin cancer.

## DIABETES

Diabetics should be under the care of a physician for periodic examinations and possible adjustment of control measures. Derivatives of the sulfanilamides are being used effectively in some cases. With this exception, diet and diet with insulin injections are the only recognized treatments for controlling this disease. Reliance upon advertised treatments may cause early death.

## DIAGNOSTIC DEVICES

Devices have been promoted by quack practitioners as possessing magical properties in the diagnosis and, sometimes, the treatment and cure of serious ailments. The sick person who relies on quack practitioners and his devices is gambling with his life, and is causing needless damage to his pocketbook.

## DIATHERMY

Employing the use of heat, diathermy is an aid in treatment of certain conditions, particularly by giving temporary relief from the pain associated with such conditions. There are many conditions involving pain, however, where diathermy should not be used and its use by unskilled persons may cause burns and serious damage. Diathermy devices should not be used in unsupervised self-treatment.

## EPILEPSY

There are drugs which help to control the "fits" or seizures of epilepsy, but they are not a "cure" for the condition, the cause of which is unknown. Epilepsy is too complicated and serious a condition for self-treatment or mail-order treatment.

## EYE DISEASES

The human eye is a complex and delicate mechanism and should not be tampered with by the unskilled. No known medical preparation may be truthfully offered to the public as a cure, remedy, or treatment for pathological conditions of the eye or to correct error of refraction. However, properly compounded eye drops and lotions may be used to help cleanse the eyes and allay irritation due to minor local conditions. Causes of defective vision are multitudinous. Eye glasses cannot be accurately nor safely fitted by mail; nor can mail-order courses in eye treatment be truthfully offered to the public to correct defects of vision.

## EYEBROW DYES AND EYELASH GROWERS

Preparations containing coal-tar dyes, and at least most metallic dyes, should never be used to color the eyebrows or eyelashes. Mascara or colorings having a carbon black basis will accomplish the purpose harmlessly.

## HAIR DYES

Most hair dyes on the market today are not harmful to the majority of people when properly used but are potentially dangerous when misused, some representing greater danger than others. Best and safest results are obtained when the hair is dyed by a qualified operator. If you dye your hair, be sure to follow directions exactly and make all prescribed skin tests to determine possible allergy to the dyes. No one, as yet, has discovered a means of 'restoring' color to gray hair or achieving permanent coloration results. Consumption of vitamin products is worthless for those purposes.

## HAIR REMOVERS

Electrolysis, in expert hands, is the only known method of removing superfluous hair permanently and safely. Misused by inexperienced people, electrolysis can cause tragic disfigurements. There are many chemical depilatories, epilators, abrasives, etc., which, when used according to directions, will accomplish temporary removal of hair in a satisfactory and reasonably safe manner, but results are not permanent and these products do not retard regrowth of hair. Bleaching creams or lotions, including those alleged to generate oxygen, will not remove hair, even temporarily. X-ray machines, generally under fanciful trade names, have been advertised for hair removal, but such treatments are extremely dangerous.

## HEALTH FOODS

The term "health foods" is a misnomer since it implies that the products have health-giving or curative properties, when, in general, they merely possess some of the nutritive qualities to be expected in any wholesome food products. More specifically and, contrary to what has been advertised, mate or Paraguay tea has no more healing properties than ordinary tea; kelp is not a cure for stomach ailments or obesity; honey is not a cure for whooping cough; root beer is not a tonic for the nerves; baking soda does not cure colds; grape juice will not reduce weight; gelatin does not prevent fatigue; blueberry juice is not a cure for diabetes, and olive oil will not prevent appendicitis.

## HIGH BLOOD PRESSURE

High blood pressure, or hypertension, is not a disease, but may be a symptom of various diseases or disordered conditions. There are no known substances which may be properly advertised for the self-treatment of high blood pressure. Garlic tablets have been offered for that purpose. Although credited with magical properties by the ancients, garlic has no therapeutic value in the treatment of hypertension (high blood pressure) or its symptoms.

## HORMONES

The value of male hormones in the treatment of impotence is very limited and the potentialities for danger in such products are so great that they should not be used in self-treatment. The Food and Drug Administration conducted an extensive investigation of the use and abuse of female and male hormones, concluding that in its opinion, such hormones could not be safely and efficaciously used for therapeutic purposes except under the supervision of a physician.

## INFLUENZA

There is no known effective home treatment that many be truthfully advertised to the public as a cure, preventive, remedy, or treatment for this contagious and extremely serious disease. Proper treatment of influenza requires the personal attention of a physician.

## KIDNEY DISEASE

No known preparation may be truthfully advertised as a cure, remedy, treatment or relief for "kidney trouble," "bladder trouble," "kidney disorders," or diseases of the kidney or bladder. These are serious ailments not amenable to self-treatment.

## MOLE REMOVERS

Tampering with a mole may encourage it to develop into a dangerous growth; hence, avoid advertised preparations. Only a skin specialist or physician should remove a mole.

## OBESITY AND REDUCING SCHEMES

The essential cause of obesity is overeating. Lack of exercise may be a coordinate cause. Reduction of the amount of food consumed by careful and proper dieting is therefore essential. This may involve some discomfort and requires will power. Stringent dieting and reduction for purposes of weight should be considered in relation to one's physical condition, and, therefore, needs the advice of a physician. Plans calling for adherence to low-calorie diets and endurance of the hunger consequent thereto, should not be offered to the public as "easy" or "pleasant" or as enabling reducers to eat "plenty," "eat what they want," etc. Too hasty reducing may be unsafe.

Unless proved to be safe, the public should avoid products advertised to reduce weight by curbing appetite, and to enable users to adhere to low-calorie diets without experiencing hunger and its attendant discomforts.

Laxative products have no value in reducing weight.

Massage is not recognized as of any fat- or weight-reducing value. Massage devices will not reduce in spots or remove bumps or bulges; nor are creams of value except as lubricants.

Belts, girdles, etc. may cause the wearer to appear slimmer, but they do not remove fat or reduce weight.

Obesity is not effectively and permanently reduced by sweating. Rubber garments, perspiration-inducing baths or devices, and soaps, creams, and other external preparations are of no value for fat or weight reduction.

We repeat: To reduce weight, reduction of the amount of food consumed by careful and proper dieting is essential.

## PEP PILLS

"Pep pills"—stimulant drugs such as Benzedrine, Dexedrine, and other brands of amphetamine sulfate are prescription drugs and have valuable medical uses. But they are also habit forming and may be dangerous if improperly used. They should not be employed as a substitute for rest, especially on the highways. Serious accidents have resulted from this cause.

## HEMORRHOIDS

Ointments and other external applications may be of palliative value in relieving soreness, itching, or burning caused by piles or hemorrhoids, but do not constitute a cure, remedy, or competent treatment for the condition. Serious cases may require surgery or other specialized treatment. Do not attempt self-treatment of bleeding piles, because bleeding may indicate a serious condition requiring prompt medical attention. Laxative preparations should not be used for the self-treatment of piles.

## PITCHMEN

Pitchmen, otherwise called barkers, posing as health lecturers may have a selfish interest behind their talks—selling courses of instruction, or books, or other products on which they make a profit. Many of them attack well-known foods and products in order to sell their own special products at special prices. Many health fad lecturers are in this class.

## PROSTATE GLAND DISORDERS

Devices designed to permit the application of heat to or massage of the prostate gland have been advertised for prostatitis, hypertrophy, and other prostate gland disorders. Even in skilled hands, such implements have limited value and their use by untrained persons to the neglect of more competent measures may be attended by serious consequences. Prostate gland disorders may include many diseased conditions, such as cancer, too serious for self-treatment.

## PYORRHEA

No known product can be truthfully offered to the public as a cure or remedy for pyorrhea. This disease centers deeply in the gums and the proper treatment should be by or under the directions of a competent dentist. Serious cases might require surgery.

## RADIOACTIVE PRODUCTS

Most of the waters, drugs, and other allegedly "radioactive" or "atomic" preparations and devices offered to the public for the treatment of numerous ailments have contained insufficient or no radium to justify their consideration as therapeutic agents. A genuinely radioactive or "atomic" water or drug would be extremely dangerous to use except under a physician's constant supervision. It would be illegal to sell a strongly radioactive product to the general public. Such a product would probably not be in the proper form to be of value as well as being dangerous for unsupervised use.

## RUPTURE

Surgery is generally necessary for the successful treatment of rupture or hernia in an adult. A well-constructed truss, when properly fitted, may provide palliative treatment for reducible rupture, but advertising should not encourage unskilled individuals to fit themselves. No truss, or other method of self-treatment, may be truthfully advertised to cure or heal hernia or enable the patient to engage in unlimited activity. Use of a truss for a rupture which should be otherwise treated or without competent advice and prescription, may delay and complicate proper treatment. A rupture should have competent diagnosis and prescription by one having specialized knowledge and the license or authority to do so.

## SINUS DISORDERS

Sinusitis, or sinus trouble, is an inflammation or infection of the sinuses or internal cavities of the skull. It may be associated with numerous other affections. While there are products which may afford temporary relief of symptoms such as nasal congestion, pain or discomfort, the cure or successful treatment of the condition requires medical attention. Short-wave diathermy devices should not be used for the self-treatment of sinus disorders.

## SKIN BLEMISHES

There are preparations which will relieve itching and certain other symptoms of superficial skin blemishes. However, in adopting any treatment for diseased or abnormal condition of the skin, the only sensible thing to do is to consult a physician, preferably one who specializes in the treatment of skin conditions. Self-treatment may seriously delay proper medical treatment and unnecessarily prolong the condition. Conditions diagnosed as psoriasis, impetigo, and acne should be treated by prescription based on the diagnosis.

## STOMACH ULCERS

An antacid preparation may help to relieve pain incident to stomach ulcers caused by hyperacidity, but a person suffering from an ulcer should be under the observation of a physician. In many cases, the early symptoms of stomach

cancer are similar to those of stomach ulcers. A stomach ulcer is a serious matter and its proper treatment requires a competent medical appraisal of the condition and a careful regimen of diet, rest, and other corrective measures to hold out any hope of substantial relief or eventual healing of the ulcer. Proper medication is but one of the necessary measures of treatment.

#### TOBACCO HABIT CURES

There is no known drug or combination of drugs that can be truthfully offered to the public to cure or overcome tobacco habit or permanently eliminate the desire for tobacco. A simple determination to stop, backed up by willpower, is the best way to moderate or abstain from smoking.

#### TUBERCULOSIS

For many years, no drugs were known which would have any effect upon tuberculosis other than the alleviation of symptoms when judiciously prescribed by a physician. Nevertheless, many products have been offered for the treatment of this disease and, in years past, they have undoubtedly hastened the death of many a tuberculosis victim or impeded recovery. Until very recently, the arrest of tuberculosis depended entirely upon rest, proper diet, and judicious surgery. Neglect of such measures, and attempts to treat the disease with home or advertised remedies, often proved disastrous. Now there are some drugs useful to physicians in hastening the recovery of the tuberculous but these cannot be used safely by nonmedical persons. Also, there has been a shift in the prevalence of the disease and now, many old persons, who have tuberculosis mistake it for chronic bronchitis or just chronic cough. Not only should all remedies recommended for chronic coughs be looked upon with suspicion but old people with chronic coughs should be examined to make sure it is not tuberculosis.

#### VITAMIN-MINERAL FOOD SUPPLEMENTS

Some advertisers and door-to-door salesmen, promoting the sale of vitamin-mineral food supplements, seek to create the impression that almost everyone suffers from, or is in danger of suffering from, one or more vitamin deficiencies, and that it is necessary or desirable for everyone to purchase their particular products to prevent or to help correct a wide variety of ailments.

An adequate supply of vitamins and minerals is one of many factors essential for maintaining good health. However, a well-balanced diet of adequately selected and properly prepared foods will provide a person with all the vitamins and minerals required for his physical well-being, as well as with whatever unknown vitamins or other nutritional essentials there may be. If a person is getting an adequate supply of vitamins from his diet, his health will not be improved by taking extra vitamins. Many of us do not get an adequate diet. Many fail to get enough vitamins not, primarily, because they do not get enough food but because they do not eat the right kinds of food. Those who are unwilling or unable to follow a properly regulated diet can be aided by vitamin-mineral concentrates, if appropriate selection is made according to their needs. Usually only a physician can diagnose a particular vitamin or mineral deficiency.

Mr. THROCKMORTON. Let me start at the bottom half of page 2, Senator, in order to save time.

I would like to clarify the role and responsibilities of the American Medical Association in this area. The constitution of the AMA states that, "The objects of the association are to promote the science and art of medicine and the betterment of public health." Pursuant to that purpose, in the area of quackery, we have the dual responsibility of keeping medicine's house in order; that is, stamping out any such practices among doctors of medicine, and we have our responsibility to the public to deal with quackery outside of medicine.

Our responsibilities in each of these areas can be broken down into: (1) enforcement; and (2) education. In discussing the work of the AMA against quackery, I will distinguish between our efforts directed to physicians and those directed to the general public.

On page 4, reference is made to our department of community health and health education, which conducts an extensive program of conveying valid health information to the public. This is the positive side of the coin in our fight on quackery telling the people the right things to do. We join with the governmental agencies and others in educating the people about things that are dangerous to their health.

Also on page 4, we refer to our communications division and its efforts in educating the public in this field of quackery.

Our statement does not mention the work of the council on drugs or the council on cutaneous health, for example. The point I am trying to make is that almost every department of AMA is doing something that has some bearing on this important problem.

Now, at the middle of page 5, I would like to tell you, Senator, of the specific actions we have taken since we last appeared before you. None of these actions was taken with the idea of coming back and preparing a record, because we did not know we were going to be here until last Tuesday, when we received a letter asking us to come.

It is a real pleasure briefly to outline the items you see starting on page 4. Reference has already been made to this Second National Congress on Medical Quackery.

Item 2 on page 5 refers to a luncheon we had at that time. We sat down with representatives of the Food and Drug Administration, the Federal Trade Commission, the Post Office Department and some of the State boards of medical examiners, and we talked about how we could work more closely together, not only to coordinate our information, but to coordinate our enforcement activities.

At the top of page 6, we make reference to the State quackery conferences which have been held in the last 2 years.

In item 4 (I am rather proud of this) as a result of the little luncheon we had following the quackery congress, Dr. Crabb, from Texas—Senator Yarborough—who is the Secretary of the Federation of State Medical Boards; Dr. Grabb and I agreed that on February 10 we would get up a hurried meeting in Chicago of the attorneys and the executive secretaries of the State boards of medical examiners. We spent a day discussing the three areas of the problem.

We said we would like to assist his organization in any way we could. I told him, "We know you have been sensitive to States rights problems. We have been careful not to push too hard lest you think we are trying to interfere with the way you run the board in your State. But we want you to know that we think these problems are important, and unless something is done to require joint action on the Federal and State levels, we feel we are not going to be as effective as we hope to be."

It was amazing. Dr. Crabb wrote me and said, "This is the best meeting I ever attended." We quickly scheduled a similar meeting for next year, and I believe there will be cooperation between the attorneys and others.

Senator YARBOROUGH. Mr. Throckmorton, I do not think that the burden of the protection should rest upon the medical practitioner alone, because those who practice quackery will charge him with doing this for his own financial interest, and I think the people in the Government have a broader interest where there is responsibility on the Government, on the people, to set up devices to protect people from

this quackery and not place that upon the licensed and legitimate practitioner.

Mr. THROCKMORTON. I certainly agree, Senator, and I am coming to that as I go along.

Item 5. We have scheduled a meeting in Chicago next month for attorneys, and executive secretaries of the State medical societies. We will spend 2 full days going over these same problems and will attempt to coordinate our efforts in this field.

At the top of page 7 is something I am very excited about, and it fits in with what you have been saying.

We met with representatives of the National Health Council about 2 weeks ago. They came to us and said that many of their members are asking us to provide leadership and coordination in this field. As a result, we agreed that we would call a meeting in May to which we will invite representatives of the governmental agencies and of the volunteer health agencies that are being so aggressive in this field. We will see if they are not as interested as we are in forming a volunteer committee.

This will be something, Senator Neuberger, like the correlation that was recommended by John Miner, I believe, within government. Government has limitations on its authority. We have our limitations, as pointed out in my statement.

We both need coordination. Private groups need coordination; the Government needs coordination. The two coordinating groups also need to get together.

We would hope that meetings would be held three or four times a year, but the committee would have an agenda. We can compare notes on who is doing what; what the most important problems are; how they can be most effectively handled.

I just want you to know we are in favor of this, and we are doing our best to take advantage of the council's request. We are sending out questionnaires to more than 50 agencies of the National Health Council asking them what they feel can be done about quackery. We also want to make it possible for them to participate in broader efforts.

We think it pays to start with a small handful—possibly eight or nine—groups including representatives of the three governmental agencies.

Now, at the top of page 8, we make reference to the fact that our board of trustees has appointed a committee on quackery, and that five physicians from various parts of the country have just been appointed to it.

Senator Williams, on pages 8 and 9 we make reference to the fact that you inquired about the disciplinary procedures of the medical profession at your last hearing.

I want to call to your attention one of your attachments to my statement which is a summary of the report of the medical disciplinary committee of the board of trustees made in 1961. This report was 2½ years in the making and required surveys and meetings in virtually every State in the Union.

The summary of that report sets out positive programs for State boards of medical examiners, for State medical societies, and for the AMA. I want you to know that we are implementing these recommendations. For example, we are putting out a manual on ethics and discipline.



I wish I had the time to go into detail, but speaking as a lawyer, I share the sentiments you expressed last time. However, it is my observation that the physicians are doing a much better job in keeping their house in order than is our own profession, Senator. We can document that for you if you wish.

Coming now to page 10, I want to point out that, while we have talked about physicians who get into the field of quackery and the fact that we are disciplining our members and are improving our methods of disciplining them, I do not want to leave the false impression that it is the physicians of the country who are the primary problem.

Actually, out of 278,000 physicians, there are just a very few who could be regarded as quacks. I want to point out that the meeting of this committee, among other things, has stimulated us to be more active and more aggressive in our approach to combating quackery. We think if this committee will stimulate the other professional groups—all of them—the nurses, the dentists, the pharmacists, the osteopaths, the podiatrists, the optometrists—they will solve the problem within their own ranks.

The CHAIRMAN. And the chiropractors?

Mr. THROCKMORTON. We have reason to feel that a very substantial amount of quackery is committed by the so-called "drugless healers." This is detrimental to the public health, to say the least. Chiropractic is said to have approximately 25,000 practitioners. It claims to be the second largest healing arts group in the country. Chiropractic must be labeled a "cult" practice because it is not supported by any reliable scientific or demonstrated knowledge. This, in itself, is sufficient to constitute these practitioners as "quacks" in the eyes of members of the scientific community.

Even forgoing this point, however, it is abundantly clear that many chiropractors engage in practices which exceed the scope of their licensure and competence, which often include deceptive and misleading advertising, and which frequently constitute quackery in its worst form by any conceivable standards of measurement.

For example, the case of *Correll v. Goodfellow*, decided by the Supreme Court of Iowa on January 14, 1964, discloses an incident that is simply appalling. The 70-year-old plaintiff went to the defendant chiropractor for a sore back. She purchased a series of 12 treatments in order to save \$6 from single treatment prices. Shortly after the treatment began, she turned her ankle. The chiropractor offered to treat her ankle with an ultrasonic machine. By the way, it is against Iowa law for him to use ultrasonic machines of any sort. The elderly plaintiff told him, "I am diabetic. You wouldn't dare use that on my foot." Defendant assured her, "That won't bother you at all. You don't have that much diabetes." As a result of three such treatments, it became necessary to remove the back part of the injured heel. Mrs. Correll is permanently disabled.

This is a case of unauthorized practice, as well as quackery.

One other illustration came to my attention last Friday when the Americal Medical Association received an unsolicited letter seeking information concerning a chiropractor. The writer requested, "Please do not mention our names if you do any investigating." I shall, of course, respect this request. However, I have shown the letter to Mr. Oriol.

The letter, in short, discloses that the chiropractor treated the spouse of the writer for "worms, shattered nerves, poison oak—which he claimed settled in the stomach—and for an aluminum allergy." He also treated an elderly members of the family for gallstones "that don't show up on X-rays," and he said that this elderly person "would have had leukemia if he hadn't started treating him when he did." Incidentally, the one office call that the spouse had resulted in a bill in the neighborhood of \$100. The bill indicated that the cost of the "treatment" was only \$5. However, X-rays and vitamins boosted the bill by more than \$90. Our correspondent admitted to being "stunned" by a bill of this magnitude "for one office call."

We know these are not isolated examples. This committee would be well advised to call upon the chiropractors.

If you asked the Food and Drug Administration, you would find that doctors of medicine have a very clean record with respect to the use of the devices in this room.

Senator WILLIAMS. I wonder if at that point you would advise whether the chiropractic profession has a national association in any degree.

Mr. THROCKMORTON. It has two, the so-called "straights" and the "mixers."

Senator WILLIAMS. Say that again.

Mr. THROCKMORTON. There are the so-called "straight," the straight chiropractors; and the so-called "mixers."

I know about these groups because their national headquarters are in Iowa. The "straights" are in Davenport. They are followers of Palmer who invented chiropractic. Their basic philosophy is to limit chiropractic to its original concept of manipulating the spine.

The so-called "mixers" have their national headquarters in Webster City, Iowa. This is the more aggressive group. They want to branch out and use all kinds of methods, aids, diet, and so on.

Senator WILLIAMS. Do you have the titles, the names of these associations?

Mr. THROCKMORTON. We can send those to you. I have trouble keeping them straight.

Senator WILLIAMS. I think we might find that useful, because chiropractic is licensed in many States.

Mr. THROCKMORTON. It is licensed in 47. It is not licensed in 3. In our judgment, it should not be licensed in any State.

Senator WILLIAMS. And yet 47 States have authorized it, by making it professional in the sense of licensing it.

Mr. THROCKMORTON. Yes; I understand this, Senator. The thing I am primarily urging is that the committee call on that profession and the agency to extirpate the undisputed quackery that exists in that profession. Secondly, keep chiropractic within the scope of its practice.

Senator WILLIAMS. I think we are creating an obligation here of the committee to send an invitation to the comparable professional national association in this area to testify.

Senator FONG. Does the medical fraternity have any objection to having these devices which are known to be quackery devices submitted to the Food and Drug Administration prior to their approval for sale?

Mr. THROCKMORTON. I will ask Mr. Donelan, who is our legislative expert, to comment on that, Senator Fong.

Mr. DONELAN. Senator, the association has not yet come to a final determination on the two device bills pending before the Congress, and I doubt if one will be made until the committees having jurisdiction over this legislation announce hearings.

The bills are currently under study by committees and councils of the association.

Now, if I might, I would like to point out one ramification of the device provisions. As it was indicated this morning, an item becomes a "device" when it is used for medical purposes or for the amelioration of disease. It has been indicated that this bill could extend to almost half the industry in the United States.

These are factors that are currently being considered by committees of the association, pending, as I say, the notification by the committees with jurisdiction that hearings will be held.

Senator FONG. Thank you.

Mr. THROCKMORTON. Senator, I would like to underscore what Commissioner Larrick said, that the AMA has as much interest as the Food and Drug Administration and the Federal Government in making sure these things do not happen. The only question is, what is the best way to solve this problem?

Senator FONG. I would assume you would have the same questions and you would like to see that these frauds do not happen.

The CHAIRMAN. Any further questions?

Senator NEUBERGER. I was interested in glancing ahead at the part of your statement you did not have time to read, and you very often refer to some State laws and need for effective law enforcement.

I gathered that the AMA does feel that maybe a Federal law would be useful.

Mr. DONELAN. Again, Senator, I do not know that we could indicate that one way or the other until policy has been established.

Senator NEUBERGER. All the witnesses have mentioned the word education, every single witness, and I know that you do, too, in your testimony, Mr. Throckmorton. It is necessary to educate people and you say millions of people must be repeatedly reached with medical truth until they are able to recognize quackery in many forms.

I was thinking that maybe it would behoove the AMA and Food and Drug Administration and others to work together to see that some part of public service time on television be devoted to exposing this sort of thing.

I know the BBC has a wonderful program on consumer education.

Mr. THROCKMORTON. Senator, we have had amazing cooperation from the television media. I would like to submit for the record the actual facts when I get back. I am not sure now what they are. I have heard them, and I was very impressed with the spot announcements the radio and television industries have run in the interest of the public.

I would certainly agree with what you say. But I would not like to leave the implication that we feel State laws are inadequate. We feel that State laws need better enforcement and, until recently, the AMA has felt that it should not aggressively push the States. But since we are getting requests from the States to help, we believe that a great deal can be done in improving the disciplinary procedures, getting more money for these boards, and getting State legislation.

Senator NEUBERGER. I used that because on page 10 you said, "Are unable to act because of inadequate State laws," but you do say further on law enforcement—

Mr. THROCKMORTON. Yes, the type of law I had in mind was the disciplinary law. Most boards of medical examiners do not have the right to take away the license of a physician who has violated ethical conduct.

Senator YARBOROUGH. Mr. Throckmorton, along the lines that Senator Neuberger was questioning you, I think we need laws, but I do think that continuing education is even more important than laws.

Mr. THROCKMORTON. We agree with that in our statement.

Senator YARBOROUGH. As an example, as I heard from the preceding statement of this witness on this book, "Arthritis and Common Sense," I saw it all over the country for 2 years, and the other book which he had here, recommended that a person eat things, if a person ate harmless foods for a year, hoping to cure them, whatever ailment they had might become progressively worse to the state where it could not be removed.

This type of thing does not help one bit. Maybe it is medical practice. Anyway, you come to a line between freedom of the press and the medical practice, the right of the State to regulate medical practice affecting the health of the people, and this business of drugs and food, you have the difference between treatment and fad, you get up to a pretty thin line there. So, education will always be essential in this problem.

Senator WILLIAMS. I think the American Medical Association is doing a magnificent job from all I have heard in this area.

Senator YARBOROUGH. Did you have a comment on that, Mr. Throckmorton?

Mr. THROCKMORTON. This book on honey and vinegar was written by a physician. If it were to be published today, in the improved climate which has been stimulated partially by your subcommittee, I assure you that my office would take much more aggressive action. I think the States want us to do it, and we feel we ought to do it.

We will also work with the Federal Government in any actions taken by Federal agencies.

Senator YARBOROUGH. Thank you very much. Congratulations on the work you are doing there for the enlightenment of the public.

Senator WILLIAMS. We will include all of your material in the record and we are grateful to you, Mr. Throckmorton.

We are working under an impediment here of having to go to the floor, having been called for a live quorum. I will point out that Mr. Joseph P. Adams, who does represent the International Chiropractors Association, is here.

Mr. ADAMS. That is correct, Chairman Williams, and I would like to congratulate this committee on the work you are doing and to advise you that the International Chiropractors Association only last month in San Francisco, Calif., at their midyear annual meeting, had a 2-hour session with the Public Relations Chief of the Food and Drug Administration from Washington, D.C., on the subject of quackery and they have not only taken this action of cooperation with the FDA but are consistently active in attempting to move in this area in support of the work of this committee.

Chairman WILLIAMS. I appreciate that and we cannot hear further from your association now. Perhaps we can formally later, and in the

interim, if you want to submit a statement we would be grateful for it and would include it in the record.

I might say that in the jargon of the profession, your association is made up of what Mr. Throckmorton describes as the straights. Is that right?

Mr. ADAMS. Thank you, Mr. Chairman.

Senator WILLIAMS. Am I right?

Mr. ADAMS. Yes, sir.

The CHAIRMAN. Not the mixers?

Mr. ADAMS. That is correct, Mr. Chairman.

WASHINGTON, D.C., March 10, 1964.

HON. HARRISON A. WILLIAMS, JR.,  
*Chairman, Subcommittee on Frauds and Misrepresentations Affecting the Elderly, Special Committee on Aging, U.S. Senate, Washington, D.C.*

DEAR CHAIRMAN WILLIAMS: On behalf of the International Chiropractors Association and its president, Dr. John Q. Thaxton, I wish to both congratulate you and thank you and the members of your subcommittee for the splendid 2 days of hearings that have concluded today, Tuesday, March 10.

These hearings have generated great interest in the press throughout the Nation and inasmuch as an increasingly larger proportion of our population are concerned with aging, the education and legislative steps which you are taking in protecting this segment of our population is of the greatest value.

As I indicated to you at the close of the first day of hearings, the International Chiropractors Association has been actively pursuing a cooperative program with the FDA in the area of quackery and on Saturday, February 8, the ICA, at its midyear meeting, held in San Francisco, Calif., devoted one-half day to a seminar directed by Mr. Wallace F. Janssen, Director, Office of Public Information, Food and Drug Administration.

Pursuant to the invitation extended by you and made a part of the record of these hearings on Monday, March 9, I am pleased to advise you that Dr. John Q. Thaxton, the president of the International Chiropractors Association, is pleased to make a statement for your committee at the time of these hearings. The statement of President Thaxton follows:

#### THE CONCEPT OF CHIROPRACTIC

(By Dr. John Q. Thaxton, president, International Chiropractors Association)

A review of chiropractic history reveals that an important factor retarding the advancement of the profession has been the ever-recurring charge: "Quackery." Often such accusations, magnified by the propaganda of political medicine, have been true—not because chiropractic is quackery, but because some doctors practicing under the name "chiropractor" are false pretenders to medical skills they do not possess. In the mind of the public, chiropractic and quackery, through association, have been considered as being synonymous. Because of this destructive association, created by adverse publicity, chiropractic and chiropractors have suffered needless embarrassment, and potential patients have not sought chiropractic care and sick people have not gotten well.

The quack "chiropractor," neither fish nor fowl nor competent to render professional service in either field; chiropractic or medicine, has resorted to poaching, thereby identifying himself as a quack and a pretender. Such fraudulent practices rob sick people of their money and sincere chiropractors of their respect.

In San Francisco recently a U.S. Senate subcommittee investigating frauds against the aged, found that fake cures, worthless food supplements, gadgetry, and quackery used by chiropractors and other health practitioners are bilking the elderly of vast sums. This expose, with the flames of damaging propaganda fanned by medical publicity, has done great harm to chiropractic. In addition to this, the seemingly unending series of current magazine articles tying quackery to chiropractic have been constantly inspired by fraudulent activities of pseudo-chiropractors who fleece the sick and suffering, pretending to be skilled in certain practices outside the realm of chiropractic. If the practice of chiropractic is not soon separated from such quackery, the basic freedom and responsibility of caring for patients will be lost to all chiropractors.

Those who solicit competent, sincere chiropractors, to join with the "medichiroquactor" have no sincere desire for these men of professional respect and

ability. They merely want to numerically strengthen the sagging shell of their "liberal" organization. What does membership in an organization, offering a haven for medical poachers (whose practices are questioned by the press, the Government, insurance companies, and legislators) have to offer a sincere chiropractor whose practice needs no defense as a method of restoring health? It is well known by many chiropractors (as recently and widely publicized by a former high echelon member of the medi-practor group) that the move to bring chiropractors into that association was motivated by fear that "the mixing element was about to take over" to such an extent that it was becoming known as a naturopathic rather than chiropractic group. Any name change made the naturopathic element once again a part of chiropractic and strengthened the mixing element's philosophy of chiropractic practice. The present disturbance within the mixer group is merely history repeating itself, however, the difference now is that there are too many chiefs and not enough Indians.

Chiropractic was spared another scathing denunciation at the recent AMA-FDA Quackery Congress. Vigorous action by the International Chiropractors Association members, and support of those interested in chiropractic, was the sole reason that another antichiropractic propaganda attack was prevented. However, as a result of the International Chiropractors Association's Washington activity on behalf of chiropractic, there is, today, a better understanding by officials of the U.S. Government of the limitations and scope of the true practice of chiropractic. By invitation, officers of the International Chiropractors Association, in conference with representatives of the Food and Drug Administration, had the opportunity to present the case for chiropractic. It was made clear that chiropractic is a separate and distinct health method—more especially that it is not an encroachment into areas of other health professions. Chiropractic was not described as a "branch of medicine" as was stated by a spokesman for the medi-practor group before a congressional committee some months ago.

In a meeting between the International Chiropractors Association and FDA representatives, it was interesting to learn of the steps being taken to eradicate quackery in the healing arts by the Food and Drug Administration. It was stated emphatically that misrepresentation of the effectiveness of health foods, gadgetry and certain other quackery practices will be under constant surveillance. However, because the scope of chiropractic was presented by the International Chiropractors Association as being a separate and distinct healing art, the FDA can now draw a clear line of demarcation between chiropractic and quackery.

Because of the International Chiropractors Association's efforts to divorce quackery from chiropractic, an increasingly greater number of dedicated chiropractors are becoming more concerned over the damaging effects of a medi-practor definition and scope of practice. They are joining with the International Chiropractors Association in this campaign to maintain the identity of chiropractic as a separate and distinct method of healing. The stark realization that the naturopath is a thing of the past and that the osteopath now practices medicine in its entirety, and that the food supplement industry is under Government fire is causing many in the profession to return to straight chiropractic and the International Chiropractors Association.

Chiropractic belongs to the sick and suffering. It offers a new approach in the quest for lasting health. The masses will decide whether it is to be a science of adjusting vertebral subluxations to release nerve interference for the correction of the cause of disease or just another disappointing defeat in the realization that medi-practice is merely a short-weight package of the same nostrums.

This concludes the statement of Dr. Thaxton.

Sincerely yours,

JOSEPH P. ADAMS.

Senator WILLIAMS. We will recess at this time.

Mr. Ladimer is with us. He is ready, willing, and certainly able to testify. But we must get to the Senate Chamber. Therefore, we will reconvene at the unprecedented hour of 8:30 tomorrow because of limitations on our hearing opportunities resulting from the Senate debate.

(Whereupon, at 12:25 p.m., the subcommittee was recessed, to reconvene at 8:30 a.m., Tuesday, March 10, 1964.)

(The appendix follows:)

## APPENDIX

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STATEMENT BY DR. EMMETT J. MURPHY, DIRECTOR OF INDUSTRIAL RELATIONS,  
AMERICAN CHIROPRACTIC ASSOCIATION, WASHINGTON, D.C.

Mr. Chairman, my name is Dr. Emmett J. Murphy. I am director of industrial relations for the American Chiropractic Association, Washington, D.C.

The American Chiropractic Association commends this committee on its foresight and diligence in calling these hearings. Our organization has consistently supported its purposes. We share with you a deep concern that many old people, and many others among our citizens are harassed and injured by charlatans and purveyors of fake nostrums, gadgets, and useless or harmful drugs.

Bringing these conditions to the attention of the public can serve a most worthy purpose and accomplish great good. For eternal vigilance is the price all must pay to be free from the imposition of false claims and false claimers.

Our association is not here as Pharisees, pointing the finger of scorn at other healing professions who may have members who do not fully live up to their professional responsibilities. We feel that they, like the ACA, are trying to police the members of their professions in an effort to weed out any and all charlatans and unethical practitioners.

We in the American Chiropractic Association represent the second largest healing profession in the United States. We have established a professional code of ethics to which all our members must comply, and which is enforced by the licensing boards in the several States. As the official organization of the main body of properly trained and duly licensed doctors of chiropractic, we have a dedicated membership singularly devoted to serving the needs of the public.

I wish to state here that the American Chiropractic Association has tried to cooperate with the Food and Drug Administration in its programs. We have sought to gain information from FDA officials so that the members of our profession may be alerted to the very dangers which you are exposing in your inquiry in this committee. We trust that the authority of this agency will be broadened to give the officials of the Food and Drug Administration the policing powers which may be needed to give protection to the public.

The committees of Congress likewise know of our strong position for an entirely professional approach to the problems of health and safety which properly concern our branch of the healing arts. We look forward to continued association with your committee in its constructive work.

Thank you, Mr. Chairman, for this opportunity to present the views of the American Chiropractic Association on this important subject.

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COUNTY OF LOS ANGELES,  
OFFICE OF THE DISTRICT ATTORNEY,  
*Los Angeles, Calif., March 9, 1964.*

HON. HARRISON A. WILLIAMS, Jr.,  
*U.S. Senator, Senate Office Building,  
Washington, D.C.:*

I am enclosing my promised statement on the need for a single agency in the medical executive arm to deal with the problems of medical quackery. I am sorry I can't be in Washington to deliver it in person.

Best personal regards.

Yours very truly,

JOHN W. MINER,  
*Deputy District Attorney, Chief Medicolegal Section.*

STATEMENT OF JOHN W. MINER, DEPUTY DISTRICT ATTORNEY, CHIEF MEDICO-LEGAL SECTION, OFFICE OF THE DISTRICT ATTORNEY, LOS ANGELES COUNTY, CALIF.

The needs to be fulfilled by a single agency in the Federal Government to deal with the problems of medical quackery are several:

#### IDENTIFICATION AND SCOPE OF THE PROBLEM

Nowhere nationally or locally does there exist any accurate evaluation of the total damage done by medical quackery in terms of economic loss or physical injury to the victims. The establishing of a central unit to which would flow reports from all interested agencies, public or private, national or local, would make it possible to measure for the first time this damage. That knowledge should and must be known to combat effectively the evils of quackery.

#### LOCATION

It is recommended that the central Federal agency be placed in the Office of the Surgeon General, U.S. Public Health Department, Department of Health, Education, and Welfare, with a specialist in legal medicine at its head, with the rank of Assistant Surgeon General or equivalent. The agency may be designated as the Bureau on Medical Quackery.

#### INVESTIGATION

From the data supplied, as above proposed, evaluation can be made to determine what Federal, State, county, or municipal agency would be the most appropriate one to conduct an investigation of a particular reported matter. In some instances, of course, the staff of the proposed Bureau itself might be the most effective agency to undertake such investigation. In any case, however, the Bureau would set up a file on a reported matter and follow up on all processes until it is resolved.

#### ENDORSEMENT

Where the Bureau's own investigative efforts establish that a form of medical quackery is violative of Federal law, the case will be prepared by the staff for presentation to the proper office of the U.S. Attorney General for prosecution. In other instances where the investigation has been made by another Federal agency, the Bureau will serve as a clearinghouse for channeling the case to the proper prosecuting authority, and for providing expert assistance in readying the matter for judicial and/or administrative proceedings.

#### EDUCATION

From its place as the central Federal agency on quackery, the Bureau would be able to provide information to the news media and to publish material, to inform and educate the public to the dangers of medical quackery. At present, this is done on a piecemeal basis without the compilation and coordination to make such educational activity as effective as it could be.

#### ASSISTANCE TO STATE AND LOCAL GOVERNMENT

It should be conceded that it lies within the province of local rather than Federal Government to deal with the bulk of medical quackery problems. For the most part, however, little is being done on the local level to prosecute or control a "billion-dollar racket" which unlawfully takes the lives of thousands. As one local prosecutor who has at least done something in this field, I believe I am qualified to say that local government would welcome having its attention called to a quackery situation within its jurisdiction, and receive gratefully any expert advice on how to deal with it.

#### LEGISLATIVE RECOMMENDATIONS

After gaining a unique body of knowledge about medical quackery, the Bureau would be in an excellent position to suggest remedial legislation to the Congress. Moreover, local government could seek the help of the Bureau in drafting legislation to meet the needs of the State.



## CONCLUSION

The foregoing outline briefly sets forth the reasons for the establishment of a central Federal agency on medical quackery. Considering that as a single field of criminal activity, medical quacks do more harm economically and to the health of the public than any other field of lawbreaking, it appears desirable that a constructive step be taken to solve the problem. It is respectfully submitted that the adoption of the proposal here made would be of great value to the American people.

