RHODE ISLAND MEDICAL JOURNAL

April 1990

Volume 73, Number 4



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Medical Quackery in Rhode Island

RHODE ISLAND MEDICAL JOURNAL



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Cover: A lithograph by Honoré Daumier published in *la* Caricature, October 30, 1842. The text below the drawing states: "The Hydropathic Doctor - "Today, two buckets will do . . . tomorrow you can bring four. - Ah, what a fine doctor! . . . One can't like water too much . . . (aside) I'm only afraid that it will end up by killing his taste for food forever! . . .

Rhode Island Medical Journal is owned and published by the Rhode Island Medical Society. 106 Francis Street, Providence, Rhode Island 02903, Ph: 401/331-3207. Single copies \$2.00 — Subscriptions \$20.00 per year (members of the Rhode Island Medical Society — \$5.00 annually). Published articles represent opinions of the authors and do not necessarily reflect the official policy of the Rhode Island Medical Society unless clearly specified. Advertisements do not imply sponsorship or endorsement by the Rhode Island Medical Society. Second class postage paid at Providence, Rhode Island and at additional mailing offices. ISSN 0363-7913 POSTMASTER: Send address changes to RHODE ISLAND MEDICAL JOURNAL, 106 Francis Street, Providence, RI 02903.

Combatting Medical Quackery: Health Professionals' Responsibility, A Symposium

In June of 1989, a group of regulators, educators, advocates and consumers convened a conference entitled Combatting Medical Quackery: Health Professionals' Responsibility. The sponsoring agencies included the United States Food and Drug Administration, the Rhode Island Medicine Education Committee. the Rhode Island Consumers' Council, Brown University, the Rhode Island Department of Health, the Rhode Island Pharmaceutical Association, the Rhode Island AFL/ClO, United Way, the United States Consumer Product Safety Commission, and the Rhode Island Department of Elderly Affairs. The one-day conference, held in the Ray Conference Center, Butler Hospital, had a stated goal to "provide information about questionable products and treatments, those agencies to which the provider can report suspect treatments, and most importantly, better communication methods between the health-care provider and healthcare consumer." Participants included representatives of the sponsoring organizations as well as the Rhode Island Attorney General's Office, a medical editor of a local television station, and a dietician.

This issue of the *Journal* features three papers selected from the conference proceedings. The papers clearly present the issue of medical quackery as a big business and mounting problem. Though occasionally so outlandish as to seem humorous, the medical harm to individuals makes this a very real issue calling for serious thought by practicing physicians.

As in so much of medicine, the physician must accept his or her role as an educator if we are to combat this problem. The introduction to the American Medical Association annotated bibliography on alternative therapies, unproven methods and health fraud¹ gives the following sound advice to the health-care provider when the patient discusses a questionable health pursuit:

- 1. Ask yourself why the person is telling you this story.
- 2. Hear the person out.
- 3. Watch your attitude.
- 4. Be careful what you say.
- 5. Turn your new insight into a person's motives to that person's advantage in helping them deal with health related anxieties.

It is our hope that these papers will inform and motivate the medical community to combat medical quackery.

Peter A. Hollmann, MD

New England's Patent Medicines

This issue of the *Journal* discusses medical quackery, particularly as it persists in Rhode Island. 'Quack' is a curious bit of jargon, defined usually as a pretender to medical skills and one who boasts of access to wondrous cures. Its origins are found in the sixteenth century Dutch word, *qwakzalver*, the German cognate, *Quacksalber*, and the English, *quacksalver*, all meaning a person who boasts [quacks] about the merits of his salves [ointments].

In usage, 'quacksalver' was quickly abbreviated to 'quack' as the noun describing a medical charlatan or mountebank. Charlatan carries a somewhat broader meaning suggesting more an unscrupulous salesperson, the word rooted in the Italian, *ciarlatano*, a babbler or prattler. The origins of mountebank are also found in the Italian, *montambanco*, an itinerant charlatan who mounts a bench when selling his wares.

As literacy advanced in nineteenth century New England, roadside leaflets and newspaper advertisements replaced the human voice as the persuasive medium for health care fraud. The current problems of medical guackery in Rhode Island are not, therefore, the itinerant charlatan or the individual mountebank dispensing snake oil from the back of a wagon. Rather, the danger lingers in the various advertising media which now hawk unproven, worthless, and even occasionally harmful, health care products.

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Sullivan-Fowler M, Austin T, Wiltafner A: Alternative Therapies, Unproven Methods and Health Fraud: A Selected Annotated Bibliography. AMA Division of Library & Information Management 1988;2.

New England has contributed materially to the lore of medical quackery. During the nineteenth century some of the leading purveyors of worthless medications started their operations in this region. Neither the content nor the claims of their patent medicines were subject to any external regulation. Their 'active' ingredients were often extracts of celery, sarsaparilla or coca leaves. Virtually all contained substantial concentrations of ethyl alcohol explained as a necessary solvent for the vegetable extracts and as a means of preventing the medication from freezing in the winter. Few of these original nineteenth century compounds have survived but their memory still persists in carbonated drinks containing celery tonic, sarsaparilla and the colas.

Sarsaparilla (Aralia nudicau*lis*) was introduced during the early years of the last century as a "natural remedy" for the undefined ills and sluggishness experienced during early springtime. It was advocated as a tonic to counteract fatigue, to purify the blood and to cure numerous chronic ailments and infections. In 1841, James C. Ayer, a newly graduated physician, purchased a small pharmacy in Lowell, Massachusetts and invested his energies and funds in a line of home remedies. The Avers' Extract of Sarsaparilla became the most famous and profitable product of his pharmaceutical factory, at its peak manufacturing in excess of 600,000 doses daily. The formula, according to its label, contained the following substances in a fluid base of 21 percent ethyl alcohol:

fluid extract of sarsaparilla 3 oz fluid extract of stillingia 3 oz fluid extract of of yellow

dock	3	ΟZ
fluid extract of May apple	3	ΟZ
sugar	1	OZ

potassium iodide90 gr. ferric iodide10 gr.

Aver's entrepreneurial and managerial talents were legendary and his enterprises prospered. He became one of Lowell's most respected and wealthy citizens. Upon his death, the nearby Massachusetts town of Aver was renamed in his honor. Despite these successes, none of the botanical compounds used in the various sarsaparilla formulations have ever been found to have any therapeutic value except for those competitor celery tonics containing the cathartics, cascara and senna.

No historic or mythologic evidence exists to suggest that extracts of celery contain agents which strengthen the brain and nerves. Wells and Richardson, Civil War veterans whose business zeal brought them to the wholesale drug business, nevertheless began to manufacture a celery compound, the formula for which they had purchased from a Vermont widow named Mrs. Paine. Through the genius of advertising [particularly in free pamphlets distributed in New England drug-stores their Paine's Celery Compound emerged as one of the leading proprietaries for "nervous diseases" in the United States. The compound contained 21 percent ethyl alcohol as well as some celery tonic, hops and coca. The manufacturers were particularly proud of the coca content and proclaimed that this was the very same product which South American Indians chewed to provide them with unusual strength and a means of forgetting their misfortunes.

In 1843 a young school teacher in Lynn, Massachusetts, Lydia Estes, married Isaac Pinkham. She resigned her teaching position, leaving to her husband the duties of supporting the family. In one

of his many failed business ventures, he was left with a vegetable-based remedy described as a cure for the ailments of females. His wife Lydia assumed responsibility for the formula, modified it somewhat in her kitchen and dispensed it periodically, without fee, to family and neighbors. Its commerical utility was not appreciated for years, but when finally Lydia E. Pinkham's Vegetable Compound was marketed, now fortified by 18 percent alcohol, its sales brought it to the forefront of patent medicines. Through creative advertising the compound found a ready and eager market throughout the United States and in virtually every country accessible to commercial shipping. This herbal compound used for a spectrum of "female complaints" became a household necessity in millions of homes and a symbol of reliant self-help in a culture which regarded organized medicine with much skepticism. Lydia Pinkham died at age 62 but her patent medicine lived on for many more decades and her name became synonymous with Mother Nature's bountiful health aids.

By the onset of this century, America was witness to increasing numbers of fraudulent and occasionally harmful products flooding its unregulated marketplace. Many were laced with various opiate and coca-leaf alkaloids and alcohol was the nearuniversal diluent. The names of these proprietaries remain in faded barnside advertisements, attic magazines and history texts, names such as swamp-root compound, Kickapoo Sagwa [first sold in Providence, RI], Pitcher's Castoria, little liver pills, Warner's Kidney Cure, Hadacol, Katonka, and the various Universal Balms. Congressional investigation of the patent medicine industry, during the first decade of this century saw Rhode Island's Senator Nelson

Aldrich resolutely opposing the enactment of the Federal Pure Food and Drug Act, while the American Medical Association, and its membership of 135,000 physicians, urgently demanded its passage. The AMA position prevailed and the bill was signed into law by President Theodore Roosevelt in 1906.

The many recent advances achieved by medicine cannot hide our residual inabilities, particularly in curing chronic ailments of the elderly. Human credulity and these therapeutic limitations become the two fertile substrates for those who seek quick miracles and for those who would exploit such persons.

Stanley M. Aronson, MD

Response to Editor's Mailbox: RIMJ, March, 1990 Re: Detoxification of the Chemically Dependent Patient

l greatly appreciate your kind comments on my paper on detoxification of the chemically dependent patient, and I would like to comment on your concerns about the lack of facilities for detoxification of indigent patients. A very substantial number of patients presenting for detoxification to Emergency Departments do not require medical detoxification, and could be managed in a social-setting detoxification program. It is clear that there is a need for increased beds at this facility, and probably the creation of similar facilities in other parts of the state. Such social-setting programs can be operated at substantial savings over medical facilities, and can provide safe and effective services for patients, including referral to rehabilitation programs. I support your efforts to alert public officials to this need. Many of us who work in the field of chemical dependency have repeatedly communicated this point to the same officials.

I am concerned, however, at the concept that indigent patients with a need for medical detoxification should be referred to some other facility as a matter of course. I know of no other medical condition where the patient's level of insurance coverage should dictate whether they are admitted to a hospital when they present to an emergency department. As the internist in charge of admission to a hospital-based detoxification and early treatment program, I frequently communicate with area Emergency Service physicians. I have been involved in cases where patients who are intoxicated and have medical or psychiatric problems which might render detoxification dangerous or even lethal are sent out of Emergency Rooms without treatment, because my facility did not have an available bed, and the State facilities were, as usual, fully occupied.

I do not understand why alcoholic and other chemically dependent patients should be refused care, and why hospitals do not accept the responsibility of providing that care. There are no longer leprosaria and tuberculosis sanitaria, but there still appears to be a need for similar outof-the-way places in which to hide our chemically dependent. The care needed by these patients is neither so specialized nor complicated as to require such referral, except in extraordinary cases. The underlying problem is the negative attitudes so often prevalent in health professionals towards these patients, and the lack of training and knowledge base in the addictions in medical and

nursing schools. That negative stereotypes are often reality-based, that many of these patients can be difficult and disagreeable, does not justify the abrogation of our professional responsibilities towards them.

l do agree that additional facilities for both social setting and medical detoxification are needed. I would like to see our hospitals recognize their own responsibility in this area, and help train their staff in the management of the chemically dependent, so that attitudes, skills and behaviors can be altered to provide improved care. There is a drug epidemic (which includes alcohol) in America. It will not be solved by a fortress mentality in which the victims of the epidemic are relegated to the modern equivalent of Bedlam. The "notin-my-backyard" (NIMBY) mentality extends to hospitals as well as to neighborhoods.

Alan A. Wartenberg, MD, FACP Coordinator of Medical Services Substance Abuse Treatment Center

Assistant Professor of Medicine Brown University



Combatting Medical Quackery: A Message to the Physicians of Rhode Island

H. Denman Scott, MD, MPH

It takes an effort of will to recognize that medical quackery today is big business ...

As Director of the Rhode Island Department of Health, I am grateful to the *Journal* for the opportunity to share my views concerning a significant health issue, medical quackery.

As you might expect, I view the problem from a double perspective: that of the clinician and that as the Director of Health for the state. The issues are essentially the same from either view, but not necessarily the conclusions, especially about the responsibility of health professionals in controlling these abuses. At the heart of this distinction is the classical question: To what extent are the broader social goals of medicine the responsibility of individual physicians in their daily practice? l hope that my comments will serve to encourage you to adopt the conviction that practicing physicians have, indeed, both the opportunity and the responsibility to combat medical quackery.

The View From Private Practice

From the beginnings of organized society, in all known cultures, there has been an impulse to seek the help of "healers" to cure ill-

H. Denman Scott, MD, MPH, is Director of the Department of Health of the State of Rhode Island, Providence, Rhode Island. ness, repair injury, control pain, enhance beauty, assure fertility, delay death. In some cultures the healer has adopted the attributes of priest; in others, magician; in still others, wise student of nature and the body. But the impulse to seek help has been constant and remains with us still. Some of the older attitudes towards the physician as "healer" persist today coexisting with the more evolved perceptions of the health profession.

During the last two hundred years, however, tremendous advances have been made in scientific medicine, greatly enhancing our diagnostic and therapeutic skills. Equally significant, the rise of scientific medicine and experimental design has enabled us to distinguish between therapies which work and those which do not. And while this new ability has now allowed us to define the unsafe, the ineffective, and the fraudulent, it has certainly not eliminated medical guackery. Indeed, the public continues to patronize quacks as an alternative to modern medicine, and sometimes to patronize both quackery and scientific medicine simultaneously in seeking treatment for the same ills.

Physicians are taught that their first obligation to the patient is to "do no harm." This is a sound precept. It is also a conservative one. But do not physicians and other health professionals also have an obligation, when they see their patients pursuing a harmful course of self-treatment, to advise them to desist? In theory I think we would all agree, but in practice many of us do not. Why do we hesitate to intervene? And why, so often, do we avoid the pro-active role? If quackery persists, is it not with the tacit complicity of physicians, nurses and pharmacists? We must understand the basis for this complicity if we are to alter our approach.

Partly, I think, we are prisoners of a semantic heritage. The very term which we use for this medical abuse — quackery — has a vaguely comic sound, due perhaps to some subliminal association with the antics of Donald Duck. There is, thus, a tendency for us to underrate its seriousness. Yet quackery is a very serious business indeed with tremendous health and monetary implications for society.

The Oxford Dictionary defines a quack as: "An ignorant pretender to skill, especially in medicine; a charlatan." Many of us still define quackery as the pretensions of a misguided individ-

Abbreviations Used: FDA: US Food and Drug Administration ual who believes in his unique powers or nostrums, or alternatively, the cynical entrepreneur selling snake oil from the back of a medicine-show wagon. It takes an effort of will to recognize that today's quackery is big business, the commercial exploitation of human frailties, wishful thinking, gullibility, hope, and despair. There is a great deal of money to be made from the countless human dramas of failed expectation, and not a few corporate empires are based on the heartless pursuit of profits from this source. Useless and even dangerous products have superceded "ignorant pretenders to skill" as the largest part of the problem.

Then, too, health professionals have an understandable reluctance to interfere in the private lives of their patients if they believe that the patient will resent such interference. Physicians are wary of seeming to condemn a competing source of care, for fear of drawing the charge that they are only trying to maintain a profitable monopoly.

At the height of the McCarthy era, one of the characters in Walt Kelley's *Pogo* says, in resisting the officious efforts of government to "protect" him, that in a democracy the people have a "right to make damn fools of themselves." We are all, physicians and patients alike, the captives of this democratic ethos.

Physicians are wary of seeming to condemn a competing source of care, for fear of drawing the charge that they are only trying to maintain a profitable monopoly.

There are doubtless instances in which the practitioner says, in effect, if it makes patients happier to try unorthodox therapies, why not let them do so as long as they aren't clearly injurious? We are a nation given to health fads: diets, folk remedies, exercise programs, pills. Since it is not always clear initially whether a fad is helpful or harmful, the medical practitioner customarily withholds comment.

The View From a State Health Agency

Public health agencies exist to deal with those societal problems which cannot be addressed effectively or assertively by individual health professionals. Food and drug legislation, at both the federal and state level, comes under this heading.

The US Food and Drug Administration (FDA) has a national mandate to assure the safety and efficacy of prescription drugs. The Rhode Island Department of Health has a legal mandate (Chapter 31 of the Rhode Island General Laws) to prevent the sale of food, drugs, medical devices or cosmetics which are adulterated or misbranded. The existence of public authorities with mandates in these areas does not relieve individual health professionals of *their* responsibilities. Indeed, without the active support of individual medical practitioners, public authorities are hampered in fulfilling their assigned mission.

We have established a very successful program in Rhode Island which encourages physicians to report adverse drug reactions to the FDA. This program was initiated, with federal funding, because physician cooperation is essential to a continuing community monitoring of approved drugs. Yet there is irony in a situation whereby physicians report adverse reactions to medications which they have prescribed but they remain silent in the face of widespread use of quack therapies by patients under their personal care.

The Rhode Island Department of Health has a legal mandate . . . to prevent the sale of food, drugs, medical devices or cosmetics which are adulterated or misbranded.

Let me share with you some examples of quack products which have been marketed in Rhode Island over the past few years:

- So-called "natural will power" weight-loss systems using bran pills and starch blockers.
- Unapproved drugs such as Laetrile promoted as cancer cures.
- Vitamin combinations promoted as hair restoratives.
- So-called oral tanning tablets, also known as sun tan pills.
- Products labelled as steroids, but not really drugs of the steroid/anabolic class, sold in connection with muscle/building programs.
- A variety of unproven products promising relief for arthritis pain.
- Products promoted as wrinkle removers, bust developers, or sexual aids.
- Dermal patches guaranteed to cause weight loss.

Why should physicians be concerned about these products, especially those which are directed toward vanity objectives of the consumer? Do they really constitute a health problem? The answer is assuredly yes.

We are concerned about the safety of any drug or device which is promoted for health purposes. We are probably more concerned with over-the-counter and mailorder products than prescription drugs because so little is really known about many of them, particularly their chemical composition, effects of long-term use or high dosage, and potential for adverse interaction with other drugs.

... physicians report adverse reactions to medications which they have prescribed but they remain silent in the face of widespread use of quack therapies ...

We are concerned about any unorthodox product, device or therapy for serious illness which might delay a patient's seeking medical care or using proven therapies.

We are concerned about false claims made for health products, even when relatively harmless, because fraud should have no place in the health industry.

Under Chapter 31 of the General Laws, Rhode Island Food, Drug and Cosmetic Act, the Department of Health is empowered to identify and embargo:

- poisonous or deleterious substances,
- adulterated drugs or devices,
- misbranded drugs or devices, including those labelled in a false or misleading manner, and
- new drugs not yet determined to be safe and effective.

Embargoed products may not be sold pending a court hearing. If the court finds that the embargoed products are in violation of the law they are destroyed. The Department enforces these provisions on a continuing basis, usually in cooperation with the US Marshall's Office and the FDA, Division of Drug Control.

There are limits to the reach of our authority. For example, the State cannot control misleading advertising which enters the state in publications or over cable TV; furthermore, the enforcement capabilities of the State is limited by the small staff assigned to this function. A very significant limitation is the Department's inability to provide direct counselling to individuals in their personal health strategies. This is true not only of quack products and therapies, but also of unorthodox therapies which are not inherently dangerous or useless, but may be wrong for them. These are areas where the involvement of the individual health professional becomes essential.

It is my hope that a realization of the responsibility of Rhode Island health professionals in combatting medical quackery will lead to their increased commitment to: (1) better control of dangerous and useless products, and (2) more aggressive counselling of their patients concerning nonprescribed remedies. The Rhode Island Department of Health stands ready to participate actively in a strong community effort directed towards these ends.

Address correspondence to: H. Denman Scott, MD Director RI Department of Health 75 Dans Street Providence, RI 02908

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Medical Quackery in Rhode Island: The Perspective of State and Federal Drug Control Agencies

Paula B. Fairfield Charles Hachadorian, Jr, MPA, RPh

... it was a quack cancer treatment which led Congress to enact the first federal law against false claims for drugs.

Health fraud or medical quackery is the promotion, for profit, of medical remedies known to be false or unproven. This is usually accomplished by falsely representing certain products, goods, or alleging them to be of aid in the cure of various diseases. Quackery has existed throughout history.

Today, few people remember that it was a quack cancer treatment which led Congress to enact the first federal law against false claims for drugs. The congressional intention was that the 1906 Pure Food and Drug Act would do away with the thousands of useless and dangerous patent medicines on the market, but health fraud has remained alive and well. Present estimates say that be-

Paula B. Fairfield is with the Federal Food and Drug Administration Regional Office, Consumer Affairs Office, Stoneham, MA.

Charles Hachadorian, Jr, MPA, RPh, is Drug Control Administrator with the Rhode Island Department of Health, Division of Drug Control, Providence, Rhode Island. tween 10 and 40 billion dollars a year are being spent on bogus products. Remedies are still being advertised which make all sorts of promises, but fail to work. Those who invest their hardearned money in these worthless products at the very least will experience both helpless anger and frustration.

Most consumers are not in a position to take legal action against promoters of health fraud, or even to know what action can be undertaken to protect themselves. Health fraud is just as prevalent today as yesterday, and because litigation is significantly more expensive, public impotence continues to be a major problem. Therefore, Federal and State programs must focus attention on this issue. The volume of this and other problems in their jurisdiction necessitates a priority classification system. Priority classes in descending order are:

1. Direct Health Hazard — These are products that can harm the user's health, or even cause death. Whatever actions are necessary to remove these products from the market have top priority.

2. Indirect Health Hazard — These are ineffective products which, while not causing the user any direct harm, may delay or even replace proper medical care at a time when it is needed.

3. *Economic Fraud* — These products are either useless or useful products labelled with additional unsupported claims. They pose little or no health risk but cheat consumers out of dollars spent futilely.

The FDA's Boston District Health Fraud Survey

One initiative by the local office of the FDA has been to search regional and national publications in order to monitor health fraud, comparing local products to those promoted elsewhere and to note changes in the nature of fraudulent claims. This search has been ongoing for three years.

Promotions for body-building products or devices and anti-aging agents rose notably during the survey period. Numerous products were identified through the search and removed from the

Abbreviations Used: AIDS: acquired immune deficiency syndrome DMSO: dimethyl sulfoxide FDA: Food and Drug Administration GH3 rejuvenators: anti-aging products market or seized. An area receiving priority is the removal of unproven immune booster products aimed at AlDS victims. Two Connecticut firms were referred to the Postal Inspection Service and are now out of business. One firm was selling Big Bosom Tablets and the other a product to dissolve varicose veins. Inspection by the FDA found the companies to be one and the same.

One of the district office's activities is to send letters to local publishers of newspapers when an advertisement for a fraudulent product has been found. The letter requests that the publisher not print advertisements for such products, thereby doing his readers a public service. It also offers the services of the Consumer Affairs Office of the FDA in reviewing ads. Response has been varied. One publisher called and said that he is in business to make money and if the FDA felt the products were frauds, why didn't the FDA take out an advertisement saying so. Several publishers called saying they did not realize the products were frauds and would be more careful in the future. Others made no response.

The Boston District Office plans to continue its annual literature survey in order to identify the everchanging profile of health fraud in New England, to use the information compiled during the survey to respond to inquiries about new product promotions, and to select targets for appropriate regulatory and administrative followup.

Rhode Island Drug Control

The Division of Drug Control, within the Rhode Island Department of Health, is responsible for the enforcement of the Food, Drug and Cosmetic Act. Marketing of products in the United States requires Food and Drug Administration approval at the federal level, and marketing within Rhode Island requires the approval of the Director of Health. The Division represents the Director in matters of safety and effectiveness of new drugs, and for those currently in commerce. The Director is also responsible for post-marketing drug surveillance, and for matters of drug product selection and generic equivalence. It is the responsibility of the Director to protect the people of the State from products that are deceptively labelled, that are fraudulent, that are misbranded or adulterated, or falsely claim to prevent or treat diseases, or otherwise effect structures or functions of the human body. For these regulatory purposes then, these products are considered to be drugs, cosmetics or devices.

The Director of Health, state of Rhode Island, is ... responsible for post-marketing drug surveillance, and for matters of drug product selection and generic equivalence.

One of the most widely publicized cases in Rhode Island history involved the importation of Amygdalin, as Laetrile, into Rhode Island. Attention was gained because legislation was introduced which would have exempted this product from the Rhode Island Food, Drugs and Cosmetic Act, and therefore from enforcement by the State Division of Drug Control. Control under the Federal statutes would have been effective but the issue became one of convincing State legislators that the regulatory process for safe and effective drugs was necessary to protect the public health.

Agents of the Division of Drug Control have embargoed and/or seized vitamin B-15, ginseng, socalled natural steroids, DMSO, as well as other products used in muscle-building and increasing weight gain and body density. These products are widely sold in health food stores throughout the state.

Vitamin B-15, or Pangamic Acid, has been the subject of FDA action for many years.¹ There have been Food and Drug Administration import alerts because there is no vitamin recognized as vitamin B-15. It is being promoted as safe and effective for use in the cure, mitigation and/or treatment of a variety of diseases, including heart disease, peripheral vascular disease, diabetes, cancer, liver disease, asthma, emphysema, and alcoholism. The Division of Drug Control embargoed these products as being misbranded. It should be noted that Ernest Krebs, Jr, the originator of vitamin B-15, was also the originator of Laetrile. Despite the fact that it has been declared nutritionally useless, and that the United States government has stated that it is illegal, worthless, and possibly unsafe, it is still widely promoted in health food stores in Rhode Island.

Agents of the Division of Drug Control have embargoed and/or seized vitamin B-15, ginseng, so-called natural steroids, DMSO, as well as other products used in muscle-building and increasing weight gain and body density.

Dimethyl sulfoxide, or DMSO, presents a special problem. It is approved by the Food and Drug Administration for interstitial cystitis, with proper warnings concerning cataract formation. When DMSO is sold in hardware stores as an industrial solvent, there are no problems with misbranding or mislabelling. If however, physicians, pharmacists, or others recommend or vend the product for indications for which it is not legally approved, it is subject to the same embargo as any other misbranded drug.

The desire to lose weight, grow hair, and be free from wrinkles is all part of the "Fountain of Youth Syndrome." Many of the legitimate department store chains that are nationwide, will advertise wrinkle creams using a pharmacist or other health professional as a spokesperson.² However, the spokesperson may not necessarily be expert in the biology or pharmacology of the conditions and treatments at issue. Knowledge in one area is often capitalized upon in a promotional effort for a product in an unrelated field.

During 1987 and 1988, tanning salons in the State of Rhode Island offered skin patches for diet control. Millions of dollars worth of so-called "Diet Patches" were seized as the newest weight-loss gimmick. Tanning salons were visited by agents of the Division of Drug Control, and the product was embargoed. On June 24, 1988, the Division of Drug Control assisted the Nutrition Service with a press release warning Rhode Islanders that diet patches now being marketed in the state did not have approval by the Federal Food and Drug Administration. The press release went on to say that these patches mimic legitimate prescription transdermal patches used to deliver drugs to the skin for such conditions as motion sickness. "No non-prescription patch delivering drugs or other substances through the skin has been approved by the FDA."3

With the spread of the AIDS virus, there arises another class of desperate individuals seeking cures who may fall for fraudulent remedies. These remedies now include the processed algae, injections of hydrogen peroxide, food preservatives, and herbal capsules that were found to contain chlorine bleach solution as a wash, and injections of processed by-products of the patient's own urine.⁴

It is understandable that patients suffering from terminal diseases such as AIDS might look to macrobiotic diets, massive doses of vitamin C, body cooling with deionized water, ozone therapy, or all the other scams currently being perpetrated. However, the relatively small AIDS population could not account for the billions of dollars spent on quack products. The teas, starch-blockers, the body wraps, the hair growers, the vouth cures, the GH3 rejuvenators, the liquid protein diets, and all the rest, depend upon for their existence, the convincing of a large audience to buy. It is the duty of all health professionals to report these frauds, and to assist

the appropriate agencies in vigorous prosecution. This is done without preventing the study of new, albeit unconventional, therapies. It is done to protect the public health.

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Quackery and the Elderly

Peter A. Hollmann, MD

Whether or not older persons are more likely to fall victim to quackery, it seems certain that they are more likely to be harmed by quackery.

Elderly persons are often viewed as being at special risk for various fraudulent schemes. Not only are they more easily victimized, but they are more severely harmed when so victimized. Statistics concerning medical quackery exploiting this age group are cause for legitimate alarm. Estimates indicate that while the elderly comprise but 12 percent of the population, they now represent almost 40 percent of the healthfraud victims.1 Lest such a conclusion be regarded as an inherently ageist characterization, we are obliged to assess more critically this vulnerability of the aged to health-care fraudulence.

It must be appreciated that 'the elderly' is a term which describes a widely varied population. Indeed, one of the hallmarks of aging is the acquisition of diverse biological, behavioral and social traits. It is equally true that older individuals are members of a greater society, and are not isolated from the trends of their era. However, in considering risks, it is not inappropriate to make gen-

Peter A. Hollmann, MD, is Medical Director at Zambarano Memorial Hospital, Wallum Lake, Rhode Island and a member of the Department of Medicine, Brown University, Providence, Rhode Island. eralizations about groups, understanding the limitations of this in consideration of the individual.

Quackery has been with our society always. This has been the case despite significant increases in the average person's understanding of medical science and dramatic changes in that science itself. While there is little empiric data as to why individuals seek care from fraudulent providers, several motivating or facilitating factors have been suggested.

Motivating Factors

First, there is the perceived benefit. The tendency to embrace unproven therapies is stronger when the affliction is incurable or lifethreatening. Therefore, diseases such as the Acquired Immune Deficiency Syndrome or Alzheimer's Disease are more likely foci of a product's promotional strategy. Other chronic conditions such as arthritis are also good targets. Furthermore, diseases with naturally occurring remissions, such as the chronic musculoskeletal afflictions or multiple sclerosis, are particularly susceptible to a placebo effect. A second important factor is a willingness to consider alternative therapies. This could stem from a cynical skepticism of traditional medicine, gullibility, or merely a genuine open-mindedness. The quack seeks business from diverse groups and alters his sales pitch to appeal to selected audiences that are willing to listen. Both the individual seeking a miraculous cure from a potent healer or the educated, prevention-minded partner in health care seeking to take control of his or her body, are potential targets for the quack.

Age has the potential to alter selected risk factors for quackery. It remains debatable as to how much physiological decline is due to normal aging, but it is not controversial that the aged are more likely to have disease and functional impairment than their vounger counterparts. Four of every five community-based persons over 65 years of age have at least one chronic disability. For example, 46 percent of the elderly have arthritis and 28 percent have a hearing impairment. Arthritis, hearing impairments, hypertension, and heart conditions, together account for approximately 60 percent of all chronic disease in this senior population. In each case, the prevalence of these conditions is at least fivefold greater than that of an under 45-year-old

Abbreviations Used: OTC: Over the counter (medications) cohort.² More than 50 percent of the cancers occur in the elderly and 5 percent suffer from severe dementia. Forty-four percent of those over 85-years-old require personal care assistance. The great majority of illness in the aged, indeed, is chronic.

Four of every five community-based persons over 65 years of age have at least one chronic disability. For example, 46 percent of the elderly have arthritis and 28 per cent have a hearing impairment.

Older persons use health services at a greater frequency than their younger counterparts. They account for 39 percent of all acute hospital days and 30 percent of the prescription drug use. Despite this, knowledge of illness reporting and steps taken for health problems suggest this high use represents a surprisingly uncommon option of the elder person when faced with an illness. Nearly 90 percent of individuals interviewed in one survey had experienced symptoms of illness in the previous month, but nevertheless continued to report their health in positive terms.³

Individuals over 75 years, while acknowledging more disability than the 65-74 year old group, tend to describe their health as better.³ Self perception of health is also related to the extent to which health services are employed.

Young and old tend not to consult a physician for the great majority of their health complaints. The behavior of the elderly is of interest, however, in terms of their likelihood to expose themselves to unorthodox or improper care. When a *defined* health problem arises, the elderly will seek the advice of a physician approximately 10 percent of the time. They will use a home remedy with equal frequency. This is distinct from the use of a nonprescription drug which is depended upon one-third of the time. Roughly 15 percent of the time a prescription that is at hand is used and in onethird of instances, the symptoms are not treated at all.⁴

The elderly consume approximately one-third of the nation's health resources, be they traditional or unproven remedies. Therefore, it could be argued that the elderly are no more or less susceptible to quackery than they are to scientific medicine. This supports the hypothesis that medical need, more than an age related propensity to be victimized, contributes to the probability that help will be sought from a quack. It is apparent that the use of home remedies or nonprescription remedies is a very common behavior in response to illness. It also is the case that traditional and unorthodox therapies are used concurrently.

While over-the-counter (OTC) drugs would not properly be considered products of quackery, understanding their use sheds light upon the problem of quackery. The advertising claims of OTC drugs have bordered on quackery at times and, upon occasion, have crossed over that border prompting governmental intervention.

A perusal of the shelves of a 1990s corner drug store will reveal a wealth of "Maximum Strength," "Special Formula" products that promise fast relief, at least in most cases. They will cool or warm deeply or do both at once. Energy will be restored and appetites controlled. "United States Medical Expert Advisory Panels" vouch for safety and efficacy. While physicians may not be impressed with the maximum power of a 500mg tablet as compared to a 325mg tablet or by that special formulation of caffeine or acetaminophen, it is very tough to argue with the sage advice on the box of one product. It reminds hard-drinking, fad-dieting, chainsmoking, physically-stressed persons that a good diet, preferably reinforced by the particular vitamin contained inside the package, is important.

While the government and manufacturers have gone to considerable lengths to provide for safety warnings and instructions on proper usage, a study of respondents over age 65 years found that the surveyed individuals could not or did not read the reguired labels on OTC drugs.⁴ The most common source of information about OTC drugs was their advertising claims. It was the source depended upon twice as frequently as the interpretation offered by the pharmacist. Advice from friends, relatives, or neighbors was the second most common source of information.⁴ Of course, the source of information varies according to the nature and magnitude of the health problem. For example, a physician's advice is often sought for arthritis products, but much less likely for bowel regularity remedies.⁵

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Numerous other issues may be pertinent in comparing the elderly to the young in terms of vulnerability to quackery. Older people are more likely to accept the authority of physicians than are the young. Does this make them more readily the passive victim of a quack or less cynical about traditional medicine and therefore less likely to seek alternative therapies? Older individuals tend to have good health-promoting behaviors. Does this make them less likely to rely upon a pill or tonic or more likely to stay healthy by taking prevention-oriented, "natural" health products? Here, there may be an impact based upon the number of hours exposed to media with less expensive advertising costs where advertisements for fraudulent products would customarily be placed, magazines or radio advertisements, as compared to television. Lessened mobility may also affect the probability of the patient's use of mailorder products.

The elderly's integrity as bill payers probably make them a more appealing target. The experience of witnessing sixty years of medical miracles may make patently ludicrous claims seem plausible to the elderly who may also have fewer numbers of years of formal education. However, the significance of these generational differences is neither known nor intuitive.

Whether or not older persons are more likely to fall victim to quackery, it seems certain that they are more likely to be harmed by quackery. The high incidence of serious, adverse drug reactions and the correlation of this incidence with age, puts the elderly at greater risk from the direct negative effects of fraudulent treatments. The higher prevalence of serious, but treatable disease in the elderly places them at greater risk of being victimized by the indirect negative effect of delayed or missed proper diagnosis and treatment.

The Role of the Physician

Physicians play a major role in combatting quackery. The manner in which a geriatric patient is treated is significant in this regard. Principles of good geriatric medical care apply. The physician who responds to health con-

cerns with "What do you expect for your age?" or "There's nothing that we can do for you," invites the patient to seek alternative therapies. Expressions of concern, understanding, and a willingness to help the patient cope with chronic disease respects and serves to meet the medical and psychological needs of the elderly patient. Explanations need to be made in a manner consistent with the sensory and cognitive abilities of the patient and may need to involve caregivers. Other health care team members may be needed to provide care and support. Referral to such individuals is more appropriate than leaving the patient to shop within the health care marketplace. It is also useful to ask patients about their use of unproven remedies.

The physician who responds to health concerns (of the elderly) with, "What do you expect for your age?" or, "There's nothing that we can do for you" invites the patient to seek alternate therapies.

Health care quackery is an important issue in geriatric care. The cumulative burden of disease, the tendency to self-treat, and the high risk of adverse reactions makes quackery of special concern for the doctor who provides care for the older patient.

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Address correspondence to: Medical Director Zambarano Memorial Hospital Wallum Lake, RI 02884 (401)568-2551

