# New York State Journal of Medicine

VOL 93
NO 2
FEBRUARY
1993

## HEALTH FRAUD

# New York State Journal of Medicine



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SUBSCRIPTION INFORMATION. The annual subscription for members ($30.00) is included in the annual membership dues. The subscription rate to nonmembers in the United States and Canada is $40.00 ($45.00 for all other countries). The single copy rate is $6.00 Domestic/Canada, and $7.00 Foreign, except for special issues. This includes postage. Change of address requests should give both the old and new address and allow six weeks for changeover.

The address for EDITORIAL, CIRCULATION, and ADVERTISING OFFICES is PO Box 5404, Lake Success, New York 11042. Telephone: (516) 488-6100.

POSTAGE. Second class postage is paid at New Hyde Park, New York, and additional mailing office. POSTMASTER: Send POD Form 3579 to New York State Journal of Medicine, PO Box 5404, Lake Success, New York 11042.

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*COMMENTARIES*

# Wolves in sheep's clothing

How do you spot a wolf in sheep's clothing? The wolves are always out there, but the information in this issue of the *Journal* will help physicians and other health care providers make consumers more alert to them. In Maslov's hierarchy of needs, basic human survival is our primary motivation.[1] Good health is close to man's most important need. "Wolves," both fraudulent and just plain wishful thinkers, take advantage of people's intense desires, causing them to grasp at straws and listen to empty promises. The public is fleeced $30 billion annually by the wolves of health fraud.

The New York State Health Fraud Advisory Council was pleased to assist in the preparation of this thematic issue of the *Journal*. The authors are all experts in their fields and provide a wealth of practical information. James Harvey Young in his excellent historical review of quackery shows that, "America may still be a paradise of quacks." The paper by Lerner discusses the physician's role in promoting scientific treatment of cancer. He concludes that "encouraging scientific medicine and discouraging questionable treatments is tantamount to practicing sensitive, caring, quality medicine."

Jarvis's paper, "Allergy-Related Quackery," portrays allergy quacks as both victims and victimizers. He states that "Practitioners who hold misbeliefs about allergies and do not use proper scientific methods can easily be fooled by a combination of their expectations and their patient's responses."

In Strosberg's paper, "Reflections on the Use of Unproved Remedies," physicians are challenged to review any alternative treatment with the patient including possible harmful effects. Concurrently, it is an opportune time to educate the patient as to the unproven claims of the treatment. Strosberg appropriately concludes "although unproven remedies will always be available, there is much we as physicians can do to protect our patients."

Sufferers from diseases such as the acquired immunodeficiency syndrome (AIDS), arthritis, and cancer, for which there may be no known cures, are particularly vulnerable to fraud. In addition, the Food and Drug Administration has also identified the following most common forms of health fraud: instant weight loss schemes, fraudulent sexual aids, false nutritional schemes, baldness remedies, and other appearance modifiers. Health fraud includes worthless products and services acclaimed by those promising miracle cures they cannot deliver. Myths and magical nostrums are available from adolescence to seniority. Statistics indicate that 50 million Americans will go on a diet this year; however, only five percent will be successful.[2] In spite of advanced scientific and medical technology, all claims to effortlessly lose weight are false. Yet billions of dollars are spent on diet programs annually. Before the past decade, self-styled "experts" best exemplified by the late Adele Davis were the major source of nutrition advice. Today, scientific and sensible approaches to nutrition are available from licensed or registered dieticians. Physicians should guide their patients to these credentialed professionals rather than to someone claiming to be a "nutritionist." In the Great American Medicine Show, Elizabeth Armstrong concludes "Despite government and professional regulation, you will continue to see Americans seeking out alternative therapies, especially ones that offer hope where traditional medicine has failed."[3] Folklore tradition may predispose someone to be anti-scientific. However, physicians should be sensitive to cultural influences, which should not be confused with fraud. For example, in the May 1992 issue of the *Journal*, Rosner describes a *segulah* or nostrum which has a place in traditional Jewish practice alongside scientific medicine.[4]

Today's sensitive and caring physician is supported by the many organizations, both public and voluntary which comprise the New York State Health Fraud Advisory Council. It is the mission of the Council to inform and educate the public about health fraud, to work with appropriate public and volunteer agencies to eliminate the promotion of health fraud and to support and encourage a New York State legislative program to combat health fraud. Established in 1990, the Council's major efforts have been directed towards education. A resource directory is available. A complete listing of council members and other sources of health fraud

activity can be found elsewhere in this issue of the *Journal*. Specific questions of health fraud can be directed to the appropriate organization, one of the consumer groups, or to the New York State Department of Health.

In his proclamation for Health Education Week in 1991, Governor Mario M. Cuomo noted: "The best protection against health fraud is for people to become well informed and skeptical consumers. They must learn to evaluate health claims, to recognize the advertising and labeling ploys that are tip-offs to health fraud, and to report cases of health fraud to the appropriate governmental agencies and business associations." Health care professionals are in a unique position to help in this education process. They need to know nine ways to spot a quack:[5]

- The quack promises quick, dramatic, miraculous cures.
- The quack uses imprecise, non-medical language in his claim.
- The quack uses anecdotes and testimonials to support his claims.
- The quack recommends a wide variety of substances similar to those found in your body.
- The quack recommends that everybody take vitamins or health foods or both.
- The quack's credentials aren't recognized by the scientific community.
- The quack encourages patients to lend political support to his treatment methods.
- The quack tells you not to trust your doctor.
- The quack claims that he's persecuted by the medical community or that his work is suppressed because it's controversial.

To escape from the "wolves" of health fraud, patients should be offered the following advice, "If it sounds too good to be true, it probably is."

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# Combatting medical fraud

As a protector of consumers and promoter of public health, the Food and Drug Administration (FDA) has several levels of concern about medical fraud. They range in urgency from unsafe products that pose a direct threat to health to ineffective medicines that distract patients from medically proven treatment and to ever-present weight reduction nostrums that hurt mostly the consumer's expectations and pocketbook. All unapproved medications, however, violate the law which stipulates that drugs cannot be marketed unless FDA finds them to be safe and effective for their intended use.

The harm caused by products that do not meet these standards is widespread and pervasive. According to an FDA survey conducted a few years ago, an estimated 38–40 million Americans try fraudulent remedies each year, and one of ten users suffers from side effects. The social cost of needless suffering and damage to health is compounded by the high economic toll extracted for unapproved and ineffective remedies. The estimated $30 billion that Americans expand annually for such medications and devices place an unwarranted burden on top of the more than $738 billion our nation spends on legitimate health care.

Over the years, FDA—in cooperation with state and local authorities—has fought health fraud by initiating thousands of enforcement actions. The prosecutions of the promoters of Krebiozen and Laetrile are only two landmark examples of FDA'a insistence of the highest standards of safety and efficacy for medicines, in spite of occasional, highly emotional protests by believers in unapproved remedies. Last year alone, FDA initiated more than 70 seizures of fraudulent substances ranging from anabolic steroids and "fountain of youth" palliatives to a "serum" purported to cure both cancer and acquired immunodeficiency syndrome (AIDS). In addition, hundreds of warning letters were sent to promoters of products of dubious therapeutic value.

In recent years, however, while FDA's resources have become increasingly strained by new statutory requirements and escalating workloads, illicit promoters have been expanding their operations across national boundaries. The "fountain of youth" ring broken up last year, for instance, was part of a growing international black market in anti-aging products whose sales in the United States were estimated at two billion dollars a year. It has become clear that the agency's effectiveness against health fraud can only be improved by still closer cooperation with other authorities at all levels of government.

FDA has started this process by establishing a special Health Fraud Unit and entering into partnership with the National Association of Attorneys General (NAAG) and Association of Food and Drug Officials (AFDO).

The thrust of the new policy is two-fold. One major function of the partnership is to coordinate more closely with FDA, state or local regulatory actions against specific health fraud targets. The Health Fraud Unit, which operates a computerized data base on fraudulent health products, helps organize joint or mutually assisted enforcement actions and serves as liaison with interested federal, state and other agencies. This effort is aided by the recently established FDA criminal investigation offices in six major cities, whose specially trained agents will be involved in investigation of health fraud that violates criminal statutes.

The other key goal of the FDA/NAAG/AFDO partnership is to deflate exaggerated claims made for injurious or ineffective remedies and generally increase public awareness of the dangers of quackery. The Health Fraud Unit will support this effort by disseminating health fraud intelligence data and other information for use in press releases and educational activities by cooperating agencies. Acting on the premise that truthful information is the best weapon against illicit operators, FDA plans to hold several Health Fraud conferences, the first one of which, slated for next year, will be designed for the Hispanic community.

As always, FDA remains fully committed to providing the public with the broadest selection of safe and effective therapies, safe cosmetics and safe and wholesome food. However, our responsibility and the nation's need for combatting health fraud has never been greater. We count on the health care community and the general public to report fraudulent remedies either to the nearest FDA district office, or to the Health Fraud Coordinator, FDA Office of Regional Operations, HFC-151, 5600 Fishers Lane, Rockville, MD 20857.

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## *FROM THE LIBRARY*

### THE PROSECUTION OF QUACKS

A warrant was issued for the arrest of one Rafael Cardamone, of East New York. After two adjournments he waived examination for trial at Special Sessions. This case was reported by a citizen of Brooklyn, on his own behalf, and the arrest was made upon his affidavit alone. No detectives were required. The eastern section of Brooklyn is filled with these unlicensed foreigners, and it is rather remarkable we do not receive more complaints from respectable physicians in that vicinity. Henry Surson, of 130 East 123rd Street, who was arrested and accused of practicing medicine without a license, was sentenced yesterday in Special Sessions Court to thirty days' imprisonment and fined $100.

LEGAL NOTES
(*NY State J Med*) 1903; 3:166–167.

# Recognizing deception in the promotion of untested and unproven medical treatments

GRACE POWERS MONACO, JD, SAUL GREEN, PHD

**Bravado, self-adulation,** ready wit, double tongue, shrewdness, knowledge of the foibles of men, blunted conscience, and ignorance of the subject in which they claim competence are the characteristics of the promoters of "unproven and untested" remedies.[1] Shrewd use of recognized but little understood scientific and medical terms creates an illusion of expertise in the science on which the promoted product is said to be based. This contrived aura of scientific expertise coupled with entrepreneurial shrewdness makes the sales pitch for "cures and eternal good health" very hard to resist.

Over a quarter of the American public has used unproven products[2,3] ranging in cost from $300 a month for nutritional supplements to $30,000 for a course of treatment.[4] The frightened and vulnerable are the most common targets.[1,5] Promoters traditionally appeal to the hopelessness of patients faced with what they believe is an incurable disease, play on the fear of the side effects of proven treatments, provide halleluja testimonials, denigrate the physician as behind the times, and focus on a common belief that natural products have no toxicities or side effects.[1,5–6]

Those attracted are not only patients who have exhausted proven therapies or clinical trial options, but also nervous individuals who wish to cover all bets in case their therapy does not work. Since ethical physicians cannot say they are cured until they are, fear motivates trying everything that implies it might help. If the condition does not reappear, the patient may become a shill for the unproven "real" cure.[1,2,5–10]

**Physician Trust and Patient Disclosure as Buffers Against Health Fraud.** The physician must be the first line of defense against health fraud.[1,3,5–9] Physicians cannot anticipate health product problems without full patient disclosure of the information they are bombarded with in infomercials, the media and from relatives and friends.[1,3,5–8]

Patients expect a respectful response[6–7,9–11] to their inquiries about whether these remedies have been tested, will help them or whether they have been disproved.[1,3,5–7] Such a collaborative relationship assures patient disclosure of information and facilitates identification of misinformation, inappropriate, and potentially damaging interventions. On occasion, it may lead to the discovery of a valuable complement to care.[6,10–11] Discovering the misinformation requires constructive listening in an open, communicating doctor/patient relationship.[1,3,6,11] Inquiries into patient concerns about diet, nutrition, and media information indicates interest, a willingness to listen and empowers the patient to become an informed medical consumer, alert to the "hype" of promotional health fraud. Physician inquiry encourages patient inquiry.[1,8,12] It could alert both, for example, to the promotion of questionable use of nutritional supplements to counter the "faulty" American diet[8] or to affect longevity or the immune system.[1] It alerts both to dangerous "hygienic" measures such as coffee enemas and high colonics.

From the Medical Care Ombudsman Program, Washington, DC (Ms Monaco) and Zol Consultants, New York City (Dr Green).
Address correspondence to Dr Green, Medical Care Ombudsman Program, 123 C St, SE, Washington, DC 20003.

## COME ON'S

Patients, family, friends, neighbors may be seeing adds in the popular media that convey the message: chemotherapy, radiation, and surgery have not touched the cancer epidemic. Promotions for their suggested "alternatives" usually contain some of the following phrases, claims and tactics:[1,7,8,13]

- Cure, miraculous, nontoxic, conspiracy to suppress; testimonials with no names or objective medical record materials;
- A jump from ambiguous animal studies to use in patients;
- "World authorities," "internationally renowned experts" and "respected scientists;"
- Collaboration with international scientists and extensive foreign studies;
- Ingredients of their product is kept "secret" to prevent theft by the "establishment;"
- "Non-invasive" diagnostic tests can detect cancer, degenerative diseases and subclinical disease otherwise impossible with tests used by establishment doctors.

Promoters' tactics to convince patients not to discuss "their" remedies with their physician may include the following:

- Discrediting proven therapies and those under clinical investigation— "Clearly, the best way to treat (fill in recent fad disease) is first to do nothing orthodox,—that is, nothing harmful."
- Don't cut, burn or mutilate until you have tried our all natural, non-toxic remedy to (fill in disease).
- Don't tell your physician about our treatment—he won't understand it and he will interfere with your trust in our program. Faith is essential to its success.
- Don't use any of the approaches your primary care physician recommends because they all employ unnatural chemicals which will damage your immune system, mask the real cause of your disease and further poison your body.
- Mention a few of these books and articles to your doctor. If he hasn't heard of them, it shows that he is not in the forefront of holistic medicine and wouldn't understand this treatment.

## HOW THE PUBLIC IS FOOLED BY THE HYPE FOR THE INTERVENTION

Promotional health fraud hides behind the terms "alternative" or "complementary" medicine.[7,8,9] Interven-

tions properly called "alternative" have been shown to have worth in traditional medicine, in folk lore or in innovative modern medical programs. Complementary suggests that the intervention can augment, assist, or enhance the effect of a treatment already going on. Therapies that have not shown worth by objective standards are not truly "complementary." At best, they are "unproven and untested;" at worst, they are fraudulent and quackery.

A judicial definition of an "unproven and untested" therapy is one that "has not been developed based on a well designed and ongoing program of research, experimentation and study which can be expected to ultimately add to the body of scientific and medical knowledge."[14]

Freedom of choice is the promoters ultimate weasel phrase. It means unfettered freedom to take a clients money based only upon the "version" of the facts about their treatment that the promoters choose to disclose. It is the ultimate violation of informed consent[9,15] since a patient's decision is based upon "managed" information. It means freedom of promoters to be free of responsibility to patients! It does not meet the informed consent standards of the American Medical Association's Patient Bill of Rights. A fully informed medical decision weighs the relative merits of a therapy after full disclosure of risks, benefits and alternatives.

Promoters of "unproven and untested" remedies do not publish negative data. They do not comply with the onerous but ethically essential task of exposing their experimental and clinical results to independent peer criticism. They claim a "conspiracy" prevents them from publishing but rarely can prove that they have submitted their data to peer reviewed journals. They persist in using brochures, throwaways, popular media articles and TV and radio talk shows as their publications.[13]

## A Process for the Review of "Unproven and Untested" Medical Interventions

Structure of the review process:

**Objective.** The same considerations apply here as do when you consider referring a patient for a specialized treatment. Your review objectives are to develop materials which will support a dialogue that explains, considers and respects the patients' need to know. The dialogue covers what does the patient expects from this approach; what has the patient been led to believe this approach can deliver; how realistic is the achievement of these objectives?

**Data/Sources.** Initial data for a review are found in materials provided by the promoter. Supplemental data can be obtained from a Medline search or requested from any of the following: Cancer Information Service (1-800-4-CANCER), American Cancer Society (1-404-320-3333), Candlelighters Childhood Cancer Foundation (pediatric cancers only; [1-800-366-2223), National Council Against Health Fraud Resource Center (1-800-82-6671) and the American Medical Association. An excellent overview of most of these remedies is Congressional Office of Technology Assessment, Report on Unconventional Cancer Treatments: *Unconventional Cancer Treatments.* 1990. Office of Technology Assessment, United States Congress, Washington, DC 20510-8025. Additional information sources are the department of health and the state medical board. Check whether the approach has been reviewed by Consumers Union or the American Council on Science and Health, both in New York City.

**The Evaluation Process.** The process described here was conceived, developed, and evaluated under a National Cancer Institute grant[4] to review the most commonly used unconventional biochemical, immunologic, dietary, herbal and botanical approaches to the treatment of cancer. The completed reviews were subjected to outside peer review applying stringent evaluation criteria.

The validity of claims is easily verified. A letter requesting information will usually bring a flood of response mail. The layman is impressed with science so promoters include many references to work published by scientists. When the identity of the scientific basis for the claim is disclosed, a computerized literature search can complete the picture. This process makes the claimant entirely responsible for the conclusions reached by an evaluation. Verification of credentials or data in foreign or out of print journals can be accomplished by a letter to an author of the research cited or the appropriate agency. Promoters rarely expose themselves to the scrutiny of a true peer review process. They "publish" their findings in books for the lay public divorced from the rules of evidence which are obeyed by scientists. The books may contain unverifiable medical records, testimonials from unidentified patients or citations to unsupported statistical evaluations to prove safety and efficacy. Unlike the standard practice of medical scientists who weigh and then report the risks of a treatment as compared to its probable benefit, promoters of quackery never describe untoward effects or fatalities. Their books are thereafter cited as the scientific publications which support their claims that the remedy is safe, effective, inexpensive and a viable alternative to standard medical interventions.

**The Process Applied.** This process of data collection and evaluation is illustrated below for some aspects of two "untested and unproven" treatments described in promotional books: (1) biologically guided chemotherapy and (2) chelation therapy. Page constraints preclude a complete review.

**Biologically Guided Therapy for Cancer—Emanuel Revici.[16]** Biologically guided cancer (BGC) therapy is offered to patients in New York City by Emanuel Revici, MD. Among the diseases he claims to treat successfully are cancer, AIDS, heart disease, mental retardation and alzheimers.[16] Revici's claims are summarized in a 1961 book,[16] a transcript of a Congressional public hearing,[17] two papers on the cause and cure of AIDS,[18] a paper on the cause and treatment of radiation injury,[19] and a 1986 US Patent[20] describing preparation of the 31 compounds he uses in treatment.[10] Revici's numerous claims include the following:

**Twin Formation.** Revici said, in 1946, they found a way to determine the electrical charge of atoms in a molecule and determined that two atoms with the same electrical charge could exist bound together. He called this a twin formation.[16(p242)]

**Trienic Forms.** Revici states[17(pp26–37)] that because he could not find a definition for lipids in the scientific literature which satisfied him, he made one up which "is related directly to the forces in the molecules." Using this definition, he "discovered" abnormal lipids in the body which contained fatty acids having three conjugated double bonds and named them trienes.

**Abnormal Lipids Induced by Radiation.[19]** Revici claims that because radiation produces high levels of "abnormal lipids" in animals or men, they died. Accordingly, he says he developed a method for neutralizing these lipids, and he

sent this information to the Radiological Society in London and the Department of Radiation of the United Nations in Vienna.[17,19]

**Treatment for Cancer.** Revici's "medicines" are a series of lipids[17(pp26–37)] containing different elements.[20] Most often used is a lipid-selenium complex, which he says allows him to give patients as much as "1 million micrograms" of selenium, even though he recognizes that the National Academy of Sciences[21] says more than 150 micrograms is toxic in man. If the content of selenium in these lipid complexes is as high as 1.0/g/dose,[17] the absence of toxicity in his patients may be due to the fact that the selenium in this preparation is totally unavailable for use in the body.[22]

**The pH, Specific Gravity and Surface Tension of Urine are Determinants of the Metabolic State of the Cancer Patient.** Revici[17,19] says disease is "dualistic" (ie, an imbalance between the constructive states [anabolic] or destructive states [catabolic]). In the anabolic condition, sterols predominate; in the catabolic, fatty acids predominate. Since metabolic waste is excreted in urine, an acid urine is due to anabolic activity and an alkaline urine is due to catabolic activity. His treatment is based on a measurement of the pH, specific gravity and surface tension of a sample of a patient's urine.[17,19] Urinary pH, specific gravity and surface tension can be dramatically altered by a single meal, a medication, exercise, psychological stress, dehydration, disease or alcohol intake. Only a carefully collected 24-hour urine sample has diagnostic value.[23]

**Chelation Therapy for Coronary Artery Disease and Atherosclerosis.** Practitioners calling themselves "orthomolecular physicians" claim that 400,000 patients have been safely given 6 million chelation treatments with ethylenediamine tetraacetic acid (EDTA) for atherosclerosis and coronary artery disease with marked and lasting benefits in 75% to 95%.[24] Among others, chelation therapy is said to[24] inhibit the aging process, reverse atherosclerosis and gangrene, decrease angina, heal diabetic ulcers, reduce symptoms of multiple sclerosis, Parkinsons, psoriasis and Alzheimers, improve vision, hearing, smell and muscle coordination, decrease need for insulin and the incidence of thrombophlebitis and increase sexual potency.

EDTA binds di- and trivalent metal ions. The strength with which each metal ion is bound to EDTA varies, iron (FE++) being the strongest and calcium (Ca++) one of the weakest.[25] EDTA was synthesized in Germany in the 1930s. At that time, because citric acid was used to treat heavy metal poisoning,[26] EDTA was tried. It was also tried in patients with mitral valve calcification in 1955.[27] The hypothesis that calcified arteries could be softened when calcium was removed was tested in patient's with angina pectoris[28] but improvement was short lived.[29] In 1985[30] and 1992,[31] placebo-controlled and double-blinded clinical trials were carried out for intermittent claudication; no beneficial effect was observed. Supporters of EDTA-chelation claim that the experimental design and procedure were flawed, the blinding code was prematurely broken and the methods of statistical evaluation were unclear. [32] Their "evidence" to support these objections was not disclosed. There is no objective evidence in the numerous clinical cases reported that EDTA chelation had any modifying effect on the course of coronary artery disease.

Chelation therapy is usually delivered by an intravenous infusion of EDTA and is said to promote "unclogging" of the patients plaque-blocked arteries. In the 1960s, the action of EDTA was likened to the removal of the rivets from a steel structure (ie, without calcium) plaque would come apart. Plaque disintegration would then allow widening of the bore of the arteries. In the 1970s,[33] the mechanism described was the removal of ionic serum calcium. This caused a release of parahormone (PTH) which mobilized calcium from the bones (osteoclastic activity) to replace the calcium lost from the serum. A stimulation of new bone formation created a need for new calcium which was mobilized from the soft tissues and artery walls. This caused arteries to soften and plaque to disintegrate. In the early 1980s,[24] the chelation of calcium' hypothesis was rejected by proponents and was replaced with the hypothesis that by chelating and removing metal ions, the production of the tissue-damaging free radicals which cause diseases is inhibited.

**Review of Claims.** EDTA chelation inhibits formation of disease causing free radicals. A literature review on free radical generation by metal ions yielded the following information:[34–37]

- Chelation with EDTA does not reduce or inhibit the free radical generating capacity of iron in the circulation or tissues;[34]
- Chelation of iron with EDTA stabilizes and prolongs existence of iron in the tissues and body fluids, allowing it more time to generate free radicals;[35–36]
- Vitamin C, which may be given during EDTA-chelation therapy, plays a direct role in the mobilization of iron from stores in the body, thereby increasing the total amount of ionic iron in the blood during chelation therapy;[36]
- Oxidation of vitamin C by the iron/EDTA complex can result in additional free radical formation.[37]

The Infusion of EDTA is Safe. Literature on the biochemistry and physiology of EDTA yields the following information:[38–47]

- EDTA is a water soluble compound; it cannot get inside tissue cells to chelate the calcium;[39,46]
- The binding strength of calcium to EDTA is the weakest of all the metals; all trace metal ions in the blood and on the adjoining blood vessel walls will be chelated and removed from the body via the urine before the calcium is chelated;[40] Intravenous EDTA causes a massive loss of zinc from the body with toxic consequences for the function of the immune system and with a potential for inducing mutagenic changes in rapidly proliferating tissue cells;[38,42]
- When exposed to EDTA, the *Escherichia coli* in the bowel release their endotoxins into the gut;[43]
- EDTA is a powerful inhibitor of blood coagulation, its presence in the circulation during the four hour infusion increases prothrombin time and prevents blood clotting;[47]
- EDTA causes changes in the permeability of the membranes of the islet cells in the pancreas therefore insulin requirements of diabetics can be drastically altered and insulin shock induced;[41]
- EDTA causes pseudoleukocytosis and abnormal clumping of platelets in the blood of patients with cancer and other chronic diseases.[44,45]

## Conclusions and Recommendations

Medicine is the practice of helping people with injurious conditions. Only cartoon physicians claim infallibility. Physicians who adhere to their Hippocratic oath consider the patients' interest paramount. This means that they welcome, expect and encourage questions about appropriate protocols for treatment. Physicians take the initiative in encouraging or setting up second opinions for patients needing to look further. Physicians, rather than being threatened by other viewpoints, realize that their treatment options are expanded and improved through seeking out the opinions of their peers.

The peer-reviewed medical literature and medical newspapers reinforce the importance of peer comment and

suggestions. These publications are full of exchanges among physicians commenting on treatment protocols and research, challenging assumptions and making suggestions. Sometimes these physician to physician exchanges in print are pointed and spirited criticisms. However, physicians publish articles and provide letters to the editor in the hope that they will be commented on. If there is a better approach or an improvement to be suggested in a protocol, finding this out will benefit patients. Physicians engaging in this cross-commentary do not take each other to court for disparaging their reputations or interfering with their businesses by providing commentary on their journal articles.

In contrast, promoters of "untested and unproven" treatments do not appear to welcome comment or criticism. Promoters use the tactic of character assassination and threats of legal action to deter investigation and reporting of activities detrimental to patients and the public interest. These suits are invariably thrown out by the courts[48] but this is small comfort to those who have to pay lawyers to defend their right to safeguard patients and the public.

A new system is needed which extends the protection from litigation now accorded to peer reviewers for medical programs to persons engaged in finding and reporting misrepresentations and fraudulent practices in health care. Claims of cures are matters of public interest affecting the public health. Open discussion is essential to facilitate fully informed medical choices.[49,50] Courts have taken judicial notice that persons practicing highly controversial methods of dealing with disease can expect severe and detailed criticism:

> There may be no more serious or critical issue extant today than the health of human beings. Given the frailty of human existence, any controversy on the subject must be afforded wide open discussion and criticism so that individuals may make well educated health care choices. This is especially so in cases where serious disease is involved or death is imminent.[50 p1206]

Obstacles to promoting the public health through speaking out against promotional misrepresentations misleading patients must be removed.

**Acknowledgments.** Funding for the development of source materials for this paper was obtained under National Cancer Institute (SBIR) 2 R44 CA41953-02, Evaluative Database on "Unproven and Untested" Cancer Remedies (1988–1991).

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# AIDS fraud, finances, and fringes

WALLACE I. SAMPSON, MD

**Human immunodeficiency virus** 1 (HIV 1) disease, a social and medical disaster, has produced opportunities for fraud and fraud watchers. As opportunists make small fortunes, we have the opportunity to observe the natural history of pseudoscience and society's responses.

The cast of players is familiar—well meaning self-help organizations, self-deluded and self-important dreamers with gossamer philosophies, and outright charlatans. However, as is usual with medical fraud and pseudoscience, the distinctions are blurred, and many groups feature all three.

## BACKGROUND

The major features of the HIV-affected population's response to dubious methods is the high percentage of people who embrace them. Non-standard and ineffective therapies become most popular in the male homosexual community, starting in San Francisco. The initial meager government response to the epidemic boosted many into worthless methods as a reaction against governmental inertia. *The Plague* by Albert Camus[1] is a dramatic teacher. Written as an allegory for the world's inaction to Hitler's rise to power, it traced leaders' foot-dragging when faced with a public health threat few felt would materialize or affect them personally. The book is prophetic of the US government's slow response to the acquired immunodeficiency syndrome (AIDS) despite the warnings of the scientific, public health, and patient activist communities. According to Donald Francis, MD,[2] and author Randy Shilts[3] inertia seems to have been official policy. There is a common perception that many homosexuals and their sexual practices are aberrant, repulsive, or immoral. Gays as well as others with HIV infection, including intravenous drug users and transfusion recipients, became special social outcasts along with their families. Many in the HIV-infected gay communities perceived the medical profession as being grouped with the "Establishment," as objects of mistrust. A minority of physicians who refused to care for HIV-infected people compounded the problem.

In addition, there is the long Food and Drug Administration (FDA) drug approval process that takes years and millions of dollars for a new drug to be approved. During the investigational phase, access is limited to certain subgroups who qualify, and to the limited number selected for each trial. Geographic location also limits access to research drugs.

These factors compounded the frustration of HIV-infected people as well as of physicians witnessing HIV's devastations. Mistrust resulted in a mass movement out of mainstream medicine. R. Wachter, MD, has outlined much of this history over the last ten years.[4]

Many gays looked to gay physicians to care for them. To their credit, gay physicians stepped in to do so. They often came from unrelated specialties—oncology, dermatology, general medicine, rheumatology—and molded their practices to the epidemic, becoming AIDs specialists.

From early in the epidemic, many infected gay men used other systems such as physical exercises, homeopathy, meditation, and naturopathy. They also looked to nutritional supplements and investigational drugs obtained through black and gray markets, hoping to strengthen their immunity. Buyers' clubs sprang up nationwide to sell chemicals and drugs obtained from manufacturers and renegade secret laboratories. Some "ethical" pharmaceutical manufacturers sold directly to buyers' clubs and guerrilla clinics, violating their standards of commercial behavior, as well as FDA and state regulations.

The situation became so uncontrolled that the FDA and state agencies were unable to deal with it through standard policies. The FDA approved a number of dubious materials and devices for Investigational New Drug (IND) and Investigational Device Exemptions (IDE). This was done to mollify mounting political pressures for access to "alternative" as well as to legitimate investigational methods, and to reduce the work load on the FDA's limited and harried enforcement staff.

The percentages of people who now opt for unproven or worthless methods is not known, and probably varies with affected groups. The most active has been the gay community.

According to Molly Cooke, MD, of the University of California San Francisco, (personal communication, October, 1991) 30%–60% of people enrolled in clinical trials altered their placebo or experimental status by taking unauthorized drugs or changing the doses of what they were given.

There is no effective IV drug users' group, and users have not joined forces with gays. People with transfusion associated HIV tend to act individually or in concert with established medical organizations. The important observation is the gays' extraordinary movement to many unproven and fraudulent methods.

## COMMON UNPROVEN AND FRAUDULENT REMEDIES

In 1985, *American Medical News* described the growing market in phony AIDS remedies.[5] By 1986, the Laetrile/cancer quackery promoters had placed themselves in the AIDS world.[6] By 1988 John Renner, MD, and this author collected a list of over 200 different remedies and methods offered and sold by stores and various individuals. The Healing Alternatives Foundation of San Francisco now

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offers a list of 121 products it supplies by mail. These include vitamin and mineral supplements (seven different forms of vitamin C), amino acids, other food supplements (biotin, Spirulina [three forms] chlorella, germanium), anti-oxidants ("AOX/PLX," "BHI"), "immune stimulants" ("DNCB," levamisole), proposed antivirals (isoprinosine, compound Q-trichosanthin, AL-721), and herbs (Pau D'Arco, astragalus, Valerian root, garlic, ginseng, comfrey, etc).[7] None of the 121 products has known clinical value against HIV infection or its complicating infections, although some unapproved anti-viral agents are active against HIV or HIV infected $CD^{4+}$ T cells in vitro.

In the mid-1980s, the list contained a number of ineffective cancer remedies including vitamin C. The most prominent Laetrile organizations, the Robert Bradford Foundation and the Committee for Freedom of Choice in Medicine (formerly the Committee for Freedom of Choice in Cancer Therapy) have outpatient and inpatient programs for AIDS at their Tiajuana hospital.[8] In spite of these proponents' accusations of the high cost of ethical medical care, their own costs are not low. A week at the Bradford Research Institute Hospital in Tijuana costs $4,300 with $300 per month after that. A two-week stay costs $6,600 with $400 per month for home medication. Three weeks cost $9,900 followed by $450 per month.[9] This is not inexpensive considering that the treatments are scientifically unproven, highly unlikely to work, or fraudulent.

Bradford spokesman Michael Culbert, a former editor of the *Berkeley California Gazette,* and the author of two books on Laetrile for cancer, has also written books on AIDS[10] in which he develops theories about AIDS and HIV infection also supported by political extremists. They include claims that HIV is not the sole cause of AIDS, that other factors are syphilis, herpes viruses, Epstein-Barr virus, hepatitis, cortisol excess, and cytomegalovirus, and that predisposing factors include venereal infections, substance abuse, syphilis, antibiotic abuse, refined carbohydrates, fluoridated water, vaccinations, "environmental poisonings," and blood transfusions.

Some claim that immune systems may be partially rebuilt by "intervening therapies," and that a positive blood test corresponding to "100% mortality is a thought, not a fact." (Although some HIV positive people may live five to ten years without developing AIDS, most experts agree that HIV infection is ultimately fatal.) These claims are a standard technique of pseudoscience proponents. Because the proponents' explanations and treatments are inconsistent with scientific knowledge, they create mistrust of valid information and encourage belief in their fraudulent substitute system. Bradford and Culbert's statements cast scientific explanations of AIDS into doubt, and prepare the patient for their own extraordinary claims.

Bradford treatments are a mixture of "old metabolic therapy" for cancer and newer methods directed to "boost" the immune system and neutralize the virus. Old treatments include staphage lysate, amygdalin (one form of Laetrile), live cell therapy, herbal teas and enemas, coffee enemas, acidophilus, and chelation therapy with eidetic acid. Dietary changes include vegetarian diet, no refined carbohydrates or animal fats or protein, and "detoxifying" with fruits and vegetables. They administer broad spectrum antibiotics and penicillin because signs of advanced HIV were found in neurosyphilis, and "a number of researchers treat AIDS as if it were syphilis."

They also give "immune enhancers:" vitamins A, C, E, $B_1$, $B_3$, fatty acids, AL-721, iron, zinc, amino acids, "anti-oxidants" such as catalase, dimethyl sulfoxide, and glutathione, and anti-inflammatory and proteolytic enzymes. Another group includes "oxytherapies:" Hydrogen peroxide, ozone, and organic germanium. None of these methods has been scientifically shown to perform functions or to provide benefits to AIDS patients in the ways claimed.

An administrative and product supply arm of the Bradford Institute, American Biologics of Chula Vista, California has billing and collecting methods for what medical science considers unnecessary and ineffective services. A number of insurance companies have refused to pay, and some patients have brought suit against the companies.[10] A case against American Biologics for falsely claiming to cure cancer and AIDS is now pending with the District Attorney of San Diego County, California.[11]

State and Federal agencies usually handle violations with letters requesting cessation of the activity—known as compliance letters. Compliance letters are not made public, so that most actions against companies and individuals cannot be reviewed here. However, some other court actions have been taken. One notable case was against an Orange County, California, radiologist who produced a substance he called Viroxan in his kitchen sink and injected it into AIDS patients. He surrendered his medical license voluntarily in 1991. An associate had his medical license revoked, whereupon he sued the Medical Board of California.[11] In 1990, the owners of Oasis Purewater, Inc., of San Diego were fined $500 each and received suspended one-year prison sentences for selling industrial strength hydrogen peroxide for AIDS.[11]

One former orthopedic surgeon in Los Altos, California, gives massive doses of intravenous vitamin C to AIDS patients, claiming to raise their $CD^{4+}$ cell counts and to prolong their lives. He administers doses exceeding 100 mg daily, even though they can cause kidney failure, red cell hemolysis, and death. No one has demonstrated beneficial effects of ascorbate in AIDS patients.

Ozone therapy was given to AIDS patients by flowing blood through an ozone generator and returning the treated blood to the patient. Ozone generators along with some other dubious methods were given IDE status by the FDA. There is no proof of effectiveness for ozone use against HIV in people.

Many "health food" stores misrepresent products. In Houston, Texas, Martin surveyed 41 health food stores by requesting materials to protect the wife of a (fictional) infected husband. All stores claimed to have had HIV preventative products including multiple vitamins, vitamin C, coenzyme Q10, germanium, lecithin, raw glandular extracts, homeopathic remedies algae, hydrogen peroxide, and herbs. None of these is active against AIDS. No store clerk recommended use of a condom.[12]

### Financial Maneuvers

There are ways to make money without selling a product. One way is to sell stock in a company claiming to have a promising AIDS treatment. This scheme is modeled after stock swindles by Laetrile promoters in the 1970s and 1980s.[13]

In 1987, two physicians and a businessman formed a company with claims of having an apparatus to treat HIV disease. It was a cot with a wiring system that carried a low amperage electric current. The electromagnetic field gener-

ated, along with two wavelengths of blue light that played on the patient from above, were claimed to stimulate $CD^{4+}$ cells and improve clinical status. Eight patients were treated without Federal or state approval or permission from an institutional review board (IRB). This activity violated state and federal regulations. They then applied to the FDA for an IDE, using selected data. They claimed most patients improved. At least two consultants to the California Board of Medical Quality Assurance reviewed the raw data and found that the proponents had not reported anemia, weight loss, and other detrimental changes. Often the treatment was stopped when the $CD^{4+}$ count happened to be higher during a normal swing, thus seeming to show improvement.

FDA policy at the time was to grant IDEs and INDs for any HIV treatment not likely to be harmful. While local authorities prepared charges against the company for the Attorney General an IDE was granted. The device was then listed in two issues of the American Foundation for AIDS Research directory, numerous publications such as *Insight* and *Pennystock News* carried stories on the device,[14,15] and the company was featured on local TV news broadcasts.

The stock (several million shares) was owned by the promoters, and sold on penny stock exchanges through brokers in New Jersey and Utah. It rose from $0.06 to $0.10 per share in January 1987 to at least $0.74 per share in March/April 1987, an increase of almost 1,000%. There is no official record of how many shares changed hands. The company obtained a belated IRB approval from Mt Zion Hospital, San Francisco, and arranged for experiments on cats at the University of California, Davis, all after treatments were given to human volunteers. The company moved from an old rented house in Mountain View, California, to an upscale Silicon Valley building in Cupertino.

It subsequently did no more experiments, never marketed the device, considered marketing substances for arthritis, premenstrual syndrome, and other troublesome conditions, and disappeared one to two years later. The IDE expired when the company failed to renew. The HIV patients were not charged, but false hopes were raised and the money was made from stock sales.

## Gray Markets and Buyers' Clubs

Perhaps the most difficult area of borderline illegal activities to define and deal with. Because of the social conditions described above, HIV patients have little patience for the FDA and medial system to catch up with their desires for access to potentially beneficial medication. Starting just one year after the identification of HIV, groups of infected individuals and their associates began looking for independent access to unapproved drugs. Project Inform (PI) of San Francisco was among the first. Its activities have been covered in the *New York Times* and the *San Francisco Examiner*.[16–18]

Its controversial role derives from its strong influence in the HIV community, the Department of Health and Human Services, FDA, National Institutes of Health (NIH), and with state and local authorities. Yet, its directors are self-appointed and not subject to election by members or by the large gay community they speak for, nor has it any competing organization. Not only does PI negotiate directly with and influence FDA and NIH policy, it co-sponsored and ran the first "community" compound Q trial (GLQ 223, trichosanthin),[19] without the permission of regulatory agencies. The project was approved by an IRB of its own construction, unassociated with a hospital, university, or other independent organization. One physician who headed the trial is noted for his espousal of "clinical ecology."[20]

The "Q" clinical trial proceeded while PI was the seller of Compound Q. The trial ended with mixed results, no proven efficacy, two admitted deaths and a number of other toxic reactions. Another controlled trial was apparently devised, and a preliminary Phase I/II trial presented at the VIIIth International AIDS Conference (no conclusion of efficacy). PI continues to supply compound Q commercially and hypes it with its newsletter.[21]

Just as intriguing was PI's role in popularizing dideoxycytidine (ddC), another antiviral drug. ddC is too neurotoxic to take alone in effective doses, but seems to be tolerable at a lower dose in combination with zidovudine. In spite of this, PI was and is a distributor of ddC. It marketed, from renegade chemical laboratories, ddC that was not standardized for content or purity. Lots were found to have next to no ddC activity to two times the amount claimed when analyzed by Hoffman-LaRoche, the manufacturer of ddC.[22] PI did nothing to assure potency or purity. Neither Hoffman-LaRoche nor FDA took action. Ordinarily the FDA or state agency would order immediate seizure of the products, or more, and the patent holder, ie, LaRoche, would sue for patent infringement. However, no action was taken until the FDA stopped the trial after three deaths.[16]

This situation illustrates the power that PI wields with government agencies and its following. In late 1991, regulatory representatives met with PI and other groups to discuss the situation. They apparently forged a compromise solution. FDA and state agencies would keep a hands off policy for buyers' clubs distributing investigational drugs likely to have some role or anti-HIV effect as long as no dangerous reactions occur.[22] In return, PI and others would join in anti-AIDS fraud activities and inform their constituencies about the dangers of quack remedies.

PI has since published a "hot list" of methods to avoid. These include "Auto-immune Viracide" (M. Bilbrey, Phoenix, AZ), Roka's Plant Treatment and Clinic (Switzerland), and the long-time cancer pseudotreatment "antineoplastons" of S. Burzynski of Houston, Texas.[23] A PI member is also a member of the California AIDS Fraud Task Force.

The decision to allow buyers' clubs to operate under FDA's half closed eyes not only allows the clubs to continue and to profit, but helps PI and others to eliminate competition. In addition, the line between fraudulent products and those marketed by the clubs has not been drawn, as is seen by the long list of ineffective products available from the Healing Alternatives Foundation, that works closely with PI. In addition, PI has criticized dissenting individuals and organizations in the press.[24] FDA officials are mum on the subject, but the policy has the support of the community at risk. The compromise is felt to be the best FDA can extract.

## Self Care

A number of self-care methods have been popular from the beginning of the epidemic. These include taking nutritional supplements already mentioned, and various exercises. Many lift weights and use aerobic conditioning. Some delve into parapsychological escapism and "New Age" beliefs. One woman who contacted AIDS from her mate claims to have reverted to sero-negative status through transcendent experience.[25]

Popular in the mid- and late-1980s was a Los Angeles New Age therapist-philosopher, Louise Hay. She wrote articles and books, and gave seminars (one costing $7.50 per person) claiming that AIDS is not a fatal disease, and that faith and attitude help to overcome the disease.[26] One faith strengthening exercise was to gaze at oneself in the mirror and repeatedly utter complementary phrases and "I am well." She has not been popular recently—perhaps because common sense sometimes prevails.

Another method was organized by a woman who falsely claimed to have a PhD in biology from the University of California at Berkeley. She conducted groups at which HIV affected people sat holding hands, but were instructed not to wear underwear because warm genitals encouraged HIV growth. They also were told to drink only distilled water.

At the VIth International AIDS Conference in San Francisco in 1990, a parallel conference at a nearby hotel was held and organized by Lawrence Badgley, MD, an advocate of alternative therapies. His book, *Healing AIDS Naturally,* promotes homeopathic remedies, meditation, imagery, and a multiplicity of other maneuvers.[27]

*Conquering AIDS Now* by S. Gregory and B. Leonardo[27] describes other self-care methods from mildly humorous to ridiculous, such as improving immunity by "thumping" on the thymus, and sitting in sunlight with the genitals and anus exposed to sunlight at the recommended angle of 40°. It also recommends "dry brush massage" and "adrenal massage." Although many AIDS patients scoff at such suggestions, some are worried, frightened, and gullible enough to accept them.*

## Conspiracy Theories

An interesting offshoot of the AIDS epidemic is the rise of opposing theories on the origin of the HIV itself, and how it became a human pathogen. At the Whole Life Expo in 1989 in San Francisco, proponents of Laetrile and "live cell analysis" (diagnosing nutritional deficiencies by examining clumping of blood cells in a suspension) told attendees that HIV was introduced into hepatitis B vaccine and smallpox vaccine by the biological warfare unit of the US Army at Fort Detrick, Maryland.

The book, *AIDS: Hope, Hoax, and Hoopla*,[8] by Laetrile proponent Michael Culbert states that HIV may have been introduced into Africa by World Health Organization smallpox vaccine, or into the United States through hepatitis B and polio vaccine. A recent article in *Rolling Stone*[29] claiming that HIV was introduced into Africa by polio immunization was reviewed in *Science*.[30] A rebuttal by Hilary Koprowski, a co-developer of polio vaccine, was printed in *Science*.[31]

A Los Angeles gastroenterologist, Robert Strecker, also developed a theory that man-made HIV was intentionally introduced into the gay community via hepatitis vaccine, by agents of the then USSR, with the connivance of the NIH, and into Africa via smallpox and polio vaccines. Strecker and his supporters appeared on a nationally televised program, *Tony Brown's Journal*, during which panelists supported right-wing conspiracy theories. Strecker produced an hour-long video on the subject that he sells nationwide.

Even the Rev Louis Farrakhan and the Nation of Islam have been involved in a crank AIDS remedy. An oral form of interferon was promoted by Kenyan physicians and hyped by Rev Farrakhan. It was produced separately by two different laboratories and named Kemron and Immunex. A protein, interferon is probably destroyed by intestinal enzymes and not absorbed intact. It has no demonstrable effectiveness against HIV or AIDS outside of the anecdotal claims of its promoters. The claims were accompanied by statements that AIDS is a disease concocted to destroy blacks.[32] The interesting aspect to these conspiracy theories is that they all accuse Federal agencies, even the US Army and the Central Intelligence Agency, of conspiring to eliminate segments of the population by stealth or extraordinary incompetence. The effect is consistent with a right wing political agenda to engender mistrust of regulatory agencies. Proponents have not yet won many converts to their causes, but they amplify suspicion and resentment of agencies regulating health fraud. Suspicion of authority is a national characteristic of Americans, and is easily aroused.

## Conclusions

The spread of fraudulent and pseudoscientific methods in the HIV-infected population is a result of resentment of authority, the lack of effective remedies for a fatal disease of young people, and the ready imagination and opportunism of cranks and charlatans, as well as well-meaning yet ambitious individuals. The heady feeling of power may be a strong motivation of people who begin by merely wanting to help or to correct a perceived injustice. In the AIDS scene, the population seems not to want to control the people who may take advantage of them. AIDS has been a wellspring of opportunity for profiteering and for the propagation of pseudoscience.

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# The physician and cancer quackery

## The physician's role in promoting the scientific treatment of cancer and discouraging questionable treatment methods

IRVING J. LERNER, MD

**The promotion of** questionable methods of treatment for cancer and other serious illnesses clearly is a very long-standing phenomenon. Only relatively recently have investigators begun to analyze the dynamics of the phenomenon (eg, what are its characteristics?, who promotes it?, who uses it?, how prevalent is it?, how harmful is it?, and is there any value to it?). Studies about questionable treatments have consistently demonstrated a distressingly large number of medical physicians among the purveyors.[1] In contrast, relatively little attention has been directed to the role of the scientific physician in dissuading patients from questionable treatments in favor of proven treatments. There is at least the implication that the treating physician may be pivotal in influencing patient decision-making in this fundamental area.[2]

Questionable treatments of cancer can be defined as treatment methods which are promoted for use, but which have not met the safety and efficacy requirements of the United States Food, Drug and Cosmetic Act. Safety and efficacy are established by providing reproducible scientific data according to well-recognized methodologies. In contrast to questionable treatments, legitimate investigational treatments are those which are currently under study for safety and efficacy and consequently are not promoted for general use.

The American Cancer Society has long been the repository of information regarding questionable cancer treatments. In addition to cataloging these, in recent years the Society has made the additional effort to try to grade them according to their prevalence and their perceived risk to the user (Tables I and II). Cassileth and Brown observed that contemporary questionable treatment methods tend to differ from earlier specific "pills or potions, in that they are life style oriented remedies."[3] One notes a marked increase in dietary promotions, alleged alterations of the immune system, and mind therapies.

### PREVALENCE

In an effort to determine the prevalence of questionable cancer treatments in the United States, the American Cancer Society commissioned a random digit dialing telephone survey of 36,000 American households, ultimately querying more than 5,000 individuals.[4] It was the conclusion of this survey that questionable cancer methods were utilized nine percent of the time nationwide. Similar data from smaller or more regional surveys of the population have yielded prevalence figures ranging from 6% to 23%.[5–10] It should be noted there were marked regional differences in the use of questionable treatment methods, with the rate exceeding 15% of cancer patients in Minnesota, Massachusetts, Connecticut, Oregon, Idaho, New Mexico, and Delaware, and involving less than five percent of cancer patients in Illinois, Virginia, Louisiana, Oklahoma, Missouri, West Virginia, South Carolina, New Hampshire, Iowa, and Rhode Island.[4]

### CHARACTERISTICS OF USERS

Although one might have anticipated that less affluent and less educated individuals might be more vulnerable to the seduction of questionable cancer treatments, in fact the opposite is the case. The American Cancer Society's survey[4] demonstrated a nearly linear correlation between higher income or higher education and questionable cancer treatment use. Among cancer patients residing in households with an income of more than $50,000, 13.2% used a questionable treatment method in contrast to 6.6% in households whose incomes were less than $15,000. Of cancer patients who had post-college education, 13.9% used questionable cancer treatments compared with only five percent of those who did not complete high school. Likely simply reiterating the issue of affluence and education, Caucasians utilized questionable treatments at almost twice the rate of non-Caucasians (9.5% for Caucasians, 7.3% for blacks, and 2.3% for Hispanics).

### CHARACTERISTICS OF PURVEYORS

In the most comprehensively available study about the practitioners of questionable cancer treatments, Cassileth[1] determined that 60% of the providers of such treatments were medical physicians. Of these, 83% received medical degrees in the United States. Of the physicians, 18% were Board certified in internal medicine, family practice, surgery, neurosurgery, urology or psychiatry. The remaining 40% were also considered "professionals," that is, were chiropractors, osteopaths, naturopaths, homeopaths, or nutritionists. Undoubtedly, some in the latter categories are the products of poorly controlled "diploma mills," but this appeared to represent a relatively small number.

### PERCEPTIONS OF PATIENTS *V* PHYSICIANS REGARDING THE TREATING PHYSICIAN'S ROLE IN QUESTIONABLE TREATMENT USE

**Family and Patient Perceptions.** One of the startling conclusions of the American Cancer Society national sur-

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**TABLE I. Questionable Cancer Treatments and Promoters of Highest Concern to the American Cancer Society**

| |
|---|
| Antineoplastons |
| Cancell |
| Committee for Freedom of Choice in Medicine, Inc. |
| Contreras method |
| Greek Cancer Cure of Hariton Alivizatos |
| Immuno-augmentative therapy of Lawrence Burton, PhD, Bahamas |
| Laetrile |
| Livingston-Wheeler therapy |
| Macrobiotic diets for the treatment of cancer |
| National Health Federation |
| O. Carl Simonton, MD |
| Questionable cancer practices in Tijuana and other Mexican border clinics |
| Questionable immune modulation in the treatment of cancer |
| Revici method |

Source: American Cancer Society

vey[4] of patients was the overwhelming patient perception that the use of questionable cancer treatments was largely facilitated by physicians. Patients and their families reported that overall 35% of the time the questionable cancer treatment method had been "recommended" by the patient's primary physician, and that it had been "approved" another 15% of the time. They reported that in only 35% of cases were the questionable treatment methods used unbeknownst to the physician, and only two percent over the stated "objection" of the physician. On the basis of these responses on the part of patients and their families, the surveying firm carrying out the American Cancer Society study concluded "physicians caring for cancer patients regulate the use of unproven cancer treatments more than does any other agent."[2] Moreover, patients and their families stated that in 31% of the cases they were originally introduced to the questionable treatment method by their primary physician. As such, physicians were alleged to be the leading source of the initial information about these methods.

**Physician Perceptions.** The public contention that physicians were the prime source of information about questionable cancer treatment methods and that the primary physician usually recommended or at least approved of these treatment methods was so startling that the American Cancer Society commissioned a second national survey to evaluate physicians' perceptions. Although the physician survey[4] was distinctly smaller than the patient survey (104 physicians interviewed), the perception of the physicians was uniformly at sharp variance from that of the patients. Physicians contended that when they were aware their patients used questionable cancer treatments, they actively tried to discourage that use in 64% of cases. Moreover, physicians asserted that they "recommended" treatment in only two percent of cases, but that ultimately they "went along with" the questionable treatment 37% of the time.

**TABLE II. Questionable Cancer Treatments and Promoters of High Concern to the American Cancer Society**

| |
|---|
| Dimethyl sulfoxide (DMSO) |
| Gerson method |
| Hoxsey method |
| International Association of Cancer Victors and Friends, Inc. |
| Iscador |
| Live cell therapy |
| The metabolic cancer therapy of Harold W. Manner, PhD |
| Hans Nieper, MD |
| Nutritional and metabolic cancer therapy of William D. Kelley |
| The promotion of hydrogen peroxide, germaniun, and ozone therapy in the treatment of cancer |
| Psychic surgery |

Source: American Cancer Society.

**The Issue of Physician Responsibility.** The federal government has a clear responsibility to protect patients from questionable treatments for all forms of disease. The Food and Drug Administration (FDA) is the agency charged with enforcing the Federal Food, Drug and Cosmetic Act, which provides that all treatments must be conclusively proven to be safe and effective for their stated purpose before they can be legally marketed in the United States. Senator Edward Kennedy defined this responsibility in his remarks during the 1977 Senate Hearings about Laetrile: "The role of the Food and Drug Administration is to guarantee that the available drug therapies are the best and most effective that science can devise. Their role is to protect both the patient and his family from remedies that are neither safe nor effective. The elimination of useless treatments is a valid federal role."[11]

The responsibility of individual physicians in this area, however, is much less well defined. It has been argued that physicians should adopt a position of caveat emptor and, moreover, that according to the "forbidden fruit" argument, physician opposition to questionable treatments might make them even more attractive in the public eye.[12] In contrast, in my view, physicians have always had a major responsibility in serving as their patients' advocates, and in the complex modern world of slick marketing techniques the need for their doing so is even greater. Patients have a right to look to their doctors for counsel in health matters of all sorts, but certainly regarding unscientific, unsafe, worthless medical practices.

## Guidelines for an Effective Physician Role

**Avoid Patient Abandonment.** The patient who is either overtly or implicitly abandoned by his physician is effectively driven to the questionable practitioner. As the most successful cancer quack promoter of the 1950s put it, "Cancer victims come to us because they are unwilling to accept as final a death sentence handed them by their own doctors."[13] Even when a physician must honestly concede that there is no longer any effective treatment option remaining for a malignancy or any other disease, the fundamental responsibility persists for caring for that patient, steadfastly attempting to ameliorate physical and emotional suffering. Anything less amounts to abandonment in varying degrees and encourages the patient to seek an "alternative" therapist.

**A Strategy of Preemptive Discussion.** If patients report that they do not discuss the option of questionable cancer treatments at all with their physicians 35% of the time and if experience indicates that patients frequently originally raise the issue of questionable treatments after they have already become committed to them, it would seem that an alternative strategy for physician/patient dialogues on this subject is indicated. One could argue that the physician should take the initiative in this area and introduce the subject early on in the discussion of the cancer problem and its ramifications. Certainly the physician is in a position to identify patients who should be considered at high risk for

trying questionable cancer treatments, particularly those of higher educational status and economic means who apparently are more willing to be adventuresome and take risks. An appropriate opening for such a preemptive strategy would be: "In addition to the proven treatment modalities which we have discussed, you will very likely be approached by well-meaning persons with recommendations to try a variety of unscientific or unproven 'alternative treatments.' I can appreciate how attractive some of these ideas may sound, particularly in the context of the realities of dealing with a cancer situation, and I want you to know that I am available to discuss such proposals with you and to try to help you make a good decision."

Such a strategy has several obvious advantages. In the first place, it establishes that this body of information is as acceptable for discussion between doctor and patient as all other issues relating to the cancer. The patient clearly need not be embarrassed or hesitant to raise the subject. Secondly, the invitation is extended to learn about such treatments with the help of a scientific professional before the patient has become committed to a questionable treatment practice. Many of the questionable treatment practices are promoted with an intense evangelistic zeal, and, clearly, highly intelligent, well-educated individuals afflicted with the awesome disease, cancer, are exceedingly vulnerable to such emotional pitches. Hopefully, preempting the issue will enable the physician to avoid the later confrontation with an absolutely committed patient which frequently deteriorates into an unproductive and even hostile debate. The art in these dialogues is to disapprove emphatically, but calmly with the method without ever disapproving of the patient. Ultimately, it seems likely that inviting discussion about questionable treatment methods early on should improve the prospects of successfully guiding patients to adherence to proven scientific treatments.

**A Source of Reliable Information.** In all areas of medical practice, patients look to their physicians as their major source of medical information, and surely physicians recognize that their role as patient educators is a major aspect of medical practice. Studies indicate, however, that physicians consistently underestimate their patients' desire for complete medical information and they consistently overestimate the amount of time that they devote to the educational enterprise.[14] In the area of questionable cancer treatments, since the alternative sources of information available to patients usually represent self-interested promoters, evangelistic friends, and pure hearsay, the need for the physician as patient educator is especially critical. Unfortunately, it would appear that physicians have tended to be relatively little interested in this issue and certainly generally ill-informed. While one recognizes that all doctors clearly cannot be expert in all areas, physicians are, by virtue of their training, capable of providing invaluable information that can make the difference between a patient selecting or rejecting questionable cancer treatments.

Physicians have been traditionally well schooled in understanding "the rules of the game" for establishing safety and efficacy, and in their continued educational process are constantly exposed to treatments which are being critically evaluated. Consequently, physicians should have good insight into the critical distinctions between FDA-approved treatments, genuine investigational treatments, and questionable treatments. Patients, however, frequently find these distinctions very confusing, especially when questionable proponents employ their slick, seductive arguments. A physician should be able to explain clearly and briefly how a treatment modality passes the tests of safety and efficacy in controlled trials, in a reproducible fashion, and is exposed to peer review, so that it can meet FDA acceptance. Similarly, a physician can clarify that an investigational therapeutic, having demonstrated safety and efficacy in animal models, is currently involved in the process of controlled human trials. In contrast, a questionable method is defined as one which has either never been studied at all in a bona fide experimental setting or one which has failed that scientific study. In addition, especially to counter the common, paranoid argument of the questionable-methods promoters that the establishment is purposely withholding approval of their treatments, it is important that the physician point out that the rules of the game require any promoter to prove the safety and efficacy of his treatment, not for the "medical establishment" to disprove that.

Similarly, physicians can be expected to have good insight into the fallacies of traditional questionable treatment promotion techniques, but even sophisticated patients will frequently be confused by these. It would be worthwhile to review several of the more important such issues: *Testimonials,* usually delivered by fervent true believers, have been the bedrock of questionable method promotions for centuries. Physicians, by their training, recognize that these are nothing more than anecdotes, which may be interesting and may even merit additional evaluation, but that in their own right they hold no scientific substance. The rules of the game require objective measurement of benefit in a treated group as compared to a non-treated group and that this be reproducible before the treatment can be accepted as valuable. That an intense individual may fervently proclaim that something is so, no matter the depth of his belief, does not make it so.

Scientific medicine recognizes the value, but also the substantial limitations of the *placebo effect.* Especially in the area of advanced cancer, the argument has frequently been proposed that treatments solely producing placebo effect should be accepted as standard therapies. For example, in a state legislative hearing regarding the legalization of Laetrile, "One New York state legislator put it this way: 'When you drive your car out of a car wash, doesn't it seem to run better?' 'Maybe,' replied the FDA official, 'but my car would really run better if it had an engine job. And if anyone tells you a wash will improve your car's performance, he is committing fraud.' "[15]

**Exclusively subjective responses** frequently are the consequence of the placebo effect, but surely there are treatments which will produce improved energy, appetite and well-being of more durability than most placebo effects. Scientific medicine has just begun the very arduous enterprise of trying to evaluate these kinds of "quality of life" responses when they lack objective confirmation. It seems reasonable that we will become more sophisticated in evaluating these responses and that treatments will be approved solely for this purpose. Inasmuch as the questionable treatment promoters, however, make no scientific effort to evaluate treatment responses, their description of exclusive subjective responses is obviously highly suspect. This is especially true because the field of questionable cancer practices is replete with instances of patients who were allegedly feeling better while their diseases were unequivocally progressing to their death.

**Inappropriate diagnoses** have been a substantial problem in questionable treatment promotions in the past and

continue to some degree to be so to this day. Patients have been treated for "precancer"[16] as defined by various symptom complexes of common ailments like abdominal gas, blurry vision, or morning malaise. Certainly, treatment of such "disease" will inevitably be associated with a very high success rate and obviously have no validity. Questionable cancer practitioners differ considerably in their requirement for the establishment of a malignant disease, but clearly many will treat merely on the basis of the patient's concern that he may have cancer, and many patients are treated on the basis of cancer diagnostic tests that have absolutely no scientific validity.

A major source of confusion for patients has been the situation of a patient measurably improving in the context of a questionable cancer treatment, but also having received *coincidental conventional treatment.* Since the scientific treatment has frequently been associated with adverse effects and the patient becomes a "convert" to the questionable treatment, the patient is apt to describe all success to the questionable treatment and all trouble to the conventional treatment. Many of the most striking "successes" of questionable cancer treatments clearly were the result of preceding or coexistent conventional treatments. For example, the individual who received federal court approval to import his personal supply of Laetrile as a lifesaving drug had unquestionably been cured of his early rectal carcinoma by local surgery before ever beginning Laetrile.[15]

**Specific Questionable Methods.** One expects physicians to be generally knowledgeable on the above issues, but surely each physician can't be expected to know the vagaries of the specific questionable treatment promotions. The history of these treatments is frequently convoluted, the methodology often bizarre and out of the context of scientific medicine, and the alleged results presented as testimonials and hearsay rather than scientific data. Physicians are not expected to be expert in all areas of medicine, but they can be expected to serve as a source of medical information when asked about a new or novel test or treatment. Physicians know how to obtain such information for their patients or at least how to direct their patients to obtaining the information for themselves. In the area of questionable treatment methods, however, it appears that physicians do not recognize ready sources of information and all too often have simply expressed disapproval without an interest in obtaining information. The American Cancer Society, for example, keeps exhaustive files on a great variety of questionable treatment methods and has position papers on a large number of these, but the Society receives relatively few inquiries from medical professionals. In addition to literature regarding the treatment methods, the Society is also in a position to direct inquiring physicians to experts, locally or nationally, who are available to discuss a particular treatment with them or their patients. A single phone call to the physician's local division headquarters of the American Cancer Society or to the national office of the Society should be adequate to provide the necessary information on a great variety of questionable treatment promotions. In addition, the American Society of Clinical Oncology, the FDA, the National Cancer Institute, and the US Pharmacopeia may be additional sources for specific kinds of information.

Especially recognizing the extraordinarily sophisticated and seductive arguments of questionable method purveyors, the primary physician would be well advised not to accept the mantle of expert on a given questionable treatment method unless, in fact, he is. Debates with patient "true believers" or the promoters themselves have a major risk of deteriorating into adversarial confrontations that are at high risk for producing a "lose/lose" resolution. A physician serves his patient far better to offer to obtain objective information about the method, to help evaluate that information, and, without ever condoning the treatment method, by making it clear that he will continue to serve the patient regardless of the treatment option that the patient pursues.

### Addressing Themes of Questionable Treatment Promotions in the Context of Scientific Medicine

Particularly in the last two decades, patients' attitudes toward their health care have evolved very considerably, and questionable treatment practitioners have been especially astute in reacting to this. The traditional role of the doctor as the activist treater and the patient as a passive recipient, dutifully taking his medication, is passe. Patients want to be proactive in attending to their health needs, consistent with the contemporary, "do-it-yourself" attitude in many other walks of life. In addition, patients are much less apt now to be satisfied with being considered a faulty organ system, a failed heart, a breast cancer, a stomach ulcer; rather, they want to be considered a total being with various ailments a component of their physical and spiritual totality. Questionable treatment promoters have been extraordinarily effective in selling their concept of "holistic" health care and providing their patients with a great variety of activist approaches to their health protection and disease treatment. Traditional medicine has been much slower to react to these changes and has been put at a disadvantage in these areas.

Clearly, the increasing status of the primary care-giver as a treater of the whole patient is a major step in the right direction. Specialist medicine still too often focuses on a specific diseased organ or system rather than the whole patient. All physicians, generalists and specialists, need to be alert to this issue, working always to be sensitive to the patient's overall physical and emotional well-being.

The error in the questionable treatment purveyors' promotion of specific nutritional schemes, exercise programs, and "attitude adjustments" is not in addressing these issues, but in the specifics of their methodology and particularly in the promise of their value. Surely, scientific physicians have been remiss in underemphasizing good nutrition, good physical conditioning, and good mental attitudes. We need to encourage patients to have an adequate caloric intake and protein intake in the treatment of cancer, as well as in all other walks of life. In doing so, although, it is important that we define what is inadequate nutrition and make clear to patients that good nutrition will not fix cancer, but will help maintain their ability independently to resist the cancer and to tolerate the frequently arduous legitimate anticancer treatments. Similarly, physical conditioning is important for everyone, surely including patients afflicted with cancer. Good conditioning enhances their general well-being and their ability to tolerate treatments. The value in having a "positive attitude" is not that it will prevent cancer or diminish an existing cancer, for there is no evidence to support this.[17] The value lies in the fact that patients who are upbeat and optimistic about their situation are clearly happier individuals who are more comfortable for their family, friends, and medical therapists to interact with so that they do not become socially

isolated. It would seem that such positive people are far more likely to be able to sustain the rigors of their scientific anticancer treatment. Good nutrition, good conditioning, and a good attitude are all clearly good things which we as physicians should actively promote, but we must also be honest enough to make it clear to our patients that they will not stop cancer unless we also have effective treatment.

One apparent value of many forms of questionable cancer treatments is that they represent forms of group therapy. Patients in these settings are treated in groups, share mutual experiences, and oftentimes participate in their "self-help" endeavors in group ways. Although for some patients the cancer experience is a very private matter, for many others it is dramatically more tolerable when shared with others with similar problems. Supportive group meetings are available in the context of scientific anticancer treatment as well, but have probably been underused. Each patient should be offered the opportunity early on in a discussion of his cancer problem of participating in a support group, and it is imperative that treating physicians are knowledgeable about the groups available in their area. Again, the American Cancer Society is a sponsor of many such groups, and can be a valuable source of information for those and others in the community. Some patients will require a more intensive, more personal therapeutic experience to deal with the emotional aspects of living with cancer, so that the primary physician must identify consultants in this area as in all others.

## Conclusions

Like it or not, quality medical care of the cancer patient in the 1990s requires that the treating physician deal with the issue of questionable cancer treatment practices. Most physicians probably don't like it because they find the entire subject of "quackery" distasteful and because they are not especially knowledgeable about it. Nevertheless, with nine percent of their patients indulging in these practices nationwide, oftentimes early on in the diagnosis of their disease, not infrequently to the exclusion of scientific anticancer treatment, the issue must be addressed. That such a significant percentage of questionable treatment practitioners are medical physicians is a disgrace and clearly speaks to the need for better educational efforts at the medical school and post-graduate level, as well as for better enforcement efforts by our regulatory bodies. That such a high percentage of patients profess that their physicians introduce them to questionable treatment methods and encourage or condone those methods, while physicians clearly feel that they are attempting to discourage such treatments, speaks to a failure of doctor/patient communication. One strategy to try to address this problem is for the physician to introduce the subject of questionable treatment methods early in the discussion of the ramifications of the cancer situation. This must be presented as a topic as available for discussion as any other, with the physician being able to draw a clear distinction between approved treatments, investigational treatments, and questionable treatments, and with the physician being conversant in the many fallacies of questionable treatment promotions. In addition, physicians of the 1990s need to be thoroughly sensitive to the desire of their patients to be treated as whole persons rather than specific disease entities and as persons who wish actively to be involved in their health care maintenance or their treatment. These are legitimate expectations that we can encourage and develop without in any way sharing in the false promise of the quack.

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# Allergy-related quackery


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Quack: "a pretender to medical skill." (Websters New Collegiate Dictionary); "One who fraudulently misrepresents his ability and experience in the diagnosis and treatment of disease or the effects to be achieved by the treatment he offers." (Dorlands Illustrated Medical Dictionary)


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**Standard reference definitions** of quackery wrongly focus on pretense as the quack's chief characteristic. Although it is true that quacks are always incompetent for the job at hand, pretender implies that all quacks are impostors, disregarding the fact that many quacks are physicians who have ventured outside of their fields, or abandoned the scientific rigor and ethics of their professions. Other definitions wrongly limit quackery to fraud. This overlooks the

most dangerous of all quacks who are true believers whose zealotry knows no reasonable limits. Sincerity may make quackery more socially tolerable, but it only serves to make it more dangerous.

A Congressional committee investigating the problem defined quackery as the practices and pretensions of a quack; quack was defined as "Anyone who *promotes* (emphasis added) medical schemes or remedies known to be false, or which are unproven, for a profit."[1] The Committee rightly focused upon the word promotes as the operative term in its definition. To promote is "to contribute to the growth and prosperity of; to present for public acceptance through advertising and publicity."[2] Promotionalism is the essence of quackery because the term is derived from quacksalver which means literally to "quack like a duck about (one's) salves and remedies,"[3] Advertising represents recognizable commercial communications clearly designed to sell something. Advertisements have limited First Amendment protection in that they may not be false or misleading. Although quacks often violate the rules against false and misleading advertising, at least the public is more likely to be on its guard to a degree when dealing with recognizable advertising. Publicity includes communications that which enjoy the right to free speech. The public is at a major disadvantage when faced with false and unproven remedies in books, magazine and newspaper articles, lectures, audio and video cassettes, talk show appearances, and other such activities. The financial interest of promoters is often disguised in such communications. This type of "hidden advertising" is the most problematic because it enjoys greater First Amendment protection.

## Confusion About Allergies

Quackery thrives within an atmosphere of confusion. Allergies lend themselves to exploitation because they can be real or imagined, their true nature is poorly understood by the public and even by some health professionals, and both patients and practitioners may benefit from their misdiagnosis. Inconsistency in the terms used by physicians to refer to adverse reactions furthers the confusion surrounding this topic. Although what is usually termed allergies in non-food-related reactions manifest established immunological characteristics, food-related "allergies" are often confused with "intolerances," (eg, lactose intolerance), "idiosyncracies" (ie, unique personal reaction to specific foods), or "sensitivities." To avoid misdefinition, Bock prefers "sensitivity" to describe immunological mediated response,[4] while Truswell believes "food allergy" should be confined to immunological reactions.[5] Recognized experts agree that immunological and nonimmunological responses must be distinguished to clarify the matter.

## Allergies and Pop Culture

The public believes that food allergies are more widespread than scientific evidence will support. In a random sample of 3,300 American Adults, 43% said they have some type of adverse reaction to foods, a reaction often ascribed to a food allergy.[6] Dr Jordan Fink, chief allergist at the Medical College of Wisconsin, says that the actual incidence of true food allergy is about 2% of the population.[7] Current media attention to toxic dump sites, mysterious polychlorinated biphenyl contamination, Vietnam veteran's allegations about agent-orange-related disorders has heightened public concern.

## Misdiagnosis

**Faulty Diagnostic Tests.** A substantial amount of allergy quackery is founded on invalid diagnostic testing. Clinical laboratory entrepreneurs have been quick to market dubious allergy tests, and cooperate with maverick practitioners. Advertising and publicity generated by the marketing of bogus allergy testing and treatment reinforces common myths. The American Academy of Allergy and Immunology commented on five controversial techniques used to diagnose allergies:

1. Cytotoxic testing (Bryan's Test). Observations are made of the effects on white cells when food derivatives are mixed with blood samples. Although the test appeals to logic, it fails by producing excessive false positives and false negatives.
2. Urine autoinjection (autogenous urine immunization)
3. Skin titration (Rinkel method).
4. Provocative and neutralization testing (subcutaneous).
5. Provocative testing (sublingual).[8]

Other invalid diagnostic tests include "applied kinesiology," a chiropractic method that tests muscular strength reactions to suspected allergens;[9] radionics, which employs electronic devices alleged to measure "energy;"[10] medical dowsing, which uses a pendulum or dowsing rods; and others.

**Somatization.** What passes as environmental illness is indistinguishable from common psychiatric disorders. Somatization explains why many patients readily accept their misdiagnoses. Somatists are likely to favor a diagnosis of chemical sensitivity because it permits them to blame factors outside of themselves for their uncomfortable lives. Society's tendency to view people with psychological problems as being inferior encourages the denial of psychiatric disorder. Stewart[11–14] found that about 60% of sufferers are amenable to treatment, but the others refuse to relinquish their diagnoses for self-serving reasons. The symptoms of fictitious allergy sufferers are indistinguishable from those in the past and present who have been misdiagnosed as having "neurasthenia," "reactive hypoglycemia," or "adrenal insufficiency." Contemporary diagnoses include "yeast infection" (candidiasis), "dental amalgam toxicity," "chronic fatigue syndrome," and "environmental illness."

**Research Findings.** Objective evidence of food hypersensitivity was sought by the use of exclusion diets and provocation tests in 23 patients who attributed a wide variety of symptoms to food allergy. Hypersensitivity to ingested substances was confirmed in four, each of whom presented with typical atopic symptoms. None of these had psychological symptoms, but a high incidence of psychiatric disorder was found in patients whose belief that they had a food allergy could not be confirmed.[15] Black et al evaluated 26 subjects who had been diagnosed with environmental illness. They described the subjects as having a strong interest in their diagnosis, generally satisfied with their clinical ecologists, and dissatisfied with regular medical approaches. They found that 15 (65%) met criteria for a current or past mood, anxiety, or somatoform disorder, compared with 13 (28%) of 46 age and gender matched controls. They concluded that patients receiving this diagnosis may have one or more commonly recognized psychiatric disorders that could explain some or all of their symptoms.[16] Simon et al studied 37 symptomatic plastics workers who experienced a chemical exposure. They found that 13 subjects who developed environmental illness scored higher on all measures of somatization and psychopathology than the others. They concluded that psychological vulnerability strongly influences chemical sensitivity after exposure.[17] Brodsky described eight clinical ecology patients as sharing

common features: (1) their claim of injury by toxic elements in the work environment rarely began with a specific event of exposure; (2) no physical evidence of injury was found by established diagnostic methods; (3) most have a history of overt psychiatric symptoms; (4) all but one are women; (5) all too frequently they have been seen by the same network of physicians who subscribe to clinical ecology; and (6) their self-perception and diagnosis of "allergic" to most substances have become an organizing principle in their lives, central to their identity and life-style.[18]

**Conversion-V.** Patients who gain from their illnesses are sometimes identifiable by the Minnesota Multiphasic Personality Inventory by what is termed the "Conversion V profile" (ie, high in hypochondriasis, low in depression, and high in hysteria). This pattern is descriptive of persons who somatize emotional problems and are resistant to psychological intervention or interpretation of their symptoms.[19]

## Psychological Influences

Pediatric allergist and researcher, Alan Bock, points out that careful studies have shown that about 60% of children with histories of adverse reactions to foods cannot be confirmed when a double-blind food challenge is administered. His work strongly suggests that the reactions are based on social factors, belief or operant conditioning.

**Power of the Imagination.** The discrepancy between real and imagined food allergies is in part due to a failure to differentiate between true allergies and adverse reactions due to negative beliefs about certain foods or operant conditioning. A committed vegetarian, who believed herself to be allergic to flesh-foods, collapsed at a church potluck after tasting what she thought was meat. When told that she had not eaten meat but a new vegetarian meat-analog, although somewhat embarrassed, she recovered almost immediately. We may find it easier to empathize if we imagined ourselves in a cultural setting in which we were served repulsive foods (eg, insect larvae [dietary fare of Australian aborigines], duck brains (a Chinese delicacy), or dog meat (an American Indian ceremonial food). The author recalls that a former geography professor once said that the first question she was asked upon stepping off an airplane in India during the 1940s was "is it true that Americans eat the filthy swine?" This incredulous question came from a Hindu who, as a follower of traditional ayurvedic medicine, thought it healthful to use his own urine as mouthwash!

Operant conditioning can also cause adverse reactions to foods. A woman who previously liked caramel has reacted adversely to its smell since its odor and her ill-feelings became linked in her mind because her mother was cooking caramel while she was sick at home as a child. Although she is aware that her reaction is operant conditioning, she has been unable to overcome the response for 45 years. Psychological influences upon adverse food reactions should not be underestimated.

**Practitioner Influence.** Anxiety and depression are common psychiatric symptoms. The strong belief of a practitioner who convinces a patient that he or she has located the problem and is specifically treating it can create an enthusiasm that will itself relieve either anxiety or depression.

## Questionable Practitioners

Questionable practitioners appear more often to be guilty of bad science than malice. Clinicians unskilled in scientific methodology, and the pitfalls of uncontrolled clinical experiences, can easily fall into the "seeing is believing" fallacy. Patients may manifest any number of symptoms known to be associated with conversion illnesses. Patients exposed only to single-blind testing can react by interpreting the expectations of practitioners administering the suspected noxious agents. From a methodological perspective, the only protocol that can ensure valid results are cross-over challenge tests in which the patient, practitioner administering the treatment, and the practitioner evaluating the outcomes are all blinded. Sound clinical research methodology has been outlined in the literature.[20]

Several practice guilds have bound together into pressure groups to advance their practices both politically and economically. Like folk medicine practitioners who "merely specialize in what everyone knows; with no significant difference in conception of illness separating them from their patients,"[21] allergy quacks may be both victims as well as victimizers. Practitioners who hold misbeliefs about allergies and do not use proper scientific methods can easily be fooled by a combination of their expectations and their patients' subjective responses.

**The Shot Doctors.** Although allergy shots can be a legitimate therapeutic approach, their use sometimes takes the form of abuse. In 1988, *Consumer's Union* warned the public about doctors who send patients' blood samples through the mail for allergy diagnoses, and then treat alleged allergies with shots instead of recommending suitable medications or referring to qualified allergy specialists. The authors found significant discrepancies between samples sent to different labs offering similar services.[22]

**Clinical Ecology.** Clinical ecology is an unrecognized subspecialty of practitioners who claim that a broad range of common physical and psychological disorders can be triggered in susceptible persons by ongoing low-level exposure to chemicals or foods. Patients are said to be suffering from "environmental illness," "brain allergy," "food addiction," "ingestant intolerance," or are allergic to "the 20th century," "everything modern," or simply everything in "total allergy syndrome."

The idea of clinical ecology was originated by a physician, Theron Randolph, who diagnosed the condition in himself. Randolph married one of his patients. Both believed that they became ill if they ate ordinary food. The couple won a case brought against them by the Internal Revenue Service (IRS) for deducting $3,000 of their $6,000 food bill for the year (1971) which they spent on "organically grown" foods to avoid adverse reactions.[23]

In 1981, the California Medical Association (CMA) adopted the position that clinical ecology does not constitute a valid medical discipline and that scientific and clinical evidence to support the diagnosis of "environmental illness" and "cerebral allergy" or the concept of massive environmental allergy is lacking. As a result of requests from clinical ecologists to justify their claims, the CMA appointed a task force in 1984 to review clinical ecology. The task force concluded that (1) there is no convincing evidence that supports the hypotheses on which clinical ecology is based; (2) clinical ecologists have not identified specific, recognizable diseases caused by exposure to low level environmental stressors; (3) methods to diagnose and treat such unidentified conditions have not been shown to be effective; (4) the practice of clinical ecology can be considered experimental only when its practitioners adhere to scientifically sound research protocols and inform their patients about the experimental nature of their practice.[24]

In 1986, the American Academy of Allergy and Immunology concluded that "the diagnostic and therapeutic principles used to support the concept of clinical ecology indicates that it is an unproven and experimental methodology." [25] In 1989, the American College of Physicians also issued a position paper against clinical ecology.[26]

**Scientology.** Scientology which sells itself as a "alternative" approach to clinical psychology or psychiatry, has embraced the notion of environmental illness. Scientology operates HealthMed, some of whose physicians are clinical ecologists, and markets "Purification Rundown" (PR), a detoxification program created by Scientology's charismatic founder L. Ron Hubbard. Scientology's reputation as a cult (ie, "a system for the cure of disease based upon dogma set forth by its promulgator ")[2] is supported by the fact that its practitioners advocate Hubbard's remedy based primarily on his status as guru. On the basis of the idea that body loads of environmental poisons are at the root of many behavioral problems, PR claims to detoxify the body by megadoses of niacin for dilating blood vessels (ie, the niacin blush), and sweating out poisons through steam baths and exercise. The method was popularized in a book, *Diet for a Poisoned Planet*, by David Steinman.[27] The FDA declared that Steinman's book misrepresented FDA data, and pointed out the invalidity and potential hazards of the PR in a press release.[28]

## Benefits and Harms

Some may argue that there are positive effects to misdiagnosing psychological problems as due to food allergies or environmental toxins. Having an outside force to focus their frustrations upon could improve the child-parent relationship. A "hyperactive" child, whose parents come to believe that his or her troubles are due to dietary factors rather than behavior patterns, is able to get some relief as parents cast the blame away from the child to nasty old sugar or something of the sort. Likewise, parents may be able to assuage their guilt of having failed in their childrearing by scapegoating bad foods. However, such theoretical benefits must be balanced against harms which might accrue. For instance, diagnosing non-existent food allergies in a patient can have a major impact on his or her lifestyle and social interactions. Children may have to forego important experiences needed for normal social development such as going to camp, pajama parties, sleeping over with friends, going to birthday parties, and so forth, out of a parent's fear that they will ingest a forbidden food. Causing children to feel physically impaired can teach hypochondria and weaken self concept.

Being able to blame factors outside of themselves for their internal or relationship problems appeals to many people. A number of parents found comfort in Feingold's book *Why Your Child is Hyperactive*,[29] and groups organized around his theories. Studies failed to confirm Feingold's hypothesis, but many became believers based on their own subjective experiences and continue the movement to this day. Indirect harm can occur because Feingold groups tend to attract purveyors of nutrition quackery. We have seen raw milk, bee pollen, questionable herbs, megavitamins, and other potentially hazardous products promoted in lectures before such gatherings. Apparently, the alienation from scientific medicine and nutrition Feingold groups feel drives them to "experts" who will support their beliefs.

**A Dramatic Case of Harm.** Most misdiagnoses involve false positives in which patients are told that they have allergies which do not exist, but the opposite has also occurred. Real food allergies can be serious, even life-threatening (eg, sulfite sensitivity). Misdiagnosis of a patient can needlessly prolong suffering, but failing to diagnose a real allergy can lead to serious consequences. An unusual case in which patients were told that they did not have an allergy when in fact they did, resulted in a near-fatal episode. The incident involved Canadian physician, Irvine Allen Korman, a clinical ecologist. A mother, herself a dentist, brought her two children to Korman for treatment of allergy problems both had experienced from birth. Her boy had become worse since starting school. The children were tested, the boy more so than the girl. Two unproved tests were used. The first involved the sublingual application of a solution (ie, the sublingual provocative test) followed by ten-minutes of observation for unusual behavior. The second test employed "applied kinesiology," a method in which the patient holds a closed glass container of a solution in one hand while the examiner tests the strength of the opposite abducted arm. The mother did not understand the second test and questioned Korman about the reliability and predictability of the procedure for assessing peanut sensitivity. Korman told her that he had absolute confidence and assured her that it was all right for her to feed the children peanut butter. The mother purchased some organically grown peanut butter and gave each child a tiny amount on a piece of bread. According to the report:

> A dramatic scene followed. Both children collapsed. The girl was terribly white-faced, regained consciousness, was given medication, vomited, developed huge hives, but continued to breathe. The boy kept struggling, could not open his eyes, was gasping for breath, was blue and choking. An ambulance took the family to the hospital where the children were given adrenalin and within a few hours were fine again, but naturally somewhat shaken.

Dr Korman was given a recorded reprimand and had his license suspended for 60 days, with an additional 12-month suspension if he failed to complete the McMaster Physician Review Program with special attention to the areas of immunology, allergy, and nutrition.[30]

Korman's license was revoked in 1990 for professional misconduct and incompetence. Korman's actions included testing a patient for allergies by swinging a quartz ball attached to a string, advising her to have her metal dental filings removed, and informing her that she was allergic to electricity. Several of Korman's patients testified in glowing terms of the doctor's success in treating their "environmental illnesses."[31]

## Patients: Victims or Co-conspirators?

**A Strange Kind of Patient Activism.** Stewart notes that misdiagnosed somatization is unique in that patients organize into groups which oppose scientific study into their conditions rather than to encourage research.[14] Some patients with misdiagnosed psychiatric problems appear to be more interested in fighting doctors who practice scientific medicine. In November 1990, a meeting of the American Academy of Allergy and Immunology was disrupted by clinical ecologists and their patients. According to a report by John C. Selner, MD:

> We arrived at our workshop to find a number of patients confined to wheel chairs with oxygen masks in place, or wearing filters, who were identifiable as patients with so-called environmental illness. Approximately four hours into the workshop I was confronted by a

CBS radio news reporter who interrupted my presentation to ask if I was aware of a public demonstration in front of the hotel. The reporter indicated that he had been informed by environmental activists that a demonstration would take place. A clinical ecologist MD accompanied the demonstrators as the forced their way into the workshop. When asked to leave they refused and the ecologist demanded to have access to the platform. The workshop was recessed and the speakers dispersed to reconvene after the demonstrators had been evicted by the security personnel and local police.

It would appear that any programs which might address issues surrounding the effects of unproven and controversial methods of diagnosis and treatment may be targeted for such demonstrations in the future.

Irony might be found in the fact that the message the co-moderators of this workshop were attempting to highlight for psychiatrists and psychologists was the importance of taking patients very seriously who present without objective signs of disease, but with the so-called environmental illness scenario, and to recognize that many of these patients may be able to be helped. Furthermore, we were attempting to emphasize the importance of environmental chemicals in the induction of disease including psychological presentations.[32]

This kind of patient behavior is probably what led Benjamin Franklin, founder of the US Postal service, including the Postal Inspectors office, to remark: "There are no greater liars than quacks, except for their patients."

**Deep-Pocket Motivation.** Some somatists use their maladies as coping devices for everyday living while others are litigants with a strong financial interest in being compensated for their pain and suffering in courts of law by a "deep-pocket" entity who they blame for their illnesses.

**Harm to Society.** In his book *Galileo's Revenge,*[33] Huber recently exposed the use of "junk science in the courtroom" in which cranks and quacks have been allowed to pollute the legal process by appearing as expert witnesses. Huber points out that the 1975 Federal Rules of Evidence opened the doors to the testimony of pseudoscientific "experts" by holding the previously recognized Frye rule obsolete which required that expert testimony be founded on theories, methods and procedures "generally accepted" as valid among other scientists in the same field. Huber described the work of Bertram W. Carnow, MD, of the University of Illinois School of Public Health. Huber said:

> Carnow obtained his medical degree in 1951 but hasn't practiced medicine for 20 years. He registered for the board certification in internal medicine in 1957, 1958, 1960, 1961, 1962, 1963, and 1964, but withdrew twice and failed five times. He has since testified, under oath, that he sat for board certification in internal medicine only once. "I had completely forgotten" the other tries, Carnow explained in a 1983 UPI story. Today Carnow heads up Carnow, Conibear & Associates—the Conibear being Dr Shirley Conibear, Carnow's fourth wife (Third, testifies Carnow). The firm's best-known service is expert testimony.[34]

Carnow's testimonial line extols the theory of clinical ecology. Huber writes that Carnow is backed up by Arthur C. Zahalsky, PHD, who teaches immunology to nursing undergraduates at Southern Illinois University, even though he never studied immunology in graduate school. The two helped plaintiffs obtain a $49.2 million verdict against a chemical company in Missouri. With such large sums of money at stake, and the inherent need on the part of somatists to deny psychiatric disorders, it is not surprising to discover patient organizations which lobby politically against the intrusion of critical, objective science into the problem of allergy misdiagnosis.

## Conclusion

Allergy-related quackery is a serious problem with powerful psychological, social, and economic implications which favor its perpetuation. Health professionals, third party payers, lawmakers, regulatory agencies, the courts, and consumer groups must come together on the common ground of endorsing only sound scientific health care to curtail abuses and help patients find effective care.

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# Fertile field for fads and fraud

## Questionable nutritional therapies

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**Questionable nutritional remedies** are diagnostic tests or therapies used in the prevention, diagnosis or treatment of a disease, that, after review by qualified biomedical scientists and clinicians, are not recommended for clinical use.[1] Questionable dietary remedies differ from standard, well-accepted therapies in the quality and amount of evidence which exists for their claimed effects, safety, and use. Investigational and experimental therapies differ from questionable therapies. They are evaluated, after obtaining informed consent and review of the risks and benefits, using clinical trials or some other form of scientifically conducted investigation before clinical practice use. Questionable therapies are not subjected to such rigorous testing, risks and benefits are often not fully explained to patient users, and the questionable therapies have inadequate records of safety and effectiveness. Thus, they are not reasonable alternatives to either conventional or investigational nutritional therapies.

### Reasons for Concern About Questionable Nutritional Remedies

The use of questionable nutritional remedies sometimes diverts or delays patients from seeking more effective medical, nutritional, or psychological treatment for a curable disease, worsening it, making it more difficult to treat, and thereby causing needless illness. For example, one teenage patient with a benign tumor on her vocal cord refused to return for laser therapy, the conventional treatment for her condition. Her mother convinced her to interrupt her college studies, and to move home to Boston, where she spent over a year on a strict vegetarian regime prescribed by a lay healer who had touted the diet as curative for her condition. Only when she had lost the ability to speak altogether did she return for medical help which successfully cured her condition.

Some questionable therapies are hazardous. For example, questionable cancer remedies such as coffee enemas, diets that are devoid or very limited in animal foods, fasting, laetrile, or contaminated vaccines, have worsened the health and comfort of patients. The incidence of direct harm to patients is difficult to determine precisely, but there is good evidence that some of these cancer remedies are harmful.[2,3] In addition, self-treatment of premenstrual syndrome with megadoses of vitamin $B_6$, another questionable remedy, has caused peripheral neuropathy in some individuals who used it.[4] Self dosing with megadoses of folic acid can mask the anemia that otherwise might signal the onset of vitamin $B_{12}$ deficiency. Physicians should rule out the possible presence of $B_{12}$ deficiency with the Schilling Test or by other means if there is reason to suspect problems.

Unfortunately, systematic reporting systems for toxic reactions from questionable nutritional therapies are presently inadequate. Neither health professionals nor users may be aware of problems until after they occur in so many people that their risks become obvious. For example, large doses of L-tryptophan were frequently used in the mid-1980s for questionable therapy of such disorders as sleeping problems, premenstrual syndrome, depression, stress, drug addiction, alcoholism, and for improving athletic performance. However, it was only after reports of over 1,000 cases of eosinophilia-myalgia syndrome and one death amassed that it became apparent that L-tryptophan from a contaminated product was causing the problem and the Food and Drug Administration recalled the product.[5]

Questionable nutritional remedies have risks, even when used with conventional therapies. Their side effects may interfere with treatment, cause malnutrition, other harm to physical health, or unnecessary emotional distress. For example, in a recent study of the questionable Livingstone-Wheeler cancer therapy, individuals who used both it and conventional therapies had lesser quality of life and unaltered survival when compared to those using conventional therapies alone.[6]

Another major reason for concern about questionable nutritional remedies is that they can detract from, rather than add to, quality of life, with no increase in disease-free periods or survival. Some unproved treatments interact or conflict with conventional treatments, decreasing effectiveness or increasing side effects. For example, patients on antihypertensive medications or insulin who embark on unsupervised use of very low calorie diets for weight control may develop side effects if medication doses are not decreased.

Nutritional status may be disrupted as a result of use of some of the questionable remedies. The financial costs of questionable therapies are often considerable. One recent estimate was that Americans spent over $10 billion per year on questionable dietary practices of one sort or another.[7]

### The Appeal of Questionable Dietary Remedies

Today there is much public interest in nutritional means for promoting health and preventing disease and the mass media devotes attention to these issues. There is also much emphasis given to the importance of personal responsibility

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for one's own health and self help. Dietary measures are appealing because they seem to be more "natural," actively involve the patients, involve intimate contact with the body but are not invasive. Many individuals believe that diet caused their disease and that, ipso facto, there must be a dietary treatment for it.[8] Patients often assume that advice for preventing disease also applies to its treatment. The self-help books and programs available on the market vary in their reliability, and further add to the confusion about what can be achieved by individual efforts.[9] Patients often mistake the scientific jargon describing questionable nutritional remedies with scientifically demonstrated proof of effectiveness.[10]

The health-care establishment itself may have inadvertently added to the appeal of questionable nutritional remedies. Physicians and public health experts today urge the public to take more responsibility for changing their eating habits in more healthful directions. However, they may not ask their patients if they have questions about nutrition or provide specific advice about it in medical visits. Some patients wrongly conclude that the lack of emphasis on nutrition by health care providers is due to ignorance or a misplaced preference on the physician's part for other forms of treatment. In addition, occasionally health care professionals themselves are the source of information and advice about questionable remedies.

More attention needs to be paid to the role of effective nutritional and other life interventions in health care encounters. However, dietary measures play a role in treating some chronic diseases and conditions, but not others. When dietary measures are called for, those appropriate for disease treatment are not necessarily the same as those for preventing the disease.

## Users of Questionable Remedies

Some of the most vulnerable members of our population from the health standpoint are likely to try and use unproven remedies. There are those who suffer from chronic medical, dental, or psychological problems. In addition, the families of the handicapped and those with special health care needs are especially vulnerable to their allure.

Specific age groups may be particularly vulnerable to questionable nutritional remedies. Over 60% of all health fraud victims are older adults. Older people are particularly susceptible to false claims, perhaps because they think that questionable remedies offer simple, inexpensive ways to prevent aging, guarantee health, and relieve pain. In addition, older people suffer from chronic degenerative diseases and conditions that wax and wane in their course and for which there are no definitive cures.[11] Depending on the therapy in question, individuals of all ages may engage in the use of questionable therapies.

Within these broad groups, individuals with certain characteristics seem to be particularly vulnerable to questionable dietary remedies. They are often well educated, sophisticated, and intelligent individuals, who want to take an active role in their own therapy. Users of questionable therapies often have less trust in conventional medicine,[12] or have had negative experiences in dealing with health professionals. Other situational factors, such as characteristics of the disease, the attitudes of the therapist, and sociocultural factors may also be involved. Many patients use conventional and questionable therapies simultaneously, but do not inform their physicians that they are doing so, because they fear disapproval.

## Some Popular Questionable Remedies

The use of questionable therapies is very widespread, and pervades both medical, dental and psychological maladies, as the following examples illustrate.

**Chronic Medical Conditions: Cancer.** Some of the most popular questionnable cancer therapies used at present include diet. Iscador, an extract of mistletoe, is used in combination with vegetarian diets and other measures for cancer as well as for the acquired immunodeficiency syndrome (AIDS). Other vegetarian regimens are also currently popular. They include the Gerson regime, (a low salt, high potassium, vegetarian diet with various pharmacological agents, and coffee enemas), macrobiotic diets (consisting largely of cooked vegetables and whole grains as part of an overall macrobiotic philosophy and belief system incorporating many aspects of daily living) the Block Therapy (which employs conventional cancer treatment coupled with stress reduction, exercise, psychological support, and modified macrobiotic diet without the ideological underpinnings of macrobiotics), and the Livingstone Wheeler regimen (a vaccine, with antibiotics, vitamins, mineral supplements, and a special vegetarian diet that is low in fat and high in fiber, with psychological and behavioral components often used in conjunction with conventional cancer therapy). The Livingstone-Wheeler regimen was found to provide no improvement in quality of life or in survival over conventional treatments in one recent study.[6] Other dietary regimens include the Revici therapy, which involves lipids and lipid-based substances, and the Kelly therapy, a complex nutritional program including dietary guidelines, vitamin and enzyme supplements, and "metabolic typing." Orthomolecular psychiatry is a form of psychotherapy, the benefits of which are largely undemonstrated, that use massive doses of a variety of vitamins, minerals, and food constituents (eg, laetrile or vitamin $B_{17}$ procaine hydrochloride, Gerovital H3 or pangamic acid [vitamin $B_{15}$], other substances, such as flavinoids, and other vitamin mineral supplements. Supplements of various sorts are also popular. Antineoplastins are peptides or amino acids derived from urine and popularized by Burzynski's followers.

Eumetabolic therapies consist of drugs, vitamins, minerals, plant extracts, elimination diets and therapeutic diets of various sorts which are purported to cure the cancer.

"Middle Ground" therapies have also become increasingly popular in recent years. They involve questionable psychological, behavioral, and dietary therapies applied along with mainstream standard conventional cancer treatments. They are particularly pernicious since they lend an aura of respectability to pseudoscientific measures. A detailed critique for each therapy, and many other questionable cancer therapies, is given in a recent American Cancer Society (ACS) publication on these and other questionable cancer therapies.[13] The journals and publications of the ACS, State Cancer Society offices, and the 1-800 CANCER hotline are also good sources of information.

**Other Chronic Diseases.** Patients who suffer from other chronic diseases and conditions that are severe, have an uncertain course, involve considerable morbidity (such as obesity or arthritis) or mortality (such as AIDS) and lack totally effective treatments also turn to unproved dietary therapies. These are discussed elsewhere.[14,15]

**Chronic Dental Problems: Temporomandibular Joint Dysfunction.** Temporomandibular joint dysfunction (TMJD) describes many different disorders causing pain and discomforts in the temporomandibular region, where the jawbone joins the temporal bone. TMJD causes pain and muscle spasm in the temple and the cheek, limited jaw motion, and clicking or popping of the joint. Among the most common demonstrated causes of TMJD are external trauma to the joints or muscles of the jaw or their malfunction, occlusal problems such as poor bite or misaligned jaw, and habits, such as clenching, excessive gum chewing, and bruxing. Degenerative joint disease, inflammatory joint disorders, and growth disorders may also cause TMJD.

The most helpful treatments for TMJD are conservative, reversible therapies, which bring symptomatic relief to many patients.[16] They include analgesics, muscle relaxants, anti-inflammatory agents, moist heat, physical therapy, psychological counseling, biofeedback, temporary prosthetic devices, and electromyography, depending on the individual case. When these fail, other treatments are intramuscular and intra-articular injections into the temporomandibular joint region or surgery.

Some dentists and patients believe that dietary deficiencies are involved in TMJD. Among the questionable nutritional approaches used to treat TMJD syndrome are applied kinesiology to relax muscles. Dietary treatment involves either a diet that eliminates all refined sugar, or the addition of supplements consisting of large doses of vitamins A, C, E, B complex, calcium, and magnesium. Other dietary therapies involve supplements of vitamins A, C, $B_{12}$, iron, zinc, and protein. Finally the use of L-tryptophan to reduce pain has been suggested. There is no evidence from placebo-controlled trials that attests to the effectiveness of any of these measures. Elimination of gum chewing and a "soft" diet to rest the jaw may help to control pain, but they too have never been shown to be effective.[17]

**Women's Health Problems.** Increased interest in women's health issues has been accompanied by a proliferation of questionable nutritional remedies for various gynecological problems and complaints.

*Premenstrual Syndrome.* Premenstrual syndrome (PMS) involves chronic late luteal phase dysphoria sufficiently severe to cause marked impairment in social or occupational functioning.[18] The subjective reports of psychological and somatic symptoms occur consistently after ovulation but prior to the beginning of menstrual flow, and cease for at least a week after menses. The most common symptoms are breast swelling or pain, pelvic pain, headache, skin disorders, backache, weight gain, mood swings, irritability, depression and anxiety.

Many questionable nutritional therapies are employed to treat PMS although evidence of their efficacy is lacking. These include anti-hypoglycemic diets, supplements of ω-6 fatty acids with evening primrose oil or other oils rich in these fatty acids, magnesium supplements, vitamin E supplements, abstinence from caffeine, and treatment with large amounts of vitamin $B_6$. In our recent review of these various theories, we found no acceptable evidence that poor diet or dietary deficiencies cause PMS or that dietary therapies cure it.[19] Randomized, double-blinded, placebo-controlled clinical trials are lacking for the determining if avoidance of caffeine-containing foods, restriction of sodium or of fluids alleviates symptoms. We need for more research on the complicated hormonal and psychological relationships that may be involved in causing the syndrome; however, at present, nutritional remedies do not offer promise.

*Sex Selection by Dietary Means.* Some prospective parents long to control the sex of their offspring. A questionable nutritional therapy involving an elaborate series of dietary prescriptions for the prospective mother is currently popular.[20] The theoretical rationale for such recommendations is implausible, and there is no acceptable evidence that such dietary measures are efficacious.[21]

*Vaginal Yeast Infections.* Among the questionable nutritional remedies for vaginal yeast infections and for the candidiasis hypersensitivity syndrome are a sugar-free, yeast-free diet coupled with antifungal medications popularized by William G. Crook's book.[22] The American Academy of Allergy and Immunology found no basis for the dietary measures suggested.[23] More recent information also fails to confirm the utility of such dietary measures.[24,25]

## Children with Special Developmental and Health Needs

Fasting therapies and elimination diets (which eliminate whole groups of foods for questionable therapeutic purposes), pose risks of growth failure and nutritional deficiencies, especially when they are used in growing children for juvenile arthritis or emotional disturbances.

Megadoses of vitamins and minerals are often used by the parents of children with mental retardation, Down syndrome, and hyperkinesis, to cure these conditions.[26,27] There is no evidence that doses of vitamins and minerals in amounts in excess of the Recommended Dietary Allowances are helpful in these conditions. Large doses of specific vitamins are helpful in vitamin dependency syndromes, which involve specific metabolic defects. However, these states are very rare, and sound pediatric practice evidence from biochemical tests is necessary before prescribing such treatment.[28]

## What Can Health Professionals Do?

Health professionals and responsible individuals in government can take several steps to lessen the burden on patients imposed by questionable nutritional remedies. First, health professionals need to continue to improve their active listening skills and to develop more empathetic ways of relating to their patients. It is important that we all remember to treat the whole patient, not only the disease.

Second, they can improve reporting systems on the adverse effects of questionable unconventional treatments. This might be under the aegis of the State Department of Health or some other authoritative body.

Third, professional and voluntary associations should inform and educated the patients they deal with about nutritional issues involving chronic medical, dental, and emotional diseases. The American Dietetic Association currently operates a toll-free hot-line for general nutrition related questions. It is 1-800-366-1655. Its address is American Dietetic Association, 216 West Jackson Blvd, Chicago Illinois 60606-6995. The Food and Drug Administration's Regional Offices, State Departments of Health, and the Cooperative Extension Service are helpful information sources.

Fourth, more publicity needs to be given to the actual outcomes and costs of questionable nutritional remedies. Negative results tend to be ignored by the press, so consumers are often left with the false impression that the

therapies really are effective. In fact, the patient may never have had the disease to begin with, the disease continues to progress in spite of the use of the remedy, or positive effects are actually due to other more conventional therapies that are also being used.

Fifth, laymen, such as health food store operators, who often give extensive advice about disease treatment may be practicing medicine without a license. These and other individuals should also be discouraged from doing so, by legal means, if necessary.

Sixth, many questionable nutritional therapies are promoted or prescribed by health professionals. Voluntary and professional associations need to take a more active role in educating their members about questionable nutritional therapies, and the differences between them and more efficacious measures. Although many health professionals and others who use or encourage the use of questionable nutritional remedies sincerely believe that they work, and gain no particular financial or other advantage from advocating their use, ignorance is no excuse. In times such as these, when the application of many efficacious therapies is limited because of lack of resources, professional associations cannot continue to overlook or condone by inaction of their part the prescription of questionable nutritional therapies by their members. Physicians, osteopaths, nurses, pharmacists, some nutritionists, and chiropractors need to become more knowledgeable about clinical nutrition.

Seventh, licensing boards and self-regulatory activities by professional groups need to take a more proactive role in dealing with the use of questionable nutritional therapies by health professionals. In some cases, public monies are used to pay for such in efficacious treatments. Some individuals who know better (or who should know better) promote the use of nutritional remedies for disease for financial gain or other selfish reasons. A quack is a charlatan; a person (either a health professional or layman) who advertises or promotes fraudulent and inefficacious cures for disease. Fraud involves criminal deception and deceitfulness, using false representations to obtain unjust advantage or to injure the rights of others. The point at which honest error becomes fraud is a legal decision. Health professionals who persist in the use of questionable nutritional therapies for disease treatment may be engaging in malpractice. When education fails, professional societies need more explicit sanctions and systems for mandatory re-education and supervised probationary practice for health professionals who continue to advocate the use of questionable therapies after they have been apprised of the error of their ways.

Eighth, we need more efforts to ensure that questionable nutritional therapies are not being used in public hospitals are clinics. For example, in a New England State, debilitated AIDS patients who were being treated in a state chronic disease hospital for the medically indigent and their families were solicited by a professional staff worker who held a doctoral degree in biochemistry to buy a megadose vitamin supplement regimen which cost over a $100 a month. Legal means should be employed to remove such quacks who practice nutritional fraud on unsuspecting patients from government facilities.

**Acknowledgments.** Preparation of this manuscript was supported in part by Grants MCJ9120 and 8241 of the Maternal and Child Health Services, US Department of Health and Human Services, and by Grant R01CA54349 from the National Institutes of Health.

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# Health foods and supplements for the elderly

## Who can say no?

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**Elderly men and** women are frequent users of unproven and fraudulent nutrition products because they want to believe the claims made, that these may retard aging and bring symptom relief. They are especially targeted as purchasers of tonics, questionable nutrient mixtures, herbal remedies and rejuvenating cosmetics, by persuasive advertisements in magazines for the elderly as well as by TV and newspaper advertising. Such products are available in health food stores, pharmacies, supermarkets, and from mail order houses. Risks from using these products include both the hazards of vitamin and drug toxicity as well as the delay in seeking medical care. The public need education about these risks, and product regulation is urgently required.

To understand why the elderly are misled into believing that health foods and nostrums are useful as a means to achieve better health and to overcome the symptoms of chronic disease, it is important to understand the persuasiveness of the health claims and the vulnerability of those who are deceived.

Health and nutrition claims by individual nutrition quacks and by organizations that make the sale of health foods their business are persuasive because, as pointed out by Victor Herbert,[1] they oversimplify and exaggerate the potential of nutrients to prevent chronic disease. They also may make claims for foods and nutrients which are totally false. Furthermore, they may adopt a mystique which suggests that food substances that have the respectability of an ancient folklore to support their health-promoting properties (eg, garlic), can alter health destiny.

### Reasons the Elderly are Targeted for Health Foods and Fraudulent Nutrition Products

The elderly are targeted for health foods and related products both because the purveyor of such products may believe in their efficacy to offset the effects of aging, and because the less scrupulous vendor, even if unbelieving, hopes to persuade the elderly to use their brand of nutrition magic.

The worthless nutrition and food products intended for sale to the elderly are likely to bear claims indicating use in combatting symptoms of common chronic diseases which are prevalent in older people. In his book on the history of health quackery in 20th century America, James Young[2] has collected reasons proposed to explain the susceptibility of particular subgroups of the population to health and nutrition fraud. Those with chronic disease are identified as being most vulnerable. They may not be intellectually taken in by the advertising gimmicks of the vendors of health and nutrition quackery, but they may allow themselves to try out what is offered on the slim chance that it will work. One group of chronic disease sufferers who are generally recognized as being susceptible to fraud are those with chronic arthritis whose symptoms are unrelieved by the medical treatments they have received. Their susceptibility to health fraud is engendered not only by unrelieved symptoms, and particularly pain, but also by feelings of discouragement. It is suggested that those with chronic painful diseases are more willing to try quack remedies since they feel they have nothing to lose. Intelligence and knowledge that the quack remedy is unlikely from the scientific standpoint to offer hope of cure, may not be a defense against a trial of a phony treatment. The arguments of the vendor of quack remedies may be persuasive both to those who are unsophisticated in their selection of treatment modalities and to those who are sophisticated, but are discouraged by past experience of the outcome of accepted medical treatments.

Because the elderly form the subgroup of the population with the highest prevalence of chronic disease and disability which is not amenable to lasting relief by approved drug, diet, surgical, or physical therapy, they may seek alternate means of relief from their medical problems. However, experience indicates that acceptance of quack remedies and quack nutrition treatments by the elderly is also linked to their being deliberately targeted by the purveyors of worthless products. Not only may the elderly wish to seek relief from the pain and stiffness of degenerative arthritis, but many also seek to improve their failing memory and lessen other common symptoms of geriatric health problems.[3]

The need to seek positive health, and to prevent loss of health with aging, may explain the use of high-potency vitamins and tonics which advertise such efficacy.[4] Perceived reduction in health care costs achieved by buying nutrition products rather than incurring medical bills for office visits, may also influence decision making.

### Health Foods and Nutrition Products Presently Available

**Tonics and Nutrient Mixtures.** In the past, tonics were mixtures of bitters in an alcohol-containing vehicle that were used to stimulate appetite. Often iron salts were added to treat anemia, which was considered to be a cause of loss of appetite. Today the lay public consider tonics and nutrient mixtures to possess many of the same properties. False advertising fosters the belief that tonics containing vitamins and minerals in an alcohol-containing base will give you pep and energy. These products commonly have a "Geri" prefix.[5] Nutrient mixtures as well as extracts of plants which are questionable sources of nutrients, are also considered to be "strengthening." These products are thought to be most valuable if they come from natural sources. In addition, traditional use of the products in folk medicine increases their perceived value for health promotion. Thus, products containing aged garlic and Siberian ginseng extract may be attractive to the gullible.

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Products available in health food stores for use by the elderly include those said to contain a very large number of ingredients of plant origin which are claimed to increase energy. One such product is advertised to contain "a multivitamin with whole food concentrates." It is further stated to provide "the natural energy of over 65 wholesome food factors, including spirulina, chlorella, wheat grass juice and sprouted barley juice." In addition, this mixture is said to contain "advanced" mineral forms like chelates and citrates, antioxidants and other nutritional advances of the last billion years.

A popular magazine which, because of its name, is clearly intended for reading by older men and women, carries advertisements such as the following: "Fatigued? Revitalize with ancient Chinese ginseng/royal jelly liquid formula. 10 day supply $9.95. Herb, vitamin catalogue $2.00" and "A 57 nutrient herbal formula which 'seems to purify and oxygenate the blood.' $37.00 for a one month supply."

Certain of the nutrient mixtures sold are said to contain male formula and female formula. It is implied that the addition of these products increases sexual performance.

**Rejuvenating Cosmetics.** There are several types of rejuvenating cosmetics, including those that claim to tighten wrinkled skin, to lighten age spots, and to generally rejuvenate the skin. The rejuvenating cosmetics often contain vitamin E for topical use.

Other ingredients of such products, intended to bring back a youthful skin, are substances which might infer a food origin such as "fresh plant butters." The mistaken idea that the skin can be fed by topical applications, is encouraged. Facial creams containing vitamin E are definitely preferred and it has been recently claimed that one such cream returns the skin to a healthy and radiant state in just seven days.

A risk of actinic damage and skin cancer may be associated with the use of products that claim to "tan and protect." One such product is stated to be PABA- and benzophenone-free and contains vitamins A, C, D, and E. This information may well mislead those elderly, at risk for skin cancer, who are ignorant of the fact that presently PABA and benzophenone are two of the most important topical sunscreens and that topical preparation of vitamins A, C, D, and E have no such protective effect.

**Hair Growth Stimulants.** Certain vitamin-mineral mixtures are sold to stimulate hair growth or regrowth in balding men and in older women whose scalp hair is getting thin. One such product is advertised as a "nutritional thick-shake for healthy hair." According to this advertisement, 60% of Americans lack adequate amounts of vitamin A. The product is defined as "hair tablets," and is said to contain a combination of vitamin A and L-cysteine to improve hair texture, vitamin $B_5$ and inositol or folic acid for thinning hair, vitamin A and C, as well as unsaturated fatty acids to correct deficiencies, and folic acid, pantothenic acid and B complex for restoration of hair color. Two tablets are recommended per day. However, in the advertisement no actual information is given about the concentrations of these nutrients present. A patient of the author took six tablets a day of a similar product to encourage hair and nail growth and developed vitamin A toxicity with patchy alopecia and abnormal liver function tests.[4]

**Weight Control Products.** These products claim to include nutrients that are essential to older men and women who are on low calorie diets, and the products are available "at bargain prices." When advertised in magazines, a check or money order is requested with the come-on of the term "satisfaction guaranteed.' One such product was stated to be a source of chromium picolinate, to "trigger fat loss and lean muscle enhancement." However, there is no evidence to support these claims![5]

**Waters to Promote Energy.** An example is the "energetic water" produced by a firm in Traverse City, Michigan. This water is claimed to be "Many times purer than distilled, filtered or reverse osmosis [waters]."[6]

**Natural Products to Relieve Depression and Induce Sleep.** Tryptophan supplements have been sold as a treatment for depression and as a natural product to promote restful sleep, both for the elderly and for younger adults. Tryptophan has been sold as an antidepressant, although its effectiveness for this purpose has been questioned.[6] Doses of 1–5 g have been recommended for the purpose of sleep induction. The sale of 0.5 g tablets of tryptophan as a sleeping pill was common until recently when tryptophan supplements were found to be the cause of the eosinophilia-myalgia syndrome.[7]

**Anti-Aging Products.** Certain products claim to prevent aging itself, including a herbal mixture containing thyme. Apparently no pun on the word "time" is implied![8]

**Cancer-Prevention Products.** In a magazine recently found on the check-out counter at a grocery market, garlic was stated to "ban skin cancer." Since the size of the print was extremely large, it is likely that few elderly clients would have missed it. Other serious sources of misinformation are claims such as the one seen by the author on a large placard in a pharmacy in New York City, which stated "Take beta carotene. It reverses the effects of smoking."

## Sources of Advertising

The nutritional products under discussion are advertised in magazines, in local newspapers, and in health food stores. In addition, they may be extolled in books that describe methods to retard aging by dietary means. Anti-aging cosmetics sold in pharmacies may also be labelled to indicate their beneficial effects. TV and radio advertisements may be used and the products may be extolled on placards.

## Sources of Supply

These nutritional products can be obtained through mail-order houses that accept credit cards or checks. In addition, they are sold in health food stores, pharmacies, supermarkets, and from individual offices of chiropractors.

## Perceived Benefits

**Cost v Rx Drugs.** The elderly will often buy nutrient or other food supplements of the worthless type, because of apparent savings in cost over use of prescription drugs. Benefits relative to cost may be short-lived because of a subsequent need to purchase prescription drugs. Furthermore, as indicated by the advertisements quoted here, the cost of nostrum may be high, particularly if they are use frequently in large amounts, and/or if multiple supplements are used.

**Possible Positive Effects on the Immune System.** Single nutrients including vitamin E, zinc, and beta-carotene may promote immune function in the elderly.[7–9] However, modulation of the immune system by these nutrients is more appropriately carried out under medical supervision and using single nutrients prepared under quality control

rather than with vitamin or vitamin-trace element mixtures of unknown purity.[3]

**Sleep-Promoting Effects.** A recent text on symptom control states that "there is some evidence that L-tryptophan induces sleep when taken in doses of one gram at night."[10]

## Real Risks

**Vitamin Toxicity.** The elderly incur special risks from vitamin toxicity. For example, it has been shown that increases in plasma levels of vitamin A are greater in the elderly than in younger individuals after dosing. This may be explained by increased absorption of the vitamin with aging that has been reported.[11,12] Other factors contributing to the risk of vitamin A toxicity in the elderly include the presence of liver and kidney disease. Alcoholic liver disease in the elderly imposes a special risk for vitamin A toxicity. It has also been mentioned that those elderly who may be in the habit of taking vitamin E supplements may increase the risk of vitamin A toxicity because vitamin E may promote vitamin A absorption.[2]

**Risk of Supplement Contaminants.** In the last two years, L-tryptophan-containing products have been found to be the cause of the eosinophilia-myalgia syndrome. This is a multisystem disorder affecting muscles, skin, and fascia, as well as being associated with a vasculitis which is due to a contaminant that was developed in the course of the Japanese manufacture of tryptophan supplements. The numbers of people affected with this condition have been argued with estimates as high as 10,000. However, from early 1990 until May 1992, 1,511 cases and 38 deaths have actually been reported to the Centers for Disease Control. The oldest person reported to have the eosinophilia-myalgia syndrome was 85-years old.[13] The recent epidemic of eosinophilic-myalgia, possibly due to a contaminant in tryptophan supplements, has assuredly brought home the danger of products being sold which are not under quality control.[3]

**Drug Toxicity.** The elderly are more at risk from misuse and overuse of vitamins than younger adults because of the therapeutic drugs they take. For example, elderly who take β-adrenergic-blocking drugs as antihypertensive agents and who concurrently take pharmacologic doses of niacin on the supposition that the niacin may improve memory by dilating cerebral vessels, may develop syncope.[4]

**Delay in Seeing an MD.** Reliance on worthless nutritional products to treat symptoms may delay treatment of serious health problems. In this regard, however, it is important to mention that the elderly may buy mail order nutritional products because of difficulties in getting to the doctor, because of lack of transportation, or because they cannot afford office visits.[5]

**Not Taking Appropriate Rx Drugs.** Elderly may take nutritional products as a substitute for appropriate therapeutic drugs, particularly if the drugs they have been prescribed induce unpleasant side effects or are not effective in bringing about symptom relief.

## Previous Attempts at State Action to Combat Health and Nutrition Fraud Against the Elderly

The Republican Task Force on Health Fraud and the Elderly of New York State proposed legislation in 1986 that would strengthen false advertising statutes relative to health products, that would give the media assistance in self-regulation, create a Health Fraud Task Force within the State Attorney General's Office, expand FDA jurisdiction with regard to health fraud, and that would educate the public about developments in the area of health fraud.[14] Barriers to the implementation and enforcement of more stringent regulations in the sale of health and nutrition products to the elderly were discussed at public hearings at that time. The chief points that were made are as follows:

1. Often the products purchased do not carry false claims but rather the advertisement for the product misinforms the prospective customer.
2. The elderly often rely on mail order purchase of products which might escape regulation.

At the time of the hearings on the proposed legislation, several important recommendations were made by representatives of professional societies. For example, a representative from the New York State Dietetic Association emphasized the need for licensing those who practice nutrition counselling, and also emphasized that the elderly need to be better educated about the risks of health and nutrition fraud.

## Guidelines for Action by Health Care Providers Now

**Education of Elderly Patients.** Health care providers including physicians, nurses, dietitians, and pharmacists need to educate the elderly about the risks of worthless nutrient supplements and related products that impose health risks. The benefits of obtaining medical advice on health problems need to be stressed. However, unless the elderly have better means than now exist for accessing the medical care system, it is likely that they will still be tempted to buy the products of present concern. Furthermore, it is unlikely that educating the elderly will prevent the purchase of nostrums as long as symptom relief is still a hard-to-come-by commodity for many disabled elderly.

**Resource Information Available on Worthless and Dangerous Nutritional Products.** Health care providers and agencies providing services for the elderly should have information available about worthless and dangerous nutritional products that should be avoided.

**New Legislation.** A new effort should be made to promote the regulation of health foods and related products at the state and federal level.

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# Sports nutrition fraud

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**As far back** as Ancient Greece, Olympic athletes were in pursuit of a magical food that would enhance sports performance. Today, more than ever, athletes are searching for the "competitive edge," since the difference between winning the gold and placing out of medal contention may be a hundredth of a second or fractions of a point (the 1992 Olympics, Barcelona, Spain). Athletes may turn to ergogenic aids (performance enhancers) to provide an advantage.

General categories of ergogenic aids and examples are described by Williams[1] and include biomechanic (lighter running shoes), psychologic (hypnosis), pharmacologic (anabolic steroids), physiologic (blood doping), and nutrition aids (protein powders). The focus of this paper is on controversial dietary substances marketed to athletes.

There are several problems connected with nutrition information and products for athletes, as well as for the general public. The Federal Food, Drug, and Cosmetic Act is the law that protects consumers against harmful and misleading food, drugs, devices, and cosmetics.[2] However, the Proxmire Amendment[3] modified the law so that the Food and Drug Administration (FDA) cannot set limits on the potency of vitamin and mineral supplements except for reasons of safety, and cannot declare them drugs only because they exceed the level of potency determined to be nutritionally rational or useful. According to FDA Deputy Associate Commissioner Dykstra ". . .it is no secret that in terms of safety of dietary supplements, FDA is not doing much today. It is really 'buyer beware!'. . . The framework simply is not in place today to give consumers the type of assurance that they demanded."[4] Recently, the FDA Dietary Supplement Task Force has been investigating vitamins and minerals, amino acids, and a "catch-all" category (including such products as coenzyme Q-10, garlic oil, and herbs) for safety and nutritive value among other concerns. It is hoped that athletes, as well as the general public, soon will be better protected when they buy dietary supplements.

Another problem is that nutrition books published for the public can be inaccurate or false because of First Amendment rights of free speech. Furthermore, anyone may be called a nutritionist. A nutritionist may be someone who purchases a degree from a non-accredited institution, a PHD in nutrition, a physician who specializes in nutrition, a dietitian, or others. A registered dietitian RD is someone who has graduated from an accredited university, an internship or similar experience, passed an examination given by the American Dietetic Association, and has continuing education credits.[5] Dietitians can also be licensed by some states and use LD after their names. Athletes should ask for credentials before they follow nutritional advice.

An added problem is that research scientists sometimes go public with their conclusions before their study or experiments have been duplicated or subjected to peer review. One research study or one epidemiological survey does not test a scientific theory. Since athletics are big business in the United States, all of these problems are intensified when it comes to sports nutrition information and products. Misinformation spreads through electronic and print media to the players, their coaches, and trainers. "There is a growing need for sports nutrition counseling and education to help athletes improve their eating habits."[6]

In many cases, advice (including supplementation) for athletes is presented as if all athletes had the same needs. Nutrition advice must be individualized. When providing nutritional information, it is necessary to know if the athlete is involved in an endurance or short-term event, body composition (if possible), age, time spent practicing and training, and whether the athlete is training for a meet/match/tournament lasting one day or held on successive days. Nutrition advice that is provided for "athletes in general" makes little sense.[7]

Since proper training, coaching, and diet cannot guarantee success, athletes often resort to nutritional supplements. A recent survey of nutritional supplements in health and bodybuilding magazines found "89 brands, 311 products, and 235 unique ingredients, the most frequent of which were unspecified amino acids. . ."[8] In 1990, the Council for Responsible Nutrition estimated that retail sales of nutritional supplements was $3.3 billions.[9] Unfortunately, most of these product manufacturers have not presented research that demonstrates their claims. Lightsey, the coordinator for the National Council against Health Frauds Task Force on Ergogenic Aids has outlined a number of deceptive tactics used in selling these products.[10] These include published research taken out of context, claims of "university tested" when no research was done, unauthorized endorsement by professional organizations, false statements that research is currently being performed, testimonials, inappropriately referenced research, patented products (not of proof effectiveness), mass media publicity, and others. Even the most informed athletes may not be able to calculate the risk-to-benefit ratio of the newest product hitting the market, nor care about long-term effects.

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The younger athletes may be the most frequent users of these supplements, and they may encounter larger risks. A review of 30 (now 50) studies involving athletes and vitamin/mineral supplementation found a range in use between 6% and 100% with "most studies reporting that more than half of the athletes consumed supplements."[11] There is a definite need for more data (using larger sample sizes) to investigate the prevalence, frequency, duration, and type of nutritional supplements used by various athletes' populations.

Several factors may contribute to the athletes[1] increased use of nutritional supplements. Adequate sports nutrition or even general nutrition knowledge is lacking.[6,12] Most athletes surveyed could not pass a test of basic nutrition knowledge, although they did slightly better on sports nutrition questions. Certified athletic trainers earned higher scores on nutrition tests than athletes or coaches. Coaches indicated that they (as coaches) should provide nutrition information to the athletes, although few had any formal nutrition training. Many coaches suggested that the athletes take supplements of vitamins or amino acids. In a large study, it was found that athletes in high school and college settings ranked parents or popular media as their first or second source of nutrition education.[13] A poor understanding of nutrition combined with slick advertisement campaigns appearing in the popular press often perpetuates myths and misconceptions regarding diet and nutritional supplements. To add to the problems, athletes appear to have a poor understanding of strategies for enhancing muscle development.

Several popular body building magazines exist to promote their nutritional products. The New York City of Department of Consumer Affairs indicated that 56% of full-page advertisements for nutritional supplements in four popular body-building magazines were worthless and possibly harmful.[14] The amount of money spent on these supplements can be substantial. College athletes may spend as much as $400 per month on supplements. This is money that would be better spent on food.

There have been relatively few attempts to regulate the nutrition supplement industry at the federal, state, and local levels. This may be changing since the New York City Department of Consumer Affairs is issuing "Notices of Violation" of the New York City Consumer Protection Law for deceptive advertising against companies making product claims such as the following:[14]

- "A New! Advanced Cell Growth Formula That Stimulates Muscle Growth Even While You Sleep!!!"
- "watch ... muscles explode with incredible strength, massive size, and pure energy."
- "the most powerful muscle-building amino acid."
- "pack on the muscle" and produce "huge gains in record time."

The FDA's Dietary Supplement Task Force is a step forward. They are also examining claims made by nutritional supplement manufacturers which would make the products come under the definition of a drug. Any supplement claiming to be anabolic, stimulate hormone secretion, and/or effect body structure or function are subject to drug regulations. The National Council against Health Fraud's Task Force on Ergogenic Aids has reviewed performance enhancing claims made by 45 different products.[10]

## Vitamin Mineral Supplements

The Committee on Diet and Health (Food and Nutrition Board, National Research Council) recommends that the American public avoid taking dietary supplements in excess of the Recommended Dietary Allowance (RDA) in any one day.[15] It was concluded that healthy people can, and should, obtain essential nutrients from a variety of foods. Exceptions were noted in cases of pregnancy, lactation, newborns, people with malabsorption problems, women with excess monthly bleeding, people with very low caloric intake, and some vegetarians. Most athletes would not fall in any of the above categories except possibly the last three. Harper[16] stated that vitamin deficiency diseases "now occur so rarely in this country as to be medical curiosities. Nevertheless, large numbers of apparently healthy people take vitamin supplements." Harper asserted that there is no proof Americans need vitamin supplements, but they do need accurate nutrition information instead of the misinformation which is so widespread. The United States National Health Interview Survey[17] indicated that more than 30% of adults take vitamin and/or mineral supplements. Some adults were taking supplements 6–43× the RDA, leading to the suggestion that "excessive vitamin and mineral intakes may pose a greater hazard than nutrient deficiency for the population of the US."[18] Evaluating nutrition research is difficult. Quality nutrition research studies should have at least 50 human subjects, appropriate control groups, controlled nutrient intake, adequate consumption data for pre- and post-experimental periods, a level of food consumption that is reasonable, and significant statistical results.[19] Few survey studies meet these specifications.

Williams, in his excellent sports nutrition book, indicates that "all the current reputable research refutes an ergogenic effect of multivitamin-mineral supplements in adequately nourished athletes."[20] Others agree that vitamin supplements do not improve physical performance in those with an adequate diet.[21,22] Clarkson extensively reviewed the effect of vitamins, minerals, and trace minerals on athletic performance.[23,24] She found a lack of evidence that these products influence athletic performance, but athletes buy them because of advertisements in popular magazines and a lack of correct nutrition information.

Using a 9-month, double-blind, placebo-controlled study on male runners, Weight et al[25] found multivitamin and mineral supplementation without measurable "ergogenic effect" and concluded that this procedure is not necessary for athletes on a normal diet. The effects of a commercial dietary supplement (vitamin, mineral, plus other substances) was tested in a double-blind experiment with 20 runners.[26] It was concluded that the supplements had no useful effect on physiological performance. A group of French researchers concluded that "vitamin supplements should be used only on the advice of the team physician and should be strictly reserved for athletes with demonstrated biochemical deficiencies."[27] Since these athletes are taking "stack packs" (plastic-encased packages of a number of erogenic products), it should be noted that the biological consequence of taking these products together has not been researched.

Single vitamins are often selected, but not without consequences. Since muscle contains up to 80% of the vitamin $B_6$ in the body, athletes are prone to take these tablets. A well done study showed that vitamin $B_6$ in skeletal muscle was not easily depleted and that supplementation with this vitamin does not significantly increase vitamin $B_6$ in college age men's muscle.[28] On the other hand, it has been demonstrated that overdoses of this vitamin can be harmful. Subjects self-dosing with from 2 g

to 6 g over a period of from 2 months to 40 months developed severe sensory nervous system dysfunction which was not totally reversible when the vitamin $B_6$ supplementation was stopped.[29]

### Protein and Amino Acids

Advertisers claim that amino acids are a safe, effective means of enhancing muscular strength and more effective than anabolic steroids without the devastating side effects. Others claim that single amino acids are more readily digested, absorbed, and less taxing on the body than protein consumed from food.[1] In addition, protein powders and amino acid supplements have been marketed to endurance athletes under the assumption that these athletes need additional protein to replace energy stores, synthesize new enzymes and protein as a result of training.[30]

Several studies have surveyed the use of protein supplements by athletes. Among college athletes, 98% believed performance was improved by a high-protein diet while 80% reported that large amounts of protein are necessary to increase muscle mass.[31] Krowchuk et al[32] indicated that 56% of high school athletes would consider using protein supplements. Males were more aware of nutritional supplements than females. Parr[33] reported that 9% of high school and college athletes consumed protein supplements. Males (12%) were more likely than females (10%) to take additional protein. Football and basketball players were the largest consumers of protein supplements. Of athletes who used protein supplements, 50% used 1–10 g/day, while some used up to 50 g/day. In another study involving 943 randomly selected high school athletes, 8% regularly consumed protein and dietary supplements.[34] Barret states that "more than 100 companies are marketing vitamin and amino acid concoctions said to increase stamina, endurance, and muscle bulk. All of these products are fakes."[35] Do athletes need to take supplements or can they obtain enough from dietary intake?

While protein requirements of athletes have been researched and debated for years, [36,37] there is a body of literature indicating that protein requirements of endurance and strength athletes are higher than their more sedentary counterparts.[38–41] Although definitive recommendations for protein intake among athletes require further study, current evidence from Lemon[42] suggests that strength athletes should consume 1.2–1.7 g protein/kg body weight (BW) and endurance athletes 1.2–1.4 g/kg BW.

A protein intake of 0.9 g/kg was adequate to maintain nitrogen balance in experienced body builders with sufficient energy intake.[37] Nutrient intake data indicate that most athletes consuming adequate calories meet the recommended protein needs. Exceptions might include athletes involved in sports requiring a certain weight classification (wrestling, boxing) or certain aesthetic appeal and a high lean body mass to fat ratio (ballet, gymnastics, diving). In a four-year study of 16 different athletic teams (554 athletes) at a major university, all athletes except wrestlers and gymnasts were receiving enough protein when calculated on a per kilogram BW basis.[43]

The practice of consuming amino acid supplements is based on the observation many years ago that intravenous administration of some amino acids resulted in increased growth hormone release.[44] Body builders typically consume arginine-lysine or arginine-ornithine supplements under the assumption that these combinations will stimulate growth hormone release resulting in increased muscle protein synthesis and muscle strength.

Although oral administration of certain amino acids may promote growth hormone release, there is little evidence to suggest improvement in muscle hypertrophy or functional strength as a result of this practice.[45,46] "At present, then, there are no data to support an ergogenic effect of human growth hormone on muscle size, strength, or power beyond the effect generated by a proper weight training program."[47] The possibility of adverse health problems seems to be high. Since there are so few well controlled studies on arginine, ornithine, other amino acids and growth hormone, further research is needed to evaluate the effects of combining amino acid supplementation and weight training in promoting strength and muscle development.

Athletes should be warned of the possible complications associated with large doses of protein and amino acid supplementation. This practice could interfere with absorption of amino acids and protein in food and lead to metabolic imbalances. Some amino acids can be potentially toxic.[48,49] Supplementation can interfere with the consumption of a wide variety of foods and thus compromise nutritional status. The effects of elevated levels of growth hormone have not been adequately studied in healthy persons. Amino acid supplements are not recommended because of a lack of evidence to document enhanced muscle strength and size, no established margin of safety for single and combined doses of amino acids, and no studies to evaluate the risks associated with long-term use.

### Other Alternatives to Anabolic Steroids

A variety of products are being manufactured and marketed on the basis that they contain a natural source of testosterone or that they help stimulate endogenous testosterone levels. Glandulars or ground up animal organs are derived from hearts, livers, spleens, brains, pituitary glands, adrenal tissue, and testicles. Beef testicles, commonly sold in health food stores are "thought to be an anabolic steroid by some adolescents."[50] The amount of testosterone sequestered in the testes is very small and is destroyed during the manufacturing process or during the human digestive process. There is no evidence that other animal organs have any effect on testosterone levels including ground up hypothalamus and pituitary which are claimed to provide athletes with the precursors for testosterone production.[51]

Sapogenins are found in desert plants and marketed as a plant extract or by their chemical or plant name. Some plant species that have been advertized include Smilax, trillium, yucca, and sarsaparilla. Actual sapogenins include diosgenin, smilagenin, sarsapogenin, and hecogenin. Diosgenin is a precursor used to manufacture many useful steroids. Diosgenin is being sold to athletes under the false pretense that the body will synthesize testosterone from this precursor just as chemists do in the lab.[46] The potential for toxicity may exist for some of these sapogenins as evidenced by animal studies.[52]

The use of γ-oryzanol and plant steroids (phytosterols) have been popular among athletes.[46,53] Oryzanol is composed of ferulates of plant sterols (Campesterol, Stigmasterol, Beta-Sitosterol, Cycloartenol). Plant sterols are found in the lipid fraction of many plants and vegetables. The structural similarities of oryzanol and phytosterols to cholesterol have led to numerous claims primarily focusing on the hormonal system. General statements regarding the effects of oryzanol supplementation obtained from product bro-

chures include the following: Gamma-oryzanol raises the natural testosterone levels; Gamma-oryzanol, a natural steroid alternative develops increased lean muscle mass and definition, "Beta-sitosterol, an oryzanol component, has a chemical structure that can be readily converted into androgens, resulting in anabolic enhancement."[48] There is no evidence to indicate that γ-oryzanol or plant sterols will elicit anabolic-androgenic activity. In fact, animal studies suggest that ingested oryzanol may depress anabolic activity. Due to poor absorption characteristics of phytosterols and oryzanol (less than 5%) the medical risks appear to be minimal.

Boron, a trace mineral, seems to affect calcium and magnesium metabolism and may be part of membrane function and bone health.[54] Borates were banned as a food preservative 40 years ago, but now boron in small amounts is believed to have a beneficial effect. Boron is pervasive in our surroundings and is easily absorbed. Hunt and colleagues[55] found that good sources of boron include fruits, vegetables, tubers, legumes, and some spices. It is also a contaminant or an ingredient of some personal care products such as antihistamines, denture cleaners, antacids, laxatives, and lipsticks. An article published in 1988 stating that boron was an overlooked element of nutritional importance amazed the author, Nielsen, with its consequences.[56] Claims appeared that boron could increase muscle mass and strength in athletes although the research had shown that boron supplementation only increased testosterone in postmenopausal women. Nielsen noted that postmenopausal women normally have low levels of testosterone. Boron had been withheld from their diets, and after continuing boron supplementation the concentration of testosterone did not further increase. All of these findings have little to do with athletes. Ferrando and Green[57] failed to find an effect of using boron supplements on bodybuilders' total testosterone, lean body mass, or strength. Current evidence suggests that boron supplementation has no anabolic effects.

Chromium has been promoted as an anabolic agent that will enhance energy metabolism, increase muscle, and decrease body fat. The popularity and claims for chromium picolinate stem from studies performed at Bemidji State University, but not published in peer-reviewed scientific literature.[58]

A March 22, 1989 story in the *Los Angeles Times* quoted Evans as saying that "a new form of chromium could offer athletes an alternative to anabolic steroids, enable those with diabetes to use less insulin and cut cholesterol." At that point chromium picolinate became a popular product. The "health food" stores featured chromium and zinc picolinate as part of weight loss products and sports nutrition products.

In the scientific literature, it has been proposed that athletes have a higher dietary requirement for chromium due to documented chromium losses and a possible marginal chromium intake.[59] Acute exercise can increase urinary excretion of chromium[60,61] and may alter chromium status in trained athletes.[62] The total daily urinary chromium levels in nine runners was two times greater on an exercise day verses a non-exercise day.[56] The mean chromium intake for those consuming self-selected diets for seven days was well below the estimated safe and adequate intake (ESAI) of 50–200 μg/day.[63] It should be noted that the ESAI figures are estimates, and that this study was done on only nine athletes.

It is premature to recommend supplements such as chromium picolinate. The safety of chromium picolinate needs to be documented. Use of picolinic acid has resulted in physiological disorders while use of large doses could result in suboptimal iron status.[54] There is little evidence in peer-reviewed journals to indicate that chromium picolinate has any anabolic effects. Further research is needed to evaluate the physiological effects of other supplemental chromium compounds on chromium nutritional status and performance.

## Conclusions

The term "buyer beware" is not strong enough when considering supplements for athletes. At present, the manufacturers have all the advantages. Their products do not have to be safe or effective, but Americans tend to believe that products on the market have been researched, tested, and inspected. American athletes, and the public, are being bilked out of millions of dollars which would be better spent on food. They believe, trust, and spend their money. Fortunately, most of these products will not be harmful, but most have never been scientifically proven to build muscle or meet other claims made by the manufacturers. The program manager for the Federal Trade Commission is quoted as saying "I'm sure they (sports nutrition supplements) are all fraudulent, but we don't have the time or money to go after all of them."[14] Let us hope that the loopholes in the laws are soon plugged. It is difficult to combat such powerful multibillion dollar businesses who certainly do not want informed consumers. It is essential for correct nutrition information to reach the public. At the very least, physicians should ask their athletic patients about supplement use. Legitimate health professionals need to react. Why are so many worthless, if not harmful, supplements permitted to be advertised and sold?

**Acknowledgments.** The authors would like to thank Lois Myer (FDA Public Affairs Specialist), David Lightsey (Coordinator, Task Force on Ergogenic Aids National Council Against Health Fraud), and Peter Lemon, PhD, Kent State University, for so kindly providing current information.

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# The role of physicians in dental quackery

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**Dentistry is beset** with problems, not the least of which is the growing popularity of "alternative" methods, eagerly accepted by patients and lucrative to the practitioner, but unscientific and potentially dangerous. They amount to quackery.[1] More and more we are encountering instances of patients whose physicians, unacquainted with the dubious status of these "alternative" methods and misinformed by anecdotes or media hype, have been referring patients with chronic pain and puzzling malaise to dentists for these treatments. This article is intended to familiarize physicians with these dubious procedures so that more care will be taken with referrals to dentists. While some physicians may actually subscribe to these bizarre "alternative" theories, we suspect that most physicians referring for these therapies have trustingly accepted the misinformation they have heard from these dentists or from the media. Regardless of the physician's motive, it is still the patient who suffers.

The management of chronic pain and malaise of elusive etiology can be frustrating. Dealing with these patients is often time-consuming and aggravating. Physicians confronted with such a patient and unable to develop a

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reasonable diagnosis might well look favorably on a dentist who, claiming to have answers to the dilemma, will take the troublesome patient off his/her hands. Most referrals to dentists for chronic non-dental pain or malaise fall into one of two categories: temporomandibular joint disorders (TMJD) or mercury toxicity.

### Temporomandibular Joint Disorders

Patients with chronic pain of the head, neck, back, and legs, with headaches, tinnitus, and even menstrual problems, and other vague symptoms difficult to diagnose might be referred to a TMJD specialist. Often the referring physician is an otolaryngologist or internist, acting on the mistaken belief that vague ear pain might be related to the temporomandibular joint (TMJ), and in the equally mistaken belief that the "TMJ specialist" can successfully treat it.

There is no recognized specialty in TMJ. However, too often the self-proclaimed TMJ specialist uses unproven or disproven methods. Diagnosis may be based on the quack notion of "applied kinesiology,"[2,3] or on the use of electronic devices which have been shown to be unreliable diagnostically and without therapeutic effect. Some of these unproven electronic methods include electromyography (EMG), jaw tracking, silent period durations, thermography, sonography, and Doppler ultrasound.[4] Treatment, usually based on the long discredited theory that a "bad bite" is the cause of these symptoms, has included "improving the bite" by extensive adjusting and reshaping the teeth or making elaborate permanent or removable prosthetic devices, or even by surgery on the jaws or the TMJ. These treatments are invasive, can be disastrous to the long-term health of the mouth, and in common with other quack treatments, are not supported by either scientific data or investigations. Some 90% of patients with these symptoms will improve if left alone or if conservatively treated with anti-inflammatory drugs, moist heat, and simple jaw exercises.[5–8]

It is true that there are some dentists who treat this type of pain legitimately and who do provide valid diagnostic and therapeutic services; not every dentist in this field is a quack. In addition, there are occasions when non-invasive appliances can be appropriately used, often as placebos, and on extremely rare occasions surgery is justified. However, these are exceptions. Unfortunately, too many TMJ practitioners are of the unscientific stripe, and physicians must remember that every undiagnosed facial or body pain is not a TMJ problem, and is not a reason for referral. Only pain relating to jaw excursions might mean a legitimate TMJ problem. Most facial pain and virtually all body pain is unrelated to the TMJ.

### Mercury Toxicity

Silver amalgam fillings are about 50% mercury, and some dentists, without scientific support, are blaming a host of diseases on the minuscule amount of mercury which allegedly leaks out of amalgam fillings. Among these ailments are multiple sclerosis, Parkinson's disease, immunodeficiency diseases, and emotional problems. The anti-amalgam quacks assert that all amalgam fillings must be removed, sometimes in a specific order according to their electric "polarity," and that "chelating agents" be used to "detoxify" the body of mercury. Unreliable devices such as "Dermatron," "Amalgameter," and the Jerome Mercury detector have been used for diagnosis.[9]

The unnecessary removal of silver-amalgam fillings from a mouth can be a mutilating and dentally crippling procedure. A number of successful malpractice actions have been brought against dentists as a result of this treatment. The American Dental Association Council has declared such treatment to be "improper and unethical."[10] However, the press and media, finding the false assertions of the anti-amalgam forces irresistible, have acted to powerfully reinforce these quack notions about amalgam toxicity in the minds of the public. We suspect that many health professionals have been similarly misinformed, particularly those who look more to the media than to refereed journals for their information.

The astute reader will recognize that the conditions treated by TMJ and anti-amalgam dentists are those featuring chronic, difficult-to-diagnose pain, vague malaise, or progressive, variable-rate physical degeneration. We call these the "quack sensitive" ailments, the very complaints which quacks are eager to treat. In these conditions, symptoms wax and wane, emotional factors play a confounding role, and current medical practice is unable to offer cures or, sometimes, even encouragement. This environment provides a fertile field for the fraudulent promises and treatment excesses of quackery.

The following incident provoked us to write this article: Recently a dentist who specializes in oral surgery asked for our advice. He had performed an apicoectomy and placed a retrograde silver-amalgam filling in the root apex. This is a common and appropriate procedure. However, when the patient learned that an amalgam filling was used he was alarmed, because he had heard and believed the unfounded claim that amalgam fillings were dangerous. His fears were aggravated by a "holistic" physician who, citing a misinformed segment of a television show as his authority, told him that his symptoms were probably caused by the amalgam. This physician demanded that the dentist remove the amalgam. This would have required additional and unnecessary surgery with considerable trauma and increased risk to the patient. The surgeon of course refused, and the physician referred the patient to another dentist who extracted the tooth.

We have seen patients and have heard reports of many other patients who have been mistreated by dental quacks. Some physicians, however inadvertently, have been contributing to the spread of dental fraud by poorly informed referrals to pseudoscientific dentists. We urge physicians to evaluate your dental colleagues and their claims as critically and carefully as you evaluate your medical referrals.

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# Reflections on the use of unproven arthritis remedies

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**It is not** surprising that over $3 billion are spent annually for unproven arthritis treatments.[1] Over 40 million Americans are afflicted by our nation's number one chronic crippling illness and most have symptoms every day of their lives.[2] According to the Arthritis Foundation, arthritis quackery succeeds because of a widespread lack of understanding about arthritis, the absence of a cure at present, the tremendous pain associated with the disease and the fact that there are so many people suffering that promoters have a huge market. The symptoms of arthritis come and go like the tide, allowing people to connect the disappearance with a phony remedy they have been taking.[3]

This essay does not attempt to review the hundreds of useless treatments which have been promoted to help arthritis patients. This information is readily available at the 75 chapter offices of the Arthritis Foundation throughout the country and in the Foundation's book, *Unproven Remedies Resource Manual.* The latter is a catalogue of non-orthodox treatments which have been used by patients throughout recent years. These include alternative healing philosophies such as homeopathy and naturopathy; special diets such as elimination diets and fasting; nutritional supplements including amino acids, mega-vitamin therapy and selenium; herbal remedies including alfalfa, garlic, and kelp; procedures such as colon cleansing; diagnostic tests including hair analysis and miscellaneous treatments such as copper bracelets and snake oil. They vary from relatively harmless to potentially dangerous. Over 300 entities are discussed in this reference book with respect to therapeutic claims, adverse reactions, and scientific studies. A list of references is included under each treatment.[1]

"Unproven" or "non-orthodox" indicates that scientific studies are lacking to validate or substantiate therapeutic claims. "Quackery" or "fraud" indicates deliberate attempts to misrepresent.

It behooves a physician treatment an arthritis patient to inquire about the use of alternative treatments and to become knowledgeable about any possible harmful effects of these claims for which he is taking these treatment.

## Case Report

A 62-year-old college educated woman suffered from rheumatoid arthritis since the age of 20. Before her husband's death three years previously, she received treatment at some of the most prestigious medical centers and clinics in the Northeast. She had received gold, hydroxychloroquine sulfate, intra-articular injections of cortisone, physical and occupational therapy, and multiple anti-inflammatory drugs. She had many complications including rashes, peptic ulcer disease, thinning of her skin with multiple ecchymoses, and cataracts. At the time of her husband's death, she suffered from flexion contracture of her hips and knees which confined her to a wheelchair. Because of upper extremity deformities, she required assistance in dressing and toileting and employed a full-time health aide. She also suffered from anxiety and depression.

On the advice of a well-meaning friend, she traveled to a clinic in rural Mexico to receive what she was told was dimethylsulfoxide (DMSO). She was there for three days and received an intravenous medication and a large supply of pills to take daily for three months. On returning home, she felt like her disease had finally gone into remission. Her pain and stiffness decreased, and she was able to perform many of her activities of daily living.

About one month after her return, she developed melena and visited her internist who noted that she had developed signs of Cushing's syndrome. On analysis, the pills were found to be prednisone. She was admitted to a hospital for further diagnosis, treatment, and rehabilitation.

## Discussion

It is easy to empathize with this patient and it is easy to understand her frustration with a life of pain and disability. Her doctors did not know the cause of her rheumatoid arthritis. Numerous drugs resulted mostly in side effects rather than symptom relief. Her pain got progressively worse and her joints became more deformed. It is understandable that she was desperate and jumped at the opportunity to be cured.

In my experience, neither the educational level nor the native intelligence of patients protect them from the temptations of unproven remedies. The force of human nature, in its quest for symptom relief, overpowers the intellect.

I once treated on the same day two 50-year-old men, both engineers working in middle management, who had rheumatoid arthritis of remarkable similar severity. Both experienced several hours of pain and morning stiffness. Their joints had a comparable degree of synovitis. They both were anemic and had elevated sedimentation rates. Their radiographs showed similar erosions. They in fact were almost rheumatologic identical twins.

The first man boasted, "Doctor, I am doing great! I was able to play nine holes of golf for the first time in two years! I took the golf cart and the pain was so slight that after 12 aspirin tablets I felt comfortable! It was great!"

The second man complained, "Doctor, I am doing terribly! I tried to play golf for the first time in two years, but I had to take a gold cart. I had to quit after nine holes, the pain was so bad. I needed 12 aspirin tablets to feel comfortable."

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The second patient is a potential victim of arthritis fraud. He is "doing terribly." His physician needs to educate him about his disease. He must be questioned at each visit about non-prescribed treatments, and his doctor must become knowledgeable about such treatments to watch for side effects.

The ultimate barrier to consumer use of unproven remedies is the total doctor patient relationship. This may not be achievable with some patients who may be unable to develop trust in their physician. To decrease the possibility that our patients will resort to unproven methods, we must make them feel confident that everything scientifically possible is being done to treat their illness. To achieve this, we physicians must communicate both empathy and competence. Rheumatologists being specialists, may sometimes elicit an extra "placebo effect."

A necessary ally to the doctor-patient relationship is patient education. Physicians probably overestimate the sophistication of their patients' understanding of their illness. A telephone survey of a random sampling of 300 respondents indicated the poor level of public knowledge on the causes of arthritis.[4] Half of those questioned believed that arthritis can be caused by poor diet and cold or wet climates. Bee venom, vitamins, copper bracelets, special diets, and DMSO were accepted as treatments by more than half. It is important to note that 41% of the respondents had post-high-school education.[4]

There is an analogy between our nation's war on drugs and war on medical fraud. It is very difficult, if not impossible to eliminate the source of illegal or unproven substances. The number of people at risk is extremely large. The most viable solution, in my opinion, is education, both public education in the form of media presentations on the most common and dangerous non proven remedies, and personal one on one education, by the physician, targeted for those of his patients who are at the highest risk.

To assist doctors in educating their patients, the Arthritis Foundation produces hundreds of booklets on all aspects of rheumatic diseases and treatments. There is even a pamphlet on unproven remedies. This large body of literature is available for physicians waiting rooms and to individual patients from Chapter offices.

What about the chicken soup analogy? Most agree that this traditional remedy can not hurt and that maybe it can help. Some might say the same for copper bracelets. The concern is that when a patient has symptoms and uses an unproven remedy, he may be delaying effective treatment. An example would be the use of a copper bracelet for a septic arthritis when the joint can be destroyed in a short period of time. Obviously using unproven remedies for chest pain, could even have a more serious result.

Another argument against the chicken soup treatment is that some patients, depending on their diagnosis, may temporarily improve during the unproven treatment. This may be because of a natural remission in the disease (placebo induced or otherwise), or it may be because the symptoms would be intermittent anyway, such as muscle spasm pain of fibrositis. The end result is more "converts" to the "copper bracelet," who will promote this treatment to their friends with rheumatoid arthritis and thus discouraging them from seeking medical care. In conclusion, although unproven remedies will always be available, there is much we as physicians can do to protect our patients.

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# Remedies for a society's debilities

## Medicines for neurasthenia in Victorian America

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**George Miller Beard** wrote in 1880, that "not only for the relief of pain, but for the relief of exhaustion, deeper and more distressing than pain, do both men and women resort to the drug shop. . . ."[1] (Fig 1). Neurasthenia, commonly termed nervous exhaustion in Victorian America, was viewed by George Beard, a New York City neurologist and prolific writer on the topic, as predominantly an American phenomenon that had arisen from the "fatiguing" effects of an increasingly urbanized society. Encompassing a wide range of symptoms, including malaise, depression, insomnia, and indigestion or dyspepsia, the diagnosis gained in popularity with both physicians and the general public as the 19th century unfolded. Those professionals who were diagnosing and treating neurasthenia, neurologists, general practitioners, gynecologists, and alienists (physicians who primarily treated the insane), offered an almost endless variety of treatment regimens, including "rest cures," special diets, "electrotherapy," and medicines.[2] The medicines used for neurasthenia between the years 1869, when George Beard's first paper on the topic appeared, and the first decade of the 20th century, were a broad range of substances, from atropine to zinc oxide. Medical journals became replete with advertisements for commercial medicines that were said to be of benefit for neurasthenia or nervous exhaustion. In their endless quest for alleviation of the debilitating symptoms, however, many individuals placed their trust in the inexhaustible supply of patent medications. In an era of minimal regulation, there was no clear distinction between standard medicines for treatment and the patent medicines. The picture was further blurred by the lack of specificity in the approaches to treatment in the case of neurasthenia. The wide gamut of substances available for neurasthenias throughout the latter decades of the 19th century was used to fill a therapeutic vacuum created by the dearth of effective, scientifically proven psychopharmacological and psychological therapies.

It is not unusual for patients with symptoms of anxiety and depression to describe their experiences as "nerves" or "nervousness." Nineteenth century writers on neurasthenia ascribed psychological symptoms to somatic causes. Allusions to neurasthenia appeared in a number of popular journals, household "medical advisors" and medical advertisements, encouraging the Victorian public to biologize aspects of mental disorders. The importance of neurasthenia lies in its timelessness, as modern conditions such as chronic fatigue syndrome are comparable.[3] These diagnostic labels confer respectability on sufferers by imputing a biological rather than psychological origin to their complaints. Cultural issues such as changes in gender roles are a significant sub-text in the study of neurasthenia, making it even more relevant for contemporary historians.

George Beard observed in his book, *Treatise on Nervous Exhaustion*, published in 1880, that neurasthenia was a common condition that had acquired a number of designations. He wrote the following:

> In spite of its frequency and importance, neurasthenia although long recognized, in a vague way among the people and the profession under such terms as "general debility," "nervous prostration," "nervous debility," "nervous asthenia," "spinal weakness" and more accurately, by some of its special symptoms and accompaniments, as "spinal irritation," "nervous dyspepsia," "oxaluria," "cerebral and spinal anaemia," and "hyperaemia," is even now but just beginning to find recognition in the literature of nervous diseases.[1(p49)]

Among the myriad symptoms that were observed by physicians treating these disorders, the central feature was prostration or general weakness. E. H. Van Deusen, medical superintendent of the Michigan Asylum for the Insane, recognized "malaise," as a leading symptom, followed by "impaired nutrition and assimilation, muscular atonicity, changing the expression of the countenance, uterine displacements. . ." together with ". . .irritability, mental depression, impaired intellectuation, melancholia and mania."[4] Beard, who had worked with Thomas A. Edison, evoked the analogy of dimmed lights, resulting from an overloaded dynamo, to explain the diminution of energy described in neurasthenia.[5] Drawing on the work of the scientist Du Bois-Reymond, Beard postulated that the nervous system itself underwent molecular changes, becoming "dephosphoralized" from its use, resulting in changes that inevitably impaired the brain in those who were vulnerable.[6] Undoubtedly influenced by the works of Charles Darwin, Beard also stressed the role of heredity in the etiology of neurasthenia. He described the "nervous diathesis," or "tendency of the constitution for nervous disease," including "nervous debility." Characterized as "strongly heredity," Beard suggested that these conditions "may run in families for many generations."[7] Abbey and Garfinkel attribute Beard's argument that the higher classes were predisposed to neurasthenia because of their presumably more highly evolved nervous system to his belief in social Darwinism.[3] This presumably advanced nervous system was thought to be vulnerable to the stressful conditions of modern civilization. Beard argued that it was the duty of the psychologist to study the effects of those stressors on the human nervous system.[8]

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FIGURE 1. George Miller Beard (courtesy of The New York Academy of Medicine).

The role of diet and nutrition was often a central concern of physicians whose treatment of neurasthenia took into consideration the production of toxic substances that they thought were deleterious to the nervous network. Edward Cowles, a Massachusetts neurologist, in pointing out revelations in the field of bacteriology, added the following in 1891:

> Thus it comes to be a part of the clinical problem in mental disorders to consider whether the overworked brain may not only have its nutrition, and functional activity, diminished by imperfect removal of waste products, but that further poisoning of its cells and fibers may come from toxic substances in the circulation, due to imperfect digestion and assimilation.[9]

Beard emphasized the importance of the "digestive apparatus," as one segment of a reflex arc, including the "stomach" and the "reproductive system."[8(pp251,252)] Although this concept was a reflection of the frequent association between neurasthenia and dyspepsia or nervous indigestion, it also suggested a relationship to sexual physiology and behavior, including masturbation. Known commonly as "self abuse," masturbation as a putative etiological factor for neurasthenia was examined by Collins and Phillips, of the New York Graduate School in 1899. They stated that "masturbation, (under which we included for convenience sake other irregular forms of sexual indulgence), is generally recognized as being very important," reflecting the contemporary notion that this sexual activity drained the nerve force of men.[10] Many writers on neurasthenia, including George Beard, believed that women were especially vulnerable to this condition, a view that was also held by many physicians, during the era. Many thought that nervous prostration in women arose from "female weakness" or uterine abnormalities. Beard stated in one work published in 1878, that women ". . .seem to have more sickness, certainly more of diseases of debility and exhaustion." [7(pp138,139)] In his work on sexual neurasthenia, Beard pointed to a contrast between "the Indian squaw," who "keeps most of her nerve force," and the "sensitive white women. . .who can never hold a powerful reserve, but must live and does live, in a physical sense, from hand to mouth. . . ."[11] In her article, *The Fashionable Diseases: Women's Complaints and their Treatment in Nineteenth-Century America,* Anne Douglas Wood concluded that the general ill health of women described by many practitioners during the Victorian age had become "positively fashionable." She added that the special focus on the uterus by 19th century physicians led them to attribute many diseases, including nervous prostration, to the womb.[12] Haller, however, pointed out that not all writers on neurasthenia attributed nervous weakness in women to the taxing of a vulnerable system. The neurologist Charles Dana, for example, thought that idleness not overwork produced neurasthenia in women.[13] In contrast with the notion that the overly crowded schedule of the urban worker produced nervous exhaustion, Van Deusen focused on the "early married life" of farmer's wives as a predisposing condition, stating:

> The urgency of farm work necessitates hurried, unsocial meals, and as night closes in, wearied with his exertions, the farmer is often accustomed to seek his bed at an early hour, leaving his wife to pass the long and lonely evening with her needle. Whilst the disposal of his crop, and the constant changes in the character of farm labor afford her husband sufficient variety and recreation, her daily life and especially if she had also the unaided care of one of two ailing children, is exhausting and depressing to a degree of which but few are likely to form any correct conception. From this class come many applications for the admission of female patients.[4(p447)]

Although physicians ascribed neurasthenia primarily to an enfeebled constitution resulting from a loss of nerve force and a pathological condition of the internal organs, they also conceded the importance of environmental factors in its etiology. A common motif was that the business activity of the urban professional or "brain-worker" consumed the nerve force with which he had been endowed. In addition to "domestic trouble," "prolonged anxiety," and "pecuniary embarrassment, leading to nervous exhaustion," Van Deusen's list of predisposing factors also included "prolonged exposure to a malarial region."[4(pp445,446)] During the years before the infectiousness and transmissible nature of malaria were elucidated, the disease was often associated with nervous prostration both in etiology and treatment. Beard wrote, for example: "one of the great afflictions of America-malaria, often complicates neurasthenia; aggravates it, makes it harder to treat, masks and confuses its symptoms; and the two diseases not only exist together, but may be mistaken for each other."

The treatment regimens for neurasthenia were a reflection of theories of the etiology of this condition. Therefore, the treatment of neurasthenia by 19th century physicians was designed to restore the depleted nerve force and help buttress the body's natural healing processes. Rest cures, special diets, and medications that would stimulate the "system," rid the body of "auto-toxic" substances, and procure rest through sedation, were used. Devices were constructed for the application of static electricity, thought to "re-charge" the body's lost nerve force. Retreats were established in the outskirts of urban centers, serving as institutions of rest and relaxation. McComb, of the Emanuel Movement of Boston, offered relief for female sufferers of neurasthenia, through work in the ministry.[13(p481)] Specific treatment for neurasthenia, such as drug choice, was influenced by various schools of thought to which practitio-

ners belonged. Gossling pointed out that the majority of physicians who wrote on neurasthenia were regulars, a term used to describe those physicians subscribing to the traditional therapeutics taught at most medical schools. Other physicians who treated neurasthenia included the homeopaths who generally prescribed smaller doses of medications, and the botanics, who shunned mineral therapeutics such as mercury, and used compounds derived from plants. Electrotherapists, such as Margaret Cleaves of New York City, used devices constructed for the application of static electricity, thought to "recharge" the body's lost nerve force. Gossling emphasized that although a wide variety of clinicians offered different treatments for neurasthenia, the approach to this condition seemed to have been more dependent on the physicians' "collective gender" and class attitudes than on educational background or specialization. [2(pp143–163)] Of the different treatments, medications played a major role in the treatment of neurasthenia during the years after the appearance of Beard's first paper on the subject in 1869.

### Prescription Medicine for Neurasthenia

The long list of drugs used in physicians' prescriptions for the disorder included strychnine, phosphates, bromides, chloral hydrate, alcohol, cocaine, opium, cannabis, and cod liver oil. These were listed in the *United States Dispensatory* which, published since the 1830s, provided physicians with instructions for the preparation and administration of standard therapeutics. Prescriptions were either prepared by physicians themselves or at the pharmacy. Strychnine and its derivative, *nux vomica*, were recognized as stimulants in small doses and poisons in larger ones. Derived from the plant *Strychnos nux vomica*, its use was described by E. H. Van Deusen for one case in 1869: ". . .in the case of a female treated here, a moderate dose of the medication in the evening, followed by a second early in the morning, invariably afforded pleasant relief a few hours afterwards."[4(p460)] Collins and Phillips described that in addition to its "tonifying effect, particularly on the muscular system," strychnine "frequently restores the appetite as does arsenic or quinine."[10(p421)] Commonly known as Peruvian Bark, quinine was derived from several species of the cinchona tree on the western coast of South America and had been used since 1688 for intermittent fevers or agues.[14] This medicine was ranked "first as a nerve tonic" by Van Deusen, who administered it in dilute phosphoric acid, and he found it especially useful in "cases marked by considerable irritability with emaciation."[4(p459)] Tonics were considered substances that fortified the system with a cumulative physiological effect, the increments of which were barely perceptible. Similar to tonics, alteratives were thought to gradually reestablish health with little conspicuous effect. Arsenic was widely used as a tonic and alterative for the treatment of nervous prostration. It was one ingredient of a prescription for a "nerve tonic and sedative" for neurasthenia, along with "coca and citric acid" in 1900.[15] Other alteratives employed as stimulants to counteract neurasthenia were some ammonia preparations including bromide of ammonia salt.

Two other important tonics for neurasthenia were iron and zinc. Recommended by the Dispensatory to "improve the quality of blood" and recognized as an "essential constituent of the red corpuscle," iron was specified in many prescriptions for neurasthenia. . . .[16] These included treatments for what were considered localized conditions



FIGURE 2. A popular medicine for neurasthenia that contained phosphorus (*Science*, 1897, vol 6, copyright American Association for the Advancement of Science).

such as the spinal anemias. George Beard described his use of the zinc preparations, "particularly the bromide, valeriante, and oxide," forms as "sedatives of very great value in various neurasthenias."[1(p152)]

Phosphorus, the element that was observed to be a major component of the nerve cell, was ubiquitous in regimens for the treatment of neurasthenia (Fig 2). Judson B. Andrews, assistant physician in the New York State Lunatic Asylum, described in 1869 the application of dilute phosphoric acid as being a useful tonic for debility of the nervous system when mixed with substances that included "ammonia, glycerine and sherry wine."[17] In 1876, Samuel R. Percy, also of New York, in a prize winning essay, described the injurious effect of phosphoric acid or free phosphorus, that included Bright's disease, a renal affliction. Percy urged that the oxides of phosphorus or hypophosphates were safer and applicable to nervous debility: in one experiment, he administered "hypophosphorus" to a dog, noting that "he was more boisterous in play" and that it acted as a "powerful aphrodisiac."[18] One year later, Edward R. Squibb of Brooklyn, New York, recommended that phosphorus should be dissolved in cod liver oil, writing: "the more effective application seems to be to the functional derangements of the nervous system which are of an adynamic character, or where organic or structural changes are slight. . . ."[19]

Other stimulants in the physicians' armamentarium for neurasthenia included cocaine, cannabis, and caffeine. The 1870 *Dispensatory*, described how the South American natives obtained energy for a several days' journey by chewing the coca leaves, alleged to "support the strength for a considerable time in the absence of food."[16(pp1,591;1,592)] George Beard employed cocaine as a stimulant for the

treatment of his patients, stating in 1880 that "it has, without doubt, a special and most interesting sustaining and tonic power." He also described *Cannabis indica*, as "one of the most trustworthy, most reliable and valuable of remedies," adding that it was beneficial in headache.[1(pp148–151)] Caffeine was often used in conjunction with ergot and belladonna to abate the headache of the neurasthenic. Alcohol, or *Spiritus fermenti*, long known for its stimulating properties, served as an ingredient in many prescriptions for neurasthenia, and Beard recommended wine, particularly claret and burgundy.[1(p156)] J. Leslie Tobey, of Boston, Massachusetts, in his description of psychotherapeutics in 1887, cited a recommendation of Dr Sidney Ringer, for a "glass of bitter beer at meals" to assist "those living in the cities, whose brains are overtaxed, those having much brain work."[20]

Insomnia was a major consideration in treating the neurasthenic and bromides, chloral hydrate and narcotics were among the popular sedatives employed. In his *Treatise on Nervous Prostration*, Beard compared the qualities of the bromides to those of "electricity and massage." He claimed that both "give rest by slowing down the nerve activity."[1(p154)] Physicians treating neurasthenia employed a number of bromides, including salts of sodium, potassium, zinc ammonia, and lithium, often blending them with chloral hydrate. J. S. Greene recorded in the *Boston Medical Journal* of 1883:

> A capacity for taking extra sleep is highly to be prized as a means towards restoration; but some there are who cannot attain it. If the effect of overstrain be heavily visited upon the brain, causing actual insomnia, restlessness, excitability, it is expedient to compel sleep and a dormant disposition by liberal doses of bromides, perhaps to some extent associated with chloral.[21]

Of ten case presentations for neurasthenia in 1872, T. W. Fisher, employed chloral hydrate in the treatment of six cases, and bromides in four others,[22] Van Deusen found morphine useful for insomnia, as well as for pain in neurasthenias; he stated: "relief from intense pain to secure sleep and the strength of the patient, may be produced by the hypodermic use of the acetate of morphia which will generally be found successful." He added that "this with a carefully conducted course of nerve tonics, has in the cases coming under our observation, uniformly restored the patient to his previous health."[4(p455)] Expressing his attitude toward the use of popular hypnotics, Beard stated, ". . .a remedy to be ranked with alcohol and opium is chloral, which is now greatly over-used. . . ." He added, ". . .indeed one of the first signs and proofs of good results of treatment of these cases is that they can dispense with their opium and alcohol or chloral." [1(p154)]

Regulating the patient's nutrition was considered important in restoring his depleted energy reserve. Cod liver oil, alone or combined with phosphorus, was a common nutritive supplement. Urging that cod liver oil ". . .is not merely a nutritive agent. . .", the *Dispensatory* stated that ". . .in consequence of some peculiar principle or principles it contains it exercises a stimulant and alterative influence."[16(p602)] Koumiss, or conjugated milk products and beef tea, were commonly given to neurasthenics. "Oils and fats like cream and butter," according to Beard, "were nerve food."[1(p156)] Foods were often combined with stimulants and tonics in an endless assortment of prescriptions for neurasthenia. One passage from the pen of T. W. Fisher reflected: ". . .rest, strong beef tea at regular intervals, with

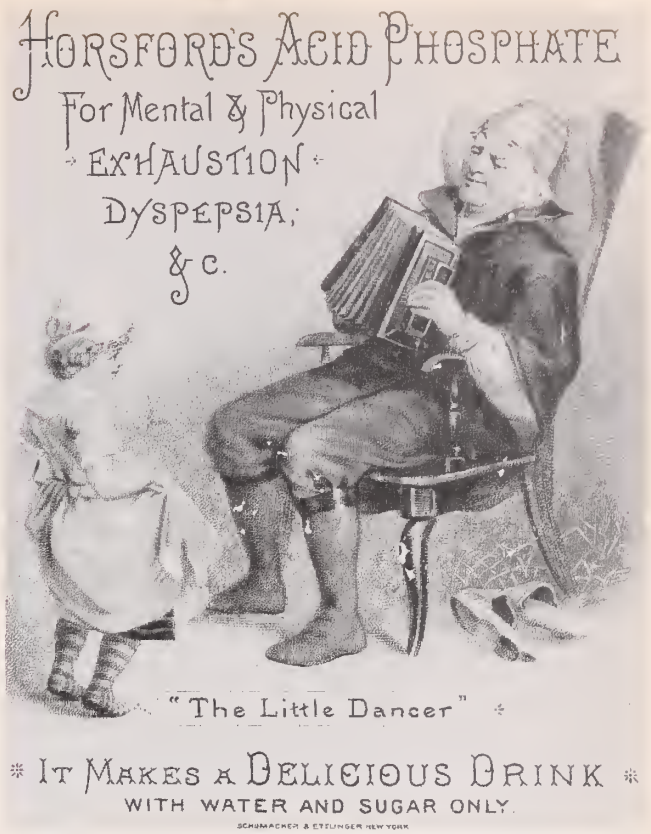


FIGURE 3. A common commercial medicine used for neurasthenia (private collection of John Stea).

capsicum instead of alcohol, seemed first indicated."[22(p65)] Capsicum, or cayenne pepper, was extracted from the plant *Capsicum annucom* and was used as a stimulant.

### Commercial Medications for Neurasthenia

After the Civil War, medical journals were replete with an ever growing number and variety of commercial medicines, and by the 1870s, many were advertised for the treatment of neurasthenia. They ranged from the crude drugs to mixtures of various substances. "Phosphorus as a remedy" headed a full page promotion in one medical journal in 1883, proclaiming the usefulness of a pill that contained ". . .unoxidized phosphorus, strychnine and reduced iron" for the ". . .loss of nerve power, neuralgia and hysteria." In addition to its purported benefit for other conditions, including those of the "cerebro-spinal system as induced by overwork and influences incidental of modern life," the announcement added a regimen to complement "this nerve tonic," including "complete rest of mind, any new hobby or study" and a "very nourishing diet, especially of shellfish."[23] The manufacturer of this pill claimed that another product, Warner's Effervescing Caffeine and Bromide of Potassium, was useful for "sleeplessness, overexertion of the brain, overstudy and nervous debility." While revealing its content of one grain of caffeine to 20 grains of bromide, the ad provided in fine print ". . .it is not a secret remedy and such as the doctors can use with confidence."[24] Another phosphorus preparation, Horsford's Acid Phosphate, was used by Beard as part of one treatment regimen (Fig 3).[2(p33)] This product comprised ingredients including magnesium, calcium, and sodium phosphate. In 1887, an advertisement for this product described a liquid prepara-

tion of the phosphates and phosphoric acid for "dyspepsia, mental and physical exhaustion, nervousness and weakened energy." The contemporary reader could have noted that on the same page was a commercial for Crosby's Vitalized Phosphites. The passage assured that the product used "a vital phosphite, not a laboratory or soda water absurdity." The ingredients of this product consisted of "nerve-given principles of the ox brain," amalgamated with the embryo of the wheat and oat and would benefit "sleeplessness, irritation, nervous exhaustion and inability to work or study."[25] Fellow's Syrup of Hypophosphites, containing "hypophosphites of iron, quinine and strychnine," was advertised in 1902 for the treatment of neurasthenia and also ascribed as effective for the treatment of "anemia, bronchitis and influenza."[26] Several products that manufacturers claimed to be advantageous in the treatment of neurasthenia, illustrated a belief in strengthening the blood among 19th century physicians. Maltine, described as an extract of malted barley, wheat and oats, was purported to contain "nitrogenous constituents," with "a composition identical to the chief constituents of blood," in one 1879 advertisement. The ad provided a detailed explanation of its manufacture, adding that Maltine, when combined with iron, quinine, strychnine and phosphorus, was a "powerful nutritive, general and nervous tonic."[27] One blood-supporting compound was Crinon's Haemoglobin, described in one 1879 advertisement as the "Albuminoid Ferruginous Principal of Blood," useful in cases of "anaemia cachexias, and exhaustion caused by excess of work and nervous debility. . . ." [27(p15)] Dr Buckland's Oats Scotch Essence, a product that actually contained oats, appeared in one medical journal as a "nerve and brain food tonic," yielding "remarkable results for nervous dyspepsia, sleeplessness, opium habit and neurasthenia." It was also described as being in "no sense a patent medicine."[24(p21)]

Other medicines for neurasthenia that were advertised in the medical journals included the "restorative wine of coca," that was promoted in 1887 as a cure for "nervous prostration, brain exhaustion and all forms of mental and physical debility." The advertisement claimed that the neurologist, William A. Hammond, had endorsed the product at the New York Neurological Society. He is quoted as stating in one meeting:

> I therefore asked a well-known gentleman of this city if he would not prepare a good wine and pure alkaloid. He has succeeded on making such a preparation. . . . A wine glass of this tonic taken when one is exhausted and worn out acts as a most excellent restorative. . . . The cocaine appears to have the power to reduce the irritations of the stomach and make it more receptive for food.[24(p24)]

Another testimonial by Hammond appeared in one advertisement for Buffalo Lithia Water, a solution purported to contain "well defined traces of lithia. I also often prescribe it in those cases of Cerebral Hyperaemia, resulting from over-mental work in which the condition called nervous dyspepsia results."[24(p6)] It should be noted that subsequent analysis of most lithia waters of the period, revealed only trace quantities of lithium.

### Patent Medicines for Neurasthenia

Many medicines that were available for direct sale to the public, commonly called patent medicines, carried claims for the cure of neurasthenia and nervous debility. Patent medicine was actually a misnomer, for these products were usually registered under a trademark rather than a patent. The trademark made it possible for the manufacturing process and contents to be maintained in secret. Since many of the more standard medical preparations were also available directly to the public, they too were often termed patent medicines. Popular patent medicines that rarely appeared in the medical journals but were widely consumed included Ayers' Sarsaparilla and Lydia Pinkham's Vegetable compound. Derived from the plant *Smilax officinasus,* Sarsaparilla was regarded for many decades as a panacea, and a tonic. The 1870 *Dispensatory* stated that the herb had been reported to support the body in disease states, including syphilis, rheumatic disease, and mercury poisoning.[16(p782)] Dr Ayers, of Lynn, Massachusetts, boasted in one advertisement, complete with a picture of a forceful lion, that this product would cure "Thin blood, Anemia, Poverty of the blood, Weakness, General Debility, Nervousness, Nerve Exhaustion, Nervous Prostration, Nervous Dyspepsia, Indigestion, Dyspepsia, Skin Diseases, etc. . ."[28] Another native of Lynn, Massachusetts, Lydia Pinkham, developed a very popular patent medicine in 1876. Her vegetable compound contained the ubiquitous alcohol and herbs, including black cohosh. Derived from the plant *Anucifuga rarenosa*, black cohosh was used as a stimulant and a cathartic. Designed for the "worst form of female complaints," the panacea, also promised to cure nervous prostration (Fig 4).[28]

Some preparations for neurasthenia, such as Cherry Malt Phosphites, were presented directly to the public as well as to the medical profession. "A combination of wild cherry, the condensed extract of the important cereals and the elixirs of the hypophosphites of lime and soda," the malt drink occupied an entire page in an 1887 edition of *The Boston Medical and Surgical Journal*.[24(p10)] An advertisement for the same product appeared on a card that same year for distribution to the public. The card depicted a young girl with a dog; the text on the reverse side boasted that the medicine "acts on the stomach and the liver. . .building up the weak and broken down system" and was applicable for the "loss of appetite, headache, insomnia, general debility, malaria and nervous prostration."[30]

Public consumption of the various over-the-counter medicines that were purported to benefit sufferers from neurasthenia and other illnesses, was catalyzed by the availability of almanacs, books and other literature issued by their producers that described their attributes and by advertisements in catalogues and popular journals. In the drug section of one department store catalogue, there were references to 14 patent medicines that claimed to ameliorate nerve weakness, prostration, or debility. Included were Dr Worden's Female Pills for Women, Brown's Vegetable Cure for Female Weakness, and Celery Malt Compound.[31] R. V. Pierce of Buffalo, New York, founder of the Invalid's Hotel and patent medicine manufacturer, wrote descriptions in his popular *Common Sense Medical Advisor* (Fig 5). One apparently satisfied customer who had suffered from nervous prostration stated in a testimonial included in the book, "I am getting along so well with the medicine that I am a standing wonder to my friends, and I shall not cease while life lasts to praise the skill that has brought such miraculous results."[32] The popular book *Household Physician* devoted an entire section to the patent medicines, the writers of the guide asserting that there were some good patent medicines, including Mellin's Food "for those suffer-

LYDIA E. PINKHAM'S
VEGETABLE COMPOUND
IS A POSITIVE CURE,
**For all those painful Complaints and Weaknesses so common to our best female population.**

It will cure entirely the worst form of Female Complaints, all Ovarian troubles, Inflammation and Ulceration, Falling and Displacements, and the consequent Spinal Weakness, and is particularly adapted to the Change of Life.

It will dissolve and expel tumors from the uterus in an early stage of development. The tendency to cancerous humors there is checked very speedily by its use.

It removes faintness, flatulency, destroys all craving for stimulants, and relieves weakness of the stomach. It cures Bloating, Headaches, Nervous Prostration, General Debility, Sleeplessness, Depression and Indigestion.

That feeling of bearing down, causing pain, weight and backache, is always permanently cured by its use.

It will at all times and under all circumstances act in harmony with the laws that govern the female system.

For the cure of Kidney Complaints of either sex this Compound is unsurpassed.

LYDIA E. PINKHAM'S VEGETABLE COMPOUND is prepared at 233 and 235 Western Avenue, Lynn, Mass. Price $1. Six bottles for $5. Sent by mail in the form of pills, also in the form of lozenges, on receipt of price, $1 per box for either. Mrs. Pinkham freely answers all letters of inquiry. Send for pamphlet. Address as above.

No family should be without *LYDIA E. PINKHAM'S LIVER PILLS.* They cure constipation, billiousness, and torpidity of the liver. 25c. per box. — FOR SALE BY

**C. F. HAYES,**
*Plattsburgh, N.Y.*

FIGURE 4. Buried within the plethora of claims for the cure of "Female Complaints," in the advertisement for the patent medicine, Lydia Pinkham's Vegetable Compound, was relief for "Nervous Prostration" (private collection of John Stea).

ing from nervous prostration," Horsford's Acid Phosphate for dyspepsia, and Metcalf's Cocoa Wine as a "stimulating tonic. . .preferable for mental trouble."[33]

### Concerns for the Use of Medication for Neurasthenia

The demand for relief from the 19th century disorder called neurasthenia, paralleled the increase and availability of remedies for the illness. The relationship between the neurasthenic's quest for relief and his faith in available medicines was recognized by Cecil MacCoy, a Brooklyn, New York, neurologist, when he wrote: ". . .neurasthenies are peculiarly liable to suggestion, and the physician who fails to avail himself of its use drops one of the most important articles out of his list of remedial agents. The history of quackery is full of lessons as to the efficacy of faith," MacCoy continued, "as the prime agent in healing."[34] The use of addictive medications within the expanding realm of substances for the relief of neurasthenia, from the standard preparations to the patent medicines, elicited the concerns of many physicians by the late 1800s.

FIGURE 5. R. V. Pierce, New York physician, and patent medicine manufacturer (*The Peoples' Common Sense Medical Advisor in Plain English or Medicine Simplified*, Buffalo, NY, World's Dispensatory Printing Office and Bindery, 1883).

Pointing out the vulnerability to narcotics of individuals who suffered from nervous prostration, Beard wrote in 1880, "when the nervous system loses through any cause much of its nervous force, so that it cannot stand upright with ease and comfort, it leans on the nearest and most convenient artificial support." Chloroform, opium, or alcohol were among the substances that, according to Beard, "may be reported at first an incident, and finally a habit."[1(p49)] F. M. Hamlin of Auburn, New York, estimated that the number of opium addicts in the United States stood at 500,000 in 1885 and, while commenting on the increase in narcotics consumption, he stated:

> How can we account for this wide-spread and enormous increase? While it is evident all the causes cannot be known, there are some so apparent as need mention only. First and greatest of all is the great increase of the so-called "nervous affections." The victims of these diseases are not only likely to become addicted to the habit themselves, but they are begetting a class of neurotics who are prone to morbid cravings and excesses of every kind their choice of alcohol, opium, chloral or hashish as a stimulant seemingly almost dependent upon accident. . . . There is no doubt the introduction of the hypodermic syringe gave a great impetus to the use of morphia and from the curiosity excited by its employment afforded greater opportunities for patients to learn what they are taking and what gave them relief.[35]

Other concerns emerged over the medications used to treat neurasthenia. Reports of side effects and toxicity increasingly surfaced. William Krauss of Buffalo, New York, commented on toxic doses of medicines for nervous disorders in 1900, including strychnine, and urged that the assignment of maximum dosages be given in their application.[36]

The net effect of all these concerns, coupled with the growing disquietude with other medications that were addictive, inadequately labeled and sold directly to the public, was to precipitate action by the American Pharmaceutical Association, the AMA and the general public, who demanded regulation. The Food and Drug Adulteration Law was passed in New York and New Jersey, for example, in 1881 and entrusted the states' boards of health with monitoring the quality of medicines. In addition that year, the state of Illinois moved to regulate the sale of poisons, including substances used commonly to treat neurasthenia, specifying morphine, strychnine, chloral hydrate, belladonna, and zinc sulfate.[37] While the use of medicines for

neurasthenia was modified because of the increased awareness of the potential dangers of the contemporary remedies among the medical community as well as the general public, the mental therapies such as hypnosis and later psychoanalysis and other psychological therapies became important both in its treatment and gradual transformation. Gossling pointed out that medications were the most popular treatment for neurasthenia used by physicians in the late 1870s but by the early 1900s, rest, travel and the mental therapies were more commonly prescribed.[2(p128)]

## Conclusions

The common denominator of the various descriptions of neurasthenia was the presence of fatigue or lack of nervous force. The advertisements of medicines for neurasthenia also revealed an emphasis on the alleviation of exhaustion. In a society that placed great emphasis on strength, industry, and productivity, these symptoms received priority over other features of the disease such as anxiety, depression, and somatic complaints. Victorian physicians recognized that fatigue arose from a number of medical conditions including malaria and consumption or tuberculosis. In addition, 19th century writers on neurasthenia felt that women were endowed with less nerve force, and that the female reproductive system further taxed the nerves, leading to nervous prostration. In the medical and social atmosphere of Victorian America, the subjective experience of exhaustion and malaise were probably related to conditions that we would now categorize under the headings of depression and possibly, such physiological afflictions as premenstrual syndrome or anemia. The higher prevalence of depression among women, together with the premenstrual syndrome, may account for the frequency with which neurasthenia was diagnosed in the female population. Weakness, the symptom common to these conditions, became the cornerstone of the illness known as neurasthenia by the process of filtration through the societal values and medical beliefs of the 19th century.

Many popular and creative people were diagnosed as having neurasthenia during the Victorian era. They included William James, Jane Addams, and Theodore Roosevelt. In his book *American Nervousness 1903*, Lutz examines neurasthenia in the context of societal changes between the Civil War and the first World War. He writes "by 1903, neurasthenic language and representations of neurasthenia were everywhere." Lutz points out that the disease became a marker of status and respectability. By the turn of the century, it permeated every aspect of society.[38] Men and women of distinction who were described as neurasthenic served as role models for people with anxiety, depression, and other psychological conditions, who could identify with their afflicted heroes.

The diagnosis of nervous exhaustion must have proven a dilemma for women in the Victorian Era, whose willingness to accept the condition of weakness imposed by the predominantly male physicians of the period contrasted with their increasing desire to participate in an industrial society. The prevailing attitude among these men was a reflection of the prevalent cultural view that women were the weaker sex. Accordingly most in the medical profession thought women to have weaker nerves. Gossling points out that the causes for neurasthenia most commonly reported for women were genital and reproductive disturbances. Even female physicians such as Margaret Cleaves found women particularly prone to neurasthenia. Many physicians also believed that neurasthenia would be induced in women by emotional stress such as accidents.[2(pp55–62)] It was easier, nevertheless, for female as well as male sufferers from neurasthenia to accept an affliction that was attributable to a physical condition rather than to mental illness. Manufacturers of medicines took advantage of this preference and in their advertising promised the abatement of exhaustion. These ads promised relief from derangements that exhausted the nerves of energy, as well as the reenergizing of weakened nerves to strengthen the body. In Victorian society, these remedies served as a staple for those who were labeled or considered themselves, weak and languid, stemming from a condition that was thought to afflict the best and the brightest. Although psychiatrists today employ efficacious medications that are aggressively advertised by drug companies, many individuals continue to self medicate with various street drugs, including cannabis, cocaine, opiates and alcohol, substances used as medicines by 19th century physicians treating neurasthenia. Much of the uneasiness expressed by the latter group of physicians with the medicines that were at their disposal for the treatment of neurasthenia, was related to adverse side effects and addiction. That such concerns are no mere remnant of a benighted past is attested by the misgivings expressed by contemporary physicians regarding the too easy, too frequent, and inappropriate use of such drugs as the benzodiazopines.

**Acknowledgments.** The authors would like to thank Marvin Lipkowitz, MD, Director of Psychiatry at Maimonides Medical Center for his inspiration in the development of the concept of this paper. In addition, we are grateful to the late Eric T. Carlson, MD, Director of the History of Psychiatry section at Cornell Medical Center for his assistance, and Gorden Mestler, Archivist at State University of New York Health Science Center at Brooklyn Library.

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30. Advertisement card, from private collection of J. Stea.
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# The paradise of quacks

James Harvey Young, PhD

**In a new** nation and a new century, opined the *New York Daily Advertiser* in 1800, quackery ran rampant as never before in America.[1] The country veritably "teemed" with "medical mountebanks." Patent medicine vendors in every town "fattened on the weakness and folly of a deluded public." Nor were the impostors all natives of the New World. "Foreigners who see this growing passion for patent physic leave their homes to try a soil where weeds of this kind flourish with liberal luxuriance. To put a stop to this species of imposition," the newspaper noted, "is an object worthy of legislative interference." Such an approach to quelling quackery, however, lay a century in the future.

The issue of the *Daily Advertiser* denouncing the nostrum boom contained only a single patent medicine advertisement, touting Dr Church's Genuine Vegetable Lotion, a skin disease cure-all. Yet, the paper's lament was accurate. In the expanding press, patent medicine promotion abounded. Whereas most nostrums were not patented, Samuel Lee's Bilious Pills, the first drug to receive this distinction, in 1796, were advertised early in the new century as far from their Connecticut place of origin as Savannah and St Louis.[2]

## The Colonial Legacy

American ingenuity and venturesomeness had not been so evident in the colonial years. An occasional itinerant quack sold health wares with extravagant claims. A New York carpenter vended therapeutic cordials; a Boston grocer, a cough cure; a Charleston goldsmith, an eye-water; a Philadelphia widow who was Benjamin Franklin's mother-in-law, an ointment for the itch.[2(pp17,18)] However, the American market for nostrums, from the early 18th century to the eve of Revolution, was dominated by imports from the mother country.[3] The development of printing had led to a proliferation of newspapers in Britain during the 17th century, their pages soon filled with nostrum advertising.[4] Advertisements for prominent British brands began to appear shortly after the colonial press was established.[3] Major exporters to America had their plants in the center of London, once the location of merchants who earlier had migrated to New England. They shipped their wares in bottles of distinctive shape to retail marketers all along the Atlantic seaboard. Colonial apothecaries, grocers, printers, booksellers, and hairdressers listed in their ads the names of patent medicines just arrived on the latest ships from London. The market grew rapidly until trade interruptions preceding revolution, then war itself, interfered. Some Americans sought to sustain supply by filling empty bottles. When peace returned, British producers sought to regain their lost customers. In 1784, a merchant published in the *New York Packet* a list of the old familiar brands as available for sale:[5]

> Medicines approv'd by royal charter, James, Godfry, Anderson, Court-plaster, With Keyser's, Hooper's, Lockyer's Pills, And Honey Balsam Doctor Hill's; Bateman and Daffy, Jesuits drops, And all the Tinctures of the shops, As Stoughton, Turlington and Greenough, Pure British Oil and Haerlem Ditto.

## The 19th-Century Boom

Overseas merchants, however, were destined for disappointment. The British proprietaries had become in effect American generics. In the powerful spirit of cultural nationalism generated by independence Americans wanted made-in-America patent medicines, be they patented or, as most were, of secret composition.[2(pp31–89)] Common schooling prepared an ever larger part of the population to read nostrum advertising. Prevailing heroic medicine as practiced by orthodox physicians came under increasing criticism, and a wave of do-it-yourself sentiment in health care accompanied the democratic wave associated in politics with Andrew Jackson's name. Even in such a more favorable market, competition among proprietors increased, and they were forced to expand the amount of advertising extolling their wares. The drabness characteristic of colonial promotion began to be replaced by imaginative vigor. Nostrum-makers pioneered the psychology of advertising with such success as to expand sales enormously. By mid-century, a pamphleteer could exclaim that "Yankeedom" was "the Paradise of Quacks."[6] Promoters sought to catch the reader's eye with pictures. The noted woodcut artist Alexander Anderson designed striking devices for at least eight major proprietary products, including Hercules and the hydra for Swaim's Panacea, a cupid for Genuine Court

Address correspondence to Dr Young, PhD, 272 Heaton Park Dr, Decatur, Georgia 30030-1027.

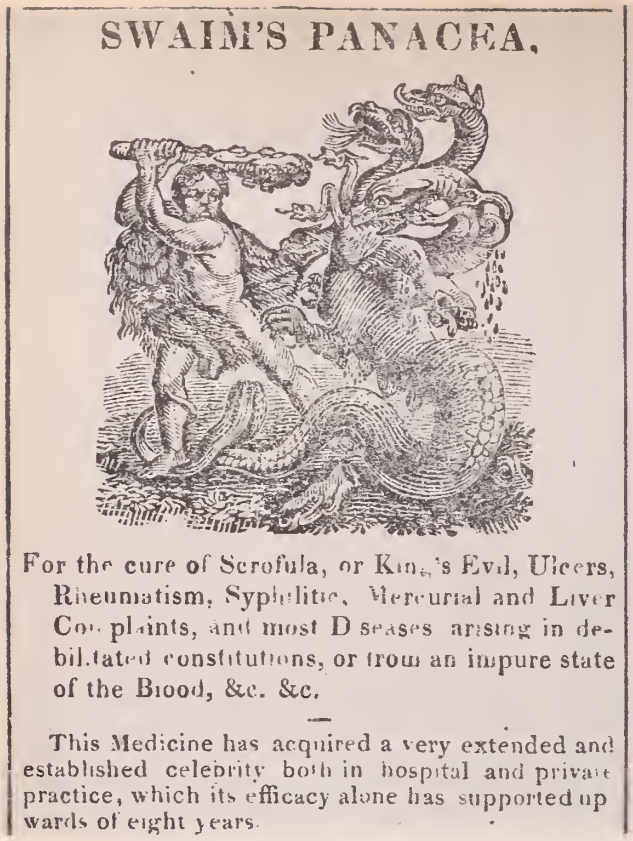


FIGURE 1. William Swaim of Philadelphia chose Hercules battling the Hydra as his mode of suggesting his Panacea's therapeutic power. The medicine contained sarsaparilla, oil of wintergreen, and corrosive sublimate, the most rigorous form of medicinal mercury (from the *Philadelphia Democratic Press*, April 28, 1827; collections of the Library of Congress).

Plaister, a lion for Low's Oriental Saponaceous Compound, and the patriotic eagle for Union Cordia (Fig 1).[7] The eagle flew for other proprietors as well; indeed, patriotism became a dominant theme in nostrum advertising. The Stars and Stripes was much on display.[8] One firm printed the Constitution, running red-ink pitches for its bitters along the borders.[9] Presidents to be, like William Henry Harrison, and presidents out of office, like Martin Van Buren, seemed to testify for the efficacy of certain nostrums.[10] Representing the Supreme Court, the great John Marshall was advertised as having endorsed Gray's Invaluable Patent Ointment.[11] In due course, 50 members of the Congress would praise Pe-ru-na, the highly alcoholic remedy for catarrh (Fig 2).[12]

Other themes that sparked public interest found their way into patent medicine promotion: the consolation of religion, the mystery of the long ago and far away, the contrasting allure of the very new as represented by science and technology, the ambivalent image of that child of nature, the Native American (Fig 3).[2(pp165–189)] Not only presidents, but the famous in other endeavors, like stage stars and sports heroes, were called upon to proclaim the merits of pills and potions. Yet, as a newspaper editor explained, testimonials "signed by plain, everyday working people" were "regarded as more valuable than the indorsement of celebrities."[13] Such assurance that others had been cured bolstered belief in the proprietor's promises. By converting common experiences like weariness, sluggishness, gloominess, nervousness, and spots before the eyes


FIGURE 2. Pe-ru-na, a high alcohol nostrum made in Cincinnati, at the turn of the century had the highest sales volume among American proprietary medicines (from the *Montgomery Advertiser*, January 17, 1904).

into harbingers of dread diseases, nostrum advertisers sought to frighten readers into believing they were doomed unless salvation be secured only by taking the proprietor's product. Explicit claims were made for the certain cure of the most feared ailments. During the nation's centennial year, the respected *Harper's Weekly* contained ads for sure cures of asthma, cancer, cholera, consumption, diabetes, diphtheria, epilepsy, gout, hay fever, nervous ailments, opium addiction, and rheumatism (Fig 4).[14] The magazine was too genteel to accept advertisements for abortifacients and for medicines to cure venereal disease and restore lost manhood, but these could be found in many religious periodicals and almost any metropolitan daily.

Recent scholarship has been less judgmental in discussing unorthodox medical practitioners of the past, including

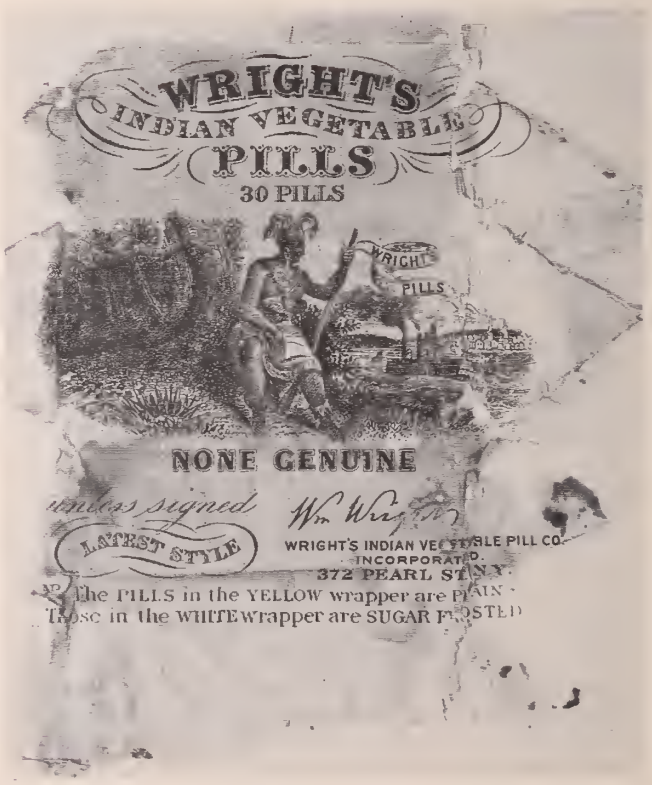


FIGURE 3. Wright's Indian Vegetable Pills featured in the mid-19th century the Native American's purported skill in bringing botanicals from the forest to cure the ills of white city residents (from the author's collection).

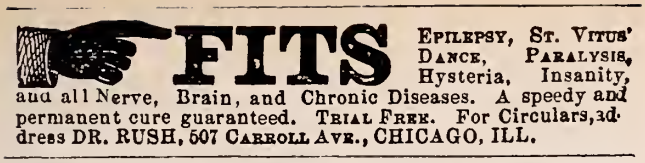


FIGURE 4. In 1876, the genteel *Harper's Weekly*, most popular magazine in the nation, accepted advertising for such dire ailments as epilepsy[14(p234)] and narcotic addiction[14(p1063)].

quacks, than earlier had been the case.[15] J. Worth Estes has demonstrated that the ingredients of many 19th-century patent medicines were the same as those in regular use by orthodox physicians and that therapeutic theories inherent in much nostrum labeling and advertising were in accord with prevailing concepts of professional medicine.[16] Nevertheless, blatant quackery did run rampant.

To define quackery in an earlier age, therefore, looking backward from present perspectives to a time in which medical efficacy rested on less developed scientific foundations, motive must be taken into account. Making categorical claims to cure diseases then recognized by responsible medicine as incurable can be denominated quackery. Making any therapeutic claims for sugar pills or pure pine oil or any other inert ingredient or mixture can also be considered health fraud. The boozers and bracers, their high proof unlabeled and their remedial promises false, must be condemned. So must narcotic soothing syrups for the travails of teething that brought babies to addiction and sometimes to death.

Even some of the patent medicines depending on the use of orthodox ingredients might warrant rebuke. So thought a committee of the Medical Society of the City of New York in 1827 after studying three prominent nostrums, Chambers' Remedy for Intemperance, Leroy's Medicine Curative, and Swaim's Panacea.[17] While discovering that all three contained ingredients useful in therapy, the physicians nevertheless condemned them. "If the untaught empiric be permitted to seize upon the approved remedies of the art," the committee concluded, "and, in order to speculate on suffering credulity, veil them under the specious garb of secrecy, their partial success will confer upon their order, an importance and character that could not be otherwise attained, to the serious detriment of the healing art."

Most military, social, and economic developments during the second half of the 19th century accelerated the boom in patent medicines.[2(pp93–110,140,141)] During the Civil War, proprietors dumped their remedies wholesale on the Union armies, and the troops took the medicine habit home to their families. The war brought the burden of a tax on proprietaries, but the private die tax stamps that the companies were permitted to design became an effective form of promotion. Fighting the tax brought proprietors together in a trade association that developed potent lobbying skills in state legislatures and the national Congress. Patent medicine makers had pioneered national marketing, and postwar expansion of national transportation and communication networks enhanced this advantage. Advertising became more sophisticated in message, design, and placement. Woodcuts were replaced by lithographs, then lithographs by photoengraving (Fig 5). Nostrum almanacs, in a dozen appropriate languages, entered almost every home in the land. One proprietor boasted that his almanacs were second only to the Bible in circulation. In prewar days a pill promoter, Benjamin Brandreth, reached




FIGURE 5. The Rochester proprietors of Duffy's Pure Malt Whiskey collected for a small fee testimonials from centenarians in the nation's old folks homes attributing their long life to taking Duffy's nostrum (courtesy of the History Office, FDA).

$100,000 in his annual advertising outlay. Toward the end of the century, the proprietors of Scott's Emulsion and Lydia E. Pinkham's Vegetable Compound each spent $1 million a year. As the 20th century began, proprietary medicines stood at the head of the list of product categories in money spent each year for magazine advertising (Fig 6).

### Rising Critique and Initial Legal Restraint

On the debit side, from the proprietors' perspective, was an increasing criticism of their products. As the sciences developed, this censure became more trenchant; however, it was generally limited to the pages of medical and pharmacy journals, seldom reaching the attention of habitual nostrum buyers. The hazards in patent medicines, however, did concern some state legislators who, beginning in the 1880s, began to propose formula disclosure bills and to include anti-nostrum provisions in food and drug bills.[2(pp228,229)] The Proprietary Association, aided by newspaper publishers who feared loss of advertising, defeated most such measures. In addition, for many years this alliance kept proprietary remedies out of the definition of drugs in a series of national food and drugs bills that had been before the Congress since 1879.

Such a law did not come until 1906, and public concern about nostrums was a significant factor in moving Congress to act.[2(pp205–244)] In 1904, a Senate bill defined drugs broadly enough to encompass patent medicines. The year before, Harvey Washington Wiley, chief of the Bureau of Chemistry of the Department of Agriculture and generalissimo of


Painting of the Statue of Liberty in the Harbor of New York. Presented to M. Mariani by Bartholdi.

"Vin Mariani" seems to brighten and increase all our faculties; this precious wine will give me the strength to carry out certain other projects already formed, for which accept thanks from yours cordially

Commandeur Légion d'honneur. Bartholdi.

FIGURE 6. In an advertising book for the American market, the designer and builder of the Statue of Liberty praised a wine and coca nostrum made in France. Facing title page of *Collective Testimony of the Benefit and Virtue of the Famous French Tonic Vin Mariana* (New York, Mariana & Co, 1910; collections of the Library of Congress).

forces fighting for a law, had first spoken out strongly against the nostrum evil. In 1905, Samuel Hopkins Adams began publication of a series of articles in *Collier's* characterizing patent medicines as "The Great American Fraud." Born in Dunkirk, New York, the son of a minister, Adams had gone to Hamilton College and had then honed his journalistic style by crime reporting on the *New York Sun.*[18] He brought both moral indignation and a respect for hard facts to the nascent muckraking movement that sought to expose the misdeeds of American business and politics.

"Gullible America," Adams began his first article, "will spend this year some seventy-five millions of dollars in the purchase of patent medicines. In consideration of this sum it will swallow huge quantities of alcohol, an appalling amount of opiates and narcotics, a wide assortment of varied drugs ranging from powerful and dangerous heart depressants to insidious liver stimulants, and far in excess of all other ingredients, undiluted fraud. For fraud, exploited by the skillfulest of advertising bunco men, is the basis of the trade."[19]

Through his series, Adams buttressed his opening generalization with explicit details, trade name by trade name, about nostrums preying on public fear during epidemics, boozers and bracers converting unwary users into alcoholics, alleged germ-killers containing 99% water, cocaine catarrh powders leading to addiction, pain-killers conducive to heart trouble, and purported sure-cures for incurable diseases. At all levels of the patent medicine business, Adams concluded, "relentless greed sets the trap, and death is partner in the enterprise."[19(p20)] Patent medicines figured prominently in the final debates before the 1906 law was passed, and that measure paid them significant attention.[20] The presence and amounts of certain dangerous drugs—alcohol, opiates, cocaine, chloral hydrate, acetanilide, and several others—must be given on the container's label. All other information provided must be accurate, for the law banned "any statement, design, or device" regarding the medicine or its ingredients that was "false or misleading in any particular." The 1906 law did not aim at curtailing self-medication with proprietary remedies but sought to make the practice safer.

The mere existence of the law brought some self-reform among proprietors, especially a reduction of opiates and alcohol in medications and greater restraint in labeling promises,[21] but the net gain seemed small. "So far as I have gone," Adams wrote Wiley in 1907, "I find a general disposition to obey the law in the letter, though to evade it as far as possible in the spirit." "Our experience," Wiley replied, "is in accord with yours."[22] Wiley, in charge of initiating enforcement actions, gave food his highest priority but launched attacks on the most flagrant abuses respecting self-dosage medications. Campaigns began against headache cures, germicides, treatments for narcotic addiction, broad-gauge tonics, male-weakness remedies, and cancer cures. However, then regulatory initiative hit the stone wall of the Supreme Court.

An eclectic physician named Johnson in Kansas City replied to the charge that his "Mild Combination Treatment for Cancer" was misbranded by denying that the law's taboo on false and misleading promises in labeling applied to therapeutic promises. When the appeals had run their course, the Supreme Court agreed. Congress was not likely to legislate, Justice Oliver Wendell Holmes surmised, in the debatable realm of what could cure and what could not.[23] President William Howard Taft, pointing out that the high court's decision would force the withdrawal of 150 cases pending in the courts, asked Congress to plug the hole.[24] The amendment enacted declared a medication misbranded if the package bore a statement or design "regarding the curative or therapeutic effect of such article . . .which is false and fraudulent."[25] Quackery did not exist unless the promoter's motive could be proven impure. Although many cases were brought by the Bureau and by its successor, the Food and Drug Administration, during the next quarter century and most of them were won, the burden of proving fraud considerably hampered the control of quackery. So too did omissions in the 1906 law. The misbranding provisions applied only to labeling; advertising was in no way restrained. So a general migration of therapeutic claims took place from nostrum packages to the pages of newspapers and magazines. The law, moreover, applied to foods and drugs but not to devices. The long parade of gadgetry with alleged healing powers that had marched through earlier American history now expanded,[26] even though postal fraud actions offered some

restraint.[21(pp66–87)] Shortly a San Francisco physician, Albert Abrams, profiting from public fascination with the wonders of radio, would develop devices that, he proclaimed, could both diagnose and cure dire diseases over vast distances.[27]

### Waxing and Waning of Regulation

In 1938, the Food, Drug, and Cosmetic (FDC) Act replaced the 1906 law, a New Deal measure coming at the end of a five-year struggle in Congress during which industrial lobbying had been intense.[28] While the Food and Drug Administration (FDA) had lost a bureaucratic contest with the Federal Trade Commission as to which agency should police nostrum advertising, a second new law increased the latter's authority.[29] In other ways, the new FDC act gave the FDA greater powers of control over quackery. The law introduced control over medical devices. The fraud joker was eliminated: medical science had developed to the extent that the motive of a drug marketer who used false or misleading labeling no longer mattered. Those who transgressed from ignorance as well as those from malice were guilty under the law, both equally deemed a menace to the public health. False labeling was expanded to include not only erroneous positive statements, but also the failure to reveal germane facts, especially the omission of needed warnings. Drugs dangerous to health when used according to directions were outlawed. Drugs and devices that aimed at affecting the body's structure were covered, like those aimed at weight reduction. For non-official drugs, labels must state the common names of all active ingredients, and for a list of potent drugs and habit-forming substances, quantity had to be given. Purported antiseptics must be truly germicidal. New drugs could not be marketed until their sponsors had persuaded Food and Drug officials that the drugs were safe for use under the directions on the label.

During the 1940s and 1950s, the Food and Drug Administration used its new powers to suppress the most hazardous deceptions.[21(pp191–289,333–389)] A dried thyroid reducing remedy was removed from the market. So were dangerous pain-killers containing cinchophen, aminopyrine, and bromides. Corrosive abortifacient pastes were attacked. A host of dangerous devices were taken to court: nipple shields, bust developers, pile pipes, a battery-powered cure-all named the Electreat Mechanical Heart, and several descendants of Abrams's cure-over-distance gadgetry. An upsurge of nutritional scams, several of them large door-to-door operations, forced FDA to launch actions aimed at restraining excessive claims. The agency closed a dubious diabetes clinic that took patients off insulin and dosed them instead with vinegar and saltpeter. In addition, FDA waged a ten-year campaign to stop Harry Hoxsey from using ineffective medications to treat cancer at his clinic in Dallas (Fig 7).

After all of FDA's efforts at wielding its new weapons, however, the gains seemed so small. Commissioner George Larrick, commenting in 1955 on the agency's "unfinished business," asserted that amazingly the "good old days" of quackery continued "to a very great extent."[30] A journalist put the annual cost to the American public at a billion dollars.[31] The belligerence with which major promoters fought back against regulators seemed astounding. Leaders of unorthodoxy also leagued together for purposes of propaganda and lobbying, and their efforts seemed to be influencing public opinion.

The dangers of burgeoning health fraud struck quackery's foes in the regulatory and medical communities as so


FIGURE 7. The FDA exposed the inability of a horsetail weed nostrum to cure diabetes during the agency's campaign in the 1930s to gain public support for stronger food and drug legislation (courtesy of the History Office, FDA).

threatening that intensified efforts to combat them seemed indispensable.[21(pp402–422)] The American Medical Association and the Food and Drug Administration combined to sponsor in 1961 a National Congress on Medical Quackery to focus the bright spotlight of publicity on the methods and hazards of pseudoscience in health.[32] Three more such congresses followed before the decade ended. Journalists spread the message in the popular media, often doing their own investigations of quack enterprises. Simultaneously the FDA, the FTC, and the Post Office mail fraud division intensified their efforts to enforce the laws against health fraud, placing special emphasis on nutrition nonsense and device deception. The FDA secured a new weapon with the enactment in 1962 of the Kefauver-Harris Amendments, which required proof of efficacy before a new drug could be marketed.[33] Under this law, the agency was able to halt interstate distribution of the falsely claimed cancer "cure," Krebiozen. Many other victories were won by the regulators, but whether the tide of battle had swung their way seemed doubtful. At the third congress on quackery in 1966, a medicolegal prosecutor from California estimated the "overall annual quackery take" in the nation at "two or more billion."[34]

The reasons for the continuing creep upward in health fraud were many and complex.[35] One was the vigor with which the champions of unorthodox therapies fought back. They organized countercongresses and health fairs to publicize their alternative approaches. While condemning their opponents for conspiracy, they brought their own separate segments into tighter liaison, energizing their faithful customers for protest demonstrations and letter-writing campaigns to regulatory agencies and legislative bodies. They centered their propaganda on cherished themes like "liberty" and "freedom." In addition, they increased the subtlety of their promotion, being more careful with their labeling and advertising while placing claims for their products in first-amendment protected magazine articles and paperback books as well as in radio and television programs.

Elements in the broader cultural climate helped quackery to flourish. The 1960s witnessed a rebellion against traditional authorities. Vietnam and Watergate left a legacy of disillusionment with big government, including its regulatory role. Environmental alarms, especially regarding nuclear power, bred skepticism of big science, not least government's scientific function. Novelist Kurt Vonnegut, in time, gave this perspective ironic expression in a commencement address: "We would be a lot safer if Government would take its money out of science and put it in

astrology and reading palms."[36] Astrology, indeed, was soaring, making millions for publishers. Palmistry, numerology, and tarot cards gained great popularity. Paperbacks on these themes were among the fastest selling items in university bookstores from Cambridge to Berkeley.[37] "Witches," a magazine reported, "are surfacing everywhere."[38] Such an atmosphere did not foster a rational approach toward health. "Magic in medicine is back," observed Lewis Thomas, "and in full force."[39]

The new climate deepened the abiding reservoir of susceptibility to quackery resting on such factors as ignorance, gullibility, the placebo effect, a suspicion of elites, the miss-no-bets attitude, and panic when confronted with the diagnosis of a dread disease.[40] No physician should be surprised, William Osler once remarked, if he should "discover accidentally a case of Warner's Safe Cure in the bedroom of. . .[his] best patient."[41]

One other crucial factor aided the expansion of unorthodoxy in the 1970s. The antiquackery crusade of the previous decade declined from its high plateau of intensity.[42] The American Medical Association, dominant in the campaign of nostrum fighting since early in the century, while not abandoning the role entirely, in 1975 abolished its quackery committee and its Department of Investigation. Liaison among regulatory agencies and voluntary health associations languished. Their major joint educational campaign against quackery lapsed. Federal regulators, with many duties to perform and tight budgets, gave combating quackery a lower priority, especially schemes that cheated but did not pose threats to health. Food and Drug Commissioner Arthur Hull Hayes, Jr, commented in retrospect that the agency had been "simply over-matched. . . . There are too many quacks, too skilled at the quick change of address and product name, for the cumbersome procedures of FDA."[43] Congressman Claude Pepper agreed that the regulatory agencies had not been doing a satisfactory job. The recent boom in quackery, he concluded in 1984, had resulted from its "immense profitability and apparent absence of risk."[44]

Congress itself shared the blame. Pressed by the mounting mail stimulated by the leaders of nutritional unorthodoxy, Congress in 1976 enacted a law sharply reducing the FDA's authority to control over-the-counter nutritional products.[45,46] The media also played a heavy role. The interpretation of unorthodoxy in print and over the airwaves largely lost the skepticism of the sixties and presented instead a favorable view. Especially was this true of the checkout-counter tabloid press, in which science, David Leff observed, amounted to a "neo-medieval fantasy world of magic, mystery and miracle."[47]

## Recent Revival of Concern

At the hearing of Congressman Claude Pepper's subcommittee in 1984, Victor Herbert, then a professor at the New York Downstate Medical Center and now at the Mount Sinai School of Medicine, gave his educated estimate of the nation's annual quackery financial toll.[44(pp88–91)] He put the figure at $25 to $26 billion, a more than 12-fold increase since John Miner's estimate in 1966. Herbert sought to categorize the types of quackery on which the largest sums were squandered. Six billion dollars went for "food supplement, pill, powder and potion quackery," and about $3 billion each for arthritis, cancer, and heart disease quackery.

The Pepper subcommittee's inquiry with the attendant publicity was one force reawakening concern about quackery's growing presence. Another factor was the persisting battle over Laetrile, the specious cancer drug, being fought in state legislatures, federal courts, regulatory agencies, and the realm of public opinion.[46(pp205–255)] Never before had a single unorthodox health substance developed such powerfully organized and well-financed pressure groups to contest for its acceptance, seeking to override the legal procedure for admitting new drugs. Still a third crucial event was the arrival of acquired immunodeficiency syndrome, a fearsome incurable disease, spawning a plethora of fake cures and preventives, "a jungle of truly questionable and quack products," as Commissioner Angelo J. Aponte of the New York Department of Consumer Affairs put it.[46(pp256–285),48] Anti-quackery forces revived their alliances and resumed the battle. The war was to be fought on many fronts, not least the ideological. The ranks of unorthodoxy were proclaiming a counter-paradigm to that of scientific medicine, two philosophers pointed out, seeking to persuade the public that their logic was sounder, their therapy more effective than those of the medical establishment.[49] "Too many people seem willing to swallow the rhetoric—even too many medical doctors—and," the philosophers asserted, "the result will not be benign." A recent assessment escalates the nation's annual quackery imposition to $40 billion.[50] America may still be deemed a paradise of quacks.

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# Kindly medicines

## A history of the physio-medicals in American medicine

JOHN HALLER, JR, PHD

**The school of** physio-medicalism originated with the founding of the Botanico-Medical Institute in Columbus, Ohio, in 1939. Seven additional colleges were established before the Civil War; all but two closed before 1862. A scattered few opened in the last quarter of the 19th century and followed a similar fate. The physios, as they were popularly known, were direct descendants of Samuel Thomson's botanic medicine and emerged as a separate school under the leadership of Alva Curtis (1797–1881) in the 1840s. Until its last college closed in 1911, physio-medicalism remained the lone surviving element of reform Thomsonianism in the United States. Its history illuminates both the promises and the delusions of 19th century sectarian medicine.

### THOMSONIANISM

Physio-medicalism originated in the observations, experiences, discoveries, and declarations of Samuel Thomson (1769–1843) of Alstead, New Hampshire, who founded a patented system of botanic therapeutics in the 1820s that spread through the northeast, south, and middle-west with a fervor that paralleled the growth and popularity of religious sectarianism in the early 19th century (Fig 1). There was little new in Thomson's medicine bag: the substitution of botanic medicines for mineral drugs, and a therapeutic regime that promised to clean out the intestinal tract and feed the patient tonics that had been popular among the Native Americans. The principles of his system, however, were surprisingly similar to regular medicine in both philosophy and effect. Nevertheless, his followers credited him with starting "one of the grandest reforms that has ever yet claimed the attention of any people."[1,2] The particular strength of Thomson's popularity lay in his democratic appeal, offering to all who were willing to pay $20 for rights to his 1813 patent (renewed in 1823 and again in 1837), the opportunity to cure themselves of sickness and disease without dependence on the pretensions of a learned profession. Here was a calling open to men and women alike, a system of self-help which allowed families to meet their health needs by a patented process of therapeutic measures. In the heyday of Thomson's leadership, the movement opposed the establishment of medical schools, infirmaries, and medical societies—all of which implied the need for a professional medical class. Instead, Thomson (known affectionately as "Old Sammy"), offered a system of health care compatible with the do-it-yourself philosophy of the common man. Although regulars condemned Thomson as an ignorant farmer, his success at marketing his patented system far outpaced his enemies' expectations given his "unlettered" background. The principles which he advocated in his *New Guide to Health* (1825), especially the idea of non-poisonous medication, appealed to a broad spectrum of American society. Indeed, Thomson's patented system offered a non-threatening alternative to the regulars' use of depletive drugs and practices in treating fevers, colics, dysentery, rheumatism, and other illnesses where sweating was deemed efficacious.[3–8]

Things were not always as they seemed, however. After a decade or more of Thomson's authoritarian and anti-intellectual leadership, the botanic movement matured to the degree that his followers began establishing infirmaries and advocating formal education as an essential component of the movement's future.[9] Those followers of Thomson who came from the "more liberal and better educated classes," felt strongly the necessity of medical education to prepare doctors for their profession. These same individuals considered it important to expand Thomson's materia medica to include other remedies, most of which the founder vigorously opposed. This deviation in the practice of herbal medicine resulted in a schism that marked the end of Thomson's personal influence over the movement and the emergence of an era of new leadership.[3(p237)]

Much of the criticism leveled at Thomson derived from his decision to limit his health care system to those who had bought the rights to his patent. Moreover, he opposed the establishment of medical colleges, insisting that medical

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FIGURE 1. Samuel Thomson (courtesy, New York Academy of Medicine).

education had become the private reserve of educational elitists. Instead, Thomson favored the establishment of Friendly Botanical Societies whose avowed purpose was to share information and cures and thereby bridge gaps in individual practice and experience. He thus tied himself to a position that opposed instruction in anatomy, surgery, and other branches of medical science, and his more intellectual and educated followers soon became restless. According to botanic reformer E. Anthony writing in 1886, those who had cast their lot with Thomson and followed his example had foolishly turned against education. Nevertheless, it became "plainly evident that uneducated men could not any longer compete with those who possessed even a meager collegiate education." Given the predicament Thomson had forced on the botanics, and believing that his narrow views had delayed the progress of botanic medicine, those who had admired and supported his cause soon found it necessary to break from his grasp. "Had he wielded the same influence for the organization of colleges, that he did in the establishment of his practice," concluded Anthony, "there might be today a prosperous college in every State in the Union."[3(p232–233)]

### The Physio-Medicals

In contrast with Thomson who explained the purpose and extent of the practitioners education as the "study of patients, not books, experience, not reading," Alva Curtis encouraged a didactic education that more closely paralleled contemporary medical training. Consistent with this approach, he advocated the establishment of colleges and infirmaries in Maryland, Georgia, Mississippi, Tennessee, Ohio, and New York, dedicated to the theory and practice of "sanative" (supportive) medicine. Over a period of two decades, Curtis and this reform wing of Independent Thomsonians transformed the self-help movement of Thomson from a highly charged mass movement representing grass roots democracy, anti-monopoly, and a therapeutic regimen of steam and puke, into a school of medicine that was quasi-intellectual, boasting a half dozen medical colleges that borrowed heavily from the symbols of science and regular medicine.[9(p426),10(p337)]

Although the physios regarded Thomson as the founder of botanic medicine, they recognized Curtis as the venerable father of physio-medicalism. Born in Columbia, New Hampshire, Alva was the son of Chauncey Curtis, a soldier of the American Revolution. In 1815, he became a teacher of Latin and mathematics on Long Island. After three years, he used his savings to enroll in a two-year program at Union College. When one of his brothers reportedly died from a mercurial treatment, Alva became attracted to medicine but, lacking money, accepted charge of the female department of Wenton Academy. During that time, he studied medicine under the mentorship of a Dr McKelway and discovered what he believed were well-founded objections to allopathic practice.

In 1820, Curtis enrolled in a course of lectures on botany, followed by a year of traveling around the country, supporting himself by selling book subscriptions. In 1821, he moved to Richmond, Virginia, where he taught language in Mrs Broomes Female Seminary. In 1827, he opened his own seminary and, although the evidence is not clear, he supposedly became enamored with the abolitionist ideas of William Lloyd Garrison. In 1831, he converted to Thomsonianism after seeing its effects on his sister and brother and, during the cholera epidemic of 1832, treated students and himself in accordance with the Thomsonian method. In practicing Thomsonianism, Curtis simply availed himself of a movement already rooted in Virginia through the earlier efforts of William Fonerden, a clergyman and botanic healer. Before long, however, Curtis became the movements best known figure in Virginia where, having become a general agent, he marketed Thomsonian books, patents, and medicines; organized Friendly Societies; popularized the sect's extraordinary cures; castigated traditional medicine; offered instruction; and managed an infirmary.[11(p173)]

Curtis' decision to support Garrison and to practice Thomsonian medicine brought opposition from the community, including the medical fraternity; not surprisingly, his actions resulted in a decline in the academy's enrollments. Forced to close the school, Curtis moved to Columbus, Ohio, in 1834 where he devoted himself exclusively to the practice of medicine and gathered around him a number of students and enthusiastic disciples. In 1835, Curtis assumed editorship (replacing Thomas Hersey) of the *Thomsonian Recorder* (1832–1890), the first periodical marketed in the West in the interest of Thomson's botanic medicines. The journal was published by Jarvis Pike and Company and subsidized by Thomson, who utilized it as the sect's official organ. Curtis also opened the unchartered Botanico Medical College and Infirmary in April of 1836 to instruct others in the practice of sanative medicine. Although the school started without a charter—and certainly contrary to Thomson's own bias against the establishment of medical schools—it did not lack students, many of whom followed Curtis from Virginia.[5(p325),11,12] Ever an entrepreneur, Curtis encouraged botanic societies to raise a fund for the education of young men who could be sent to the college for training. By selecting those "of the best talents and moral principles, and lend them, without interest, on bond payable when they shall have earned the money (say yearly after they enter practice) so much as they shall need to enable them to prepare themselves well for the work," Curtis thought he had found an alternative source of "thorough-bred Thomsonians" to counter the elitist ranks of allopathic medicine.[13]

In response to inquiries respecting the school, Curtis gave the following information:

> On the first of April we commenced the systematic and constant instruction of a Class of young gentlemen, in the true theory and Practice of Medicine. The principles of the science are clearly explained and illustrated, in so great a variety of ways as to fix them permanently in the mind. Our practice affords ample means of exhibiting to students the symptoms of disease, the modus operandi of medicines, and the various and most convenient and proper

ways and means of rendering the remedial agents and the curative processes effectual. The science of Botany is familiarly and practically taught in such a manner as not only to acquaint the student with the botanic Materia Medica; but to enable him to examine the whole vegetable kingdom with pleasure and profit. It is illustrated, not merely by books and plates, but by anatomical examinations of the natural subjects, and by oral instructions in the field, as well as in the lecture room. Each student is taught to label and preserve plants for his future benefit. Instructions are given and Lectures delivered on Natural Philosophy and Chemistry. Much attention is devoted to Midwifery, and the forms of disease peculiar to women and children. Anatomy, Physiology and Surgery receive all desirable attention, and the old theories and practices meet their just due, in thorough examination, and comparison with the Botanic.[14]

Curtis used a variety of texts in his instruction, including Thomson's *New Guide to Health*, Samuel Robinson's *A Course of Fifteen Lectures*, articles from the *Thomsonian Recorder*, Constantine S. Rafinesque's *Medical Flora*, Benjamin Smith Barton's *Elements of Botany*, Amos Eaton's *Manual of Botany*, and his own books. He offered students use of his library and a room in which lectures and instruction were given. Tuition was a dollar a week, plus an additional three dollars weekly for room and board. The course lasted from six to 18 months, depending on the students background and abilities.[7,8,15–18]

The first chartered medical school of the Thomsonian schismatics was the Literary and Botanico-Medical Institute of Ohio, founded by Curtis on March 3, 1839, in Columbus, Ohio. Its first class opened with 12 students, and lectures were given three months each year. In 1841, the college moved to Cincinnati, where it changed names regularly (sometimes called the Botanico-Medical Institute, the Botanico-Medical College, or Literary and Scientific Institute) until 1850 when it adopted the name Physio Medical College until closing in 1880. The first home for the college in Cincinnati was Madame Trollope's Bazaar Building (Fig 2). The college later moved to several other buildings but none had the flair and reputation of the Bazaar, one of the city's more notable historic structures.[19]

During its years in Cincinnati, the college became the intellectual center for the Independent Thomsonians, later known as the physio-pathists in the east and the physio-medicals in the mid-west. These appellations did not come without controversy; indeed, the reform wing of the Thomsonians suffered from the effects of regionalism, the lack of an enduring national association, and the fact that botanic reformers seemed less suited by temperament to a single source of authority (Fig 3). As a result, the names "medical reformer," "physio-pathic," and "physio-medical," were used interchangeably in the early years following the schism.[11(p172)]

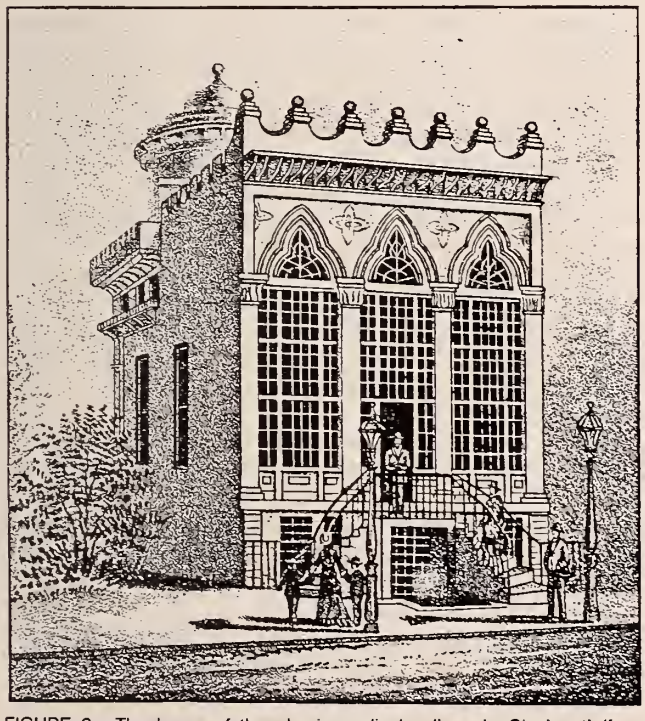

FIGURE 2. The home of the physio-medical college in Cincinnati (from Juettner O[19]).

## Natural or Sanative Medicine

Physio-medicalism was based on the principles of science, art, and reformation. In science, the physios abandoned all chemical or materialistic theories of life and substituted a physiology based on the concept of vitalism and on the inherent power of the body's vital force. In art, they promoted the physicians power to cure based on the



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FIGURE 3. Advertisement for a course of study at the Chicago Physio-Medical College, 1893 (from Juettner O[19]).

belief that Nature served as parent and guide to the judicious employment of measures that were in harmony with the body's vital force. Thus, the physician had the duty to assist the life power or vital principle by using only those measures. Finally, the physios demanded the same recognition accorded other schools of medicine. This meant the opportunity to work in army and navy hospitals, asylums, and other institutions supported by public taxes; equal privileges with other schools in all medical laws; equal representation on all state medical boards; and exemption from any professional "rulings" that were made in their absence. Throughout their history, the physios made every effort to characterize regular or allopathic medicine as the mirror image of religious orthodoxy and themselves as righteous and patriotic reformers seeking a more volunteeristic approach to health care.[20]

Since the first great principle of physio-medical practice was the belief in vitalism, the vital force, and not the physician, was the essential healer of disease. Although the physician should sometimes "lead" vital force, he must never "supersede or usurp its legitimate province." This meant working with vital force, not against it; aiding the *vis medicatrix naturae*, or the healing power of nature, not hindering it; using "sanative" therapeutics, not toxic agents; sustaining and guiding vital action, not destroying it; and relying on repletion, not depletion.[21(p317,324)]

The system of physio-medicalism claimed to be founded strictly on the immutable and infallible laws of nature. This idea, represented in the term "natural medicine," held that physio-medicalism was error free and guided solely by the laws of nature. Fever, inflammation, and irritation were simply manifestations of the vital force attempting to cure disease. As such, they were to be aided rather than opposed by medication. In this regard, the physios accused allopathy of misunderstanding the true nature of these signs, holding, for example, that fever was destructive of the organism rather than representative of the body's recuperative efforts. Accordingly, the physios rejected antipyretic treatment and, not surprisingly, received considerable criticism for their views.[22]

In their choice of medicines, the physios were remarkably similar to the early Thomsonians. Lobelia, capsicum, and the vapor-bath remained the sheet-anchors of both systems. True, the physios expanded the materia medica of Thomson, but their list of sanative medicines was well within the contours of Thomsonian practice. Although they were quick to point out the crudities and errors of Thomson, the physios never lost sight of his medical principles.[22] "Our remedies are all simple," explained botanist Horton Howard in 1854, "as nature herself is simple." Moreover, physio-medicines were harmless toward nature, but powerful in opposing disease and restoring health. Instead of "preying. . .upon the vital power, and thus contaminating the fluids and destroying the tone of the organs," physio-medical medicines were truly therapeutic in their effect on disease.[23(p6)] Any therapeutic remedy must first be a true medicine, that is, one whose inherent constituency was "kindly accepted by living matter," thus forming a "harmonious aid" to the vital force which maintained normal physiologic balance.[21(p245)]

As late as 1903, the physios accused the regulars of using at least 107 poisons in their daily practice. These included 27 combinations of phosphorus, 5 of strychnia, 47 of mercury, 25 of opium, and 14 of arsenic. Regulars responded that a little poison was sometimes a good thing. The physios retorted that the law of physics had established that the property of matter was constant, that is to say, "what is an inherent characteristic of any substance is continually the same and is impossible to change while the matter itself is unchanged." For that reason, a poison retained its essential nature for all times and was in a condition to kill living matter. "No mans skill," argued F. O. Broady in 1903, "though he be a demi-god in the brilliancy of his powers, can change the tendency of alcohol, arsenic, opium, strychnia, belladona, aconite. . .to destroy each its own peculiar form of tissue according to its special power."[24]

### Herbal Remedies

Dr Oliver Phelps Brown, author of *The Complete Herbalist; Or, the People Their Own Physicians* (1872), observed that the entire universe consisted of contrary elements (ie, negative and positive principles) which worked in harmony with the laws of nature. Both disease and its cures were embodied in the same positive and negative forces. Brown also held that plants indigenous to a given locality or country were the proper basis of herbal medicines for an individual from that area; plants introduced from other countries were "lessened or deprived of their virtues." The same held true for the "virtues" of a plant growing in a wild or natural condition versus those artificially cultivated. The wild dandelion, for example, possessed rare virtues in affections of the liver, kidneys, and respiratory organs. In its cultivated state, however, it lost its medical attributes. The botanical garden of America is so great that if rightly investigated, argued Fred G. Hoener in 1887, furnishes ample remedies for every curable disorder incident to mankind. He concluded that the creator had planted natural medicines in every field and, to the extent that physios followed natures direction, could keep patients in a progressive state of health and comfort far better than the allopaths, eclectics, and homeopaths using noxious minerals.[26]

The materia medica of the physio-medicalist was replete with agents that cured rapidly, effectually, and without benumbing the system. Each drug had its "favorite locality" in the organism and each had its own special mode of action. For example, chills resulted from the liver attempting to remove "effete," "vitiated," or "worn out" materials in the system. "As long as people can be made to believe that they are diseased by a portion of germs or microbes instead of a clogged liver," wrote Melville C. Keith, MD, they could be tricked into swallowing poisons such as calomel, mercury, and arsenic. In place of these harsh metals, Keith recommended the use of verbena and capsicum or leptandra and capsicum prescribed originally by Thomson, Curtis, and William H. Cook, to open up the clogged skin.[27(pp14,15)]

For Curtis, the treatment of disease required the physician to first relax constricted tissues in order to stimulate secretion and depuration; second, to stimulate the tissues to healthy action; and third, to restore and maintain healthy tone and condition. In achieving this first objective, he prescribed water, warm or cold, in fomentation, tepid, or vapor baths; or cold wet cloths, baths, or affusions, aided by "anti-spasmodic medicines" such as lobelia, eupatorium, catnip, asarum, sage, and soothing aromatics. To achieve the second objective, Curtis used heat, moist or dry, accompanied by capsicum, ginger, xanthoxylon, cloves, and pennyroyal. Finally, to restore healthy tone, he prescribed

gentle, steady, and permanent relaxants and stimulants, good food, pure air, exercise, and cheerful company.[28(p189)]

For fever, particularly if the patient lived in "hygienic ignorance," the physio-medicalist recommended that the entire perspiratory apparatus be "thoroughly antisepticized." This meant the administration of a steam or vapor bath, followed by "a good old-fashioned hot water and soap scrubbing" to soften the accumulations in the glands, encourage perspiration, and render the skin less susceptible to bacteria. The physician followed this regimen with frequent sponging with boiled soft water to which was added various salines, alkalies, or acids as desired. With this under control, patients were then given caullophyllum and viburnum as ganglionic stimulants; asarum and xanthoxylon frax as capillary stimulants; and cola acuminata or erythroxylon cola for the central nervous system. Curtis also prescribed buchu and juniperus for their properties as active diuretics.[21(pp97,98,102)]

Phthisis, or consumption, received special notice by the physio-medicalists, who felt they had found a treatment more successful than that employed by regulars and the hordes of patent medicine vendors. In their effort to identify the cause of consumption, the physios concluded that there were many factors which would sooner or later make the system vulnerable to the disease. Any habit or condition that devitalized the system and bankrupted its vital force furnished a fertile soil for consumption. To this end, the physios warned against onanism, excessive venery, spermatorrhea and leucorrheal discharges, nocturnal emissions, long nursing of children, tight-lacing, and poor ventilation. They also condemned belts and recommended suspenders for men and warned women to avoid corsets or elastics to hold up stockings. All clothing should be suspended from a jacket or vest and not from the hips. Then too, patients were to avoid feather beds, sleep only in well-aired apartments, take exercise by walking or riding in the open air, and obtain eight to 12 hours of sleep each night. Physios recommended the use of plain foods, including well cooked grains, raw and stewed fruits, pure milk, garden vegetables (except the Irish potato and tomato), small portions of beef and mutton, occasional use of fish and fowl, and the avoidance of tea, coffee, and chocolate. In addition, they prescribed vapor and water baths, drinking large amounts of water, and taking frequent enemas. In treating phthisis successfully they administered leptandra, hydrastis, iris or euonymus, combined with disorea, zingiber, capsicum, or xanthoxylum for the lungs; decoctions of tamarac or pine bark for the throat and chest organs; and slippery elm, gum arabic or comfrey, combined with lobelia herb, capsicum, and licorice root to keep the air passages moist.[29,30]

John Albert Burnett listed thirty remedies as the most useful and popular among the physio-medicalists in the 19th century. These included: lobelia, capsicum, bayberry, chionanthus; an antiperiodic made by taking fluid extracts of gentian and hydrastis, cascara, salicin, myrrh, and simple syrup; tincture myrrh compound; Thomsons composition; neutralizing cordial; scutellaria; ascelepias; dioscorea; stillingia; crawley; sodium chloride; euonymus; fleabane; calcium lactophosphate; cimicifuga; sodium salicylate; cactus; magnesium sulphate; iron ferrocyanide; iron sulphate; zinc oxide; polemonium reptens; amphiachyris dracunculoides; echinacea; corn silk; iron salicylate; and zingiber. In 1869, quinine received the physios approval. Until its inclusion in William H. Cooks *Physio-Medical Dispensatory* of that year, it had remained on the index of non-sanative poisons.[32(p149)] However, some stalwarts were never quite satisfied with its inclusion and chose hydrastis canadensis as the best general tonic.[33]

Other popular remedies included castor oil, wormseed oil, anise oil and tincture of myrrh for a vermifuge; valerian root, ginger root, cinnamon bark, anise seeds, prickly ash berries, and oil of sassafras as antispasmodic aromatic drops; popular bark, golden seal, bayberry, columbo root, capsicum, and cloves for bitter tonic; mandrake root, black root, blood root, gamboge, lobelia seeds, and cayenne as vegetable cathartic pills; and mayweed flowers, smartweed, bitter archangel, bittersweet, wormwood, and cayenne pepper as nerve ointment. As an alternative to opium and its derivatives, the physios recommended blue cohosh, mullen, bugle weed, cokle burr, greek valerian, twin leaf, and yellow popular. For treating specific conditions, they applied the following:

**Asthma.** Skunk cabbage in doses of a half or whole teaspoonful, repeated as occasion required, and which acted as an antispasmodic and expectorant; and lobelia given in half or whole teaspoonful doses of the pulverized seeds or leaves and pods, at bedtime, or with the onset of fits; or smoking the dried roots of the common henbane (*Datura stramonium*) which acted as an antispasmodic and expectorant.

**Nose-bleed.** A snuff made from the leaves of witch hazel, and inhaled into the nose to stop the bleeding; a tea of hazel with the addition of cayenne taken internally; and the powder of charcoal as a styptic in hemorrhages from the nose.

**Bleeding From the Lungs.** Taking freely of diaphoretic powders to promote perspiration; a tea of witch hazel or beth root; vapor bath and emetic.

**Bloody Urine.** Vapor bath and emetic, followed by the use of witch hazel, beth root, and other astringents.

**Cancer.** A tea of pipsisway, wild lettuce, narrow dock root; the application of cat-skins or the flesh of fresh killed chickens to the open ulceration; angle-worms, or fish worms, snails, frogs and toads to be laid on an ulceration alive, and remain until they became dead and putrid.

**Consumption.** The tincture of lobelia, in nauseating doses, root of the skunk cabbage in half to whole teaspoonful doses.

**Diarrhea.** A few doses of tincture of myrrh, diaphoretic powders, bitter tonic, bayberry, or any of the astringent articles, or a cholera syrup. In addition use a butternut syrup, black root, bitter root, rhubarb, or any other cathartic.

**Piles.** Tincture of myrrh, or the juice of smart weed, and the administration of a stimulating injection; a salve made by simmering the bruised leaves of the Jamestown weed or henbane, in fresh butter or hogs lard, and rubbed into the affected part.

**Cholera.** Administering tincture of myrrh and bayberry, cholera syrup or mixture; decoction of wild-cherry bark; eat tail flag root boiled in milk or any other astringent article; with diaphoretic powder or cayenne to promote perspiration.

**Costiveness.** Graham bread, ripe apples, peaches, prunes and grapes, cranberries, and stewed pumpkin.

**Hysteria and Convulsions.** Ladyslipper, sculcap, blueberry, asafoetida, formed into pills with dandelion extract.[23(pp23,24,28,33,42,43,54,138,39,180–182)30,35]

The physios divided on the use of alcohol in their medicines. From all the evidence before us from Noah

down to the present, observed A. H. Baird in 1882, "alcohol has cursed every family, tribe and nation, directly or indirectly, and the thousands of articles discovered for medicines have but increased its use, and following it is an increase of drunkenness, premature deaths, all of which clearly proves that medicated alcohol is not inert but however masked. . .is a fiend infernal."[36] Others, not so hostile, chose to employ alcohol as an essential ingredient in their drugs.

Vegetable medicines remained popular among both regular and sectarian physicians in the 19th century. A study of prescriptions in 1854 indicated that in Burlington, New Jersey, three regular physicians called for 179 different items in their 443 prescriptions written between December 1853 and March, 1854. Of that number, 105 were vegetable, 58 chemical, 7 mineral, 5 animal, and 4 proprietary. The most commonly prescribed drug of vegetable origin was opium, followed by ipecac, camphor, squill, acacia, cinchona, and rhubarb. Among the chemicals and minerals, calomel and mercury were foremost in the list of prescriptions. Although there was little polypharmacy evident in the prescriptions of these three physicians, the majority of items were liquids, followed by powders, pills, ointments, colloidals, liniments, plasters, and miscellaneous items such as bark, cerate, and seeds.

## Knights of the Lobelia-Pod

Lobelia (otherwise known as emetic weed, Indian tobacco, puke weed, gagroot, eyebright, vomitwort, and bladder-pod), official in all editions of the *US Pharmacopoeia* from 1820 to 1910, and named in honor of the English botanist Mathias de Lobel, was a plant six to twenty inches in height, with small, numerous delicate blue flowers. The plant was annual in the warm latitudes but biennial in the midwest and northeastern states, and all parts of it were considered medicinal. Its use caused a deep and bitter fight between the botanics and allopathic physicians, with the latter often condemning the plant as a poison. Most allopathic authors of herbal medicines attributed lobelia's introduction to Reverend Manasseh Cutler of Massachusetts who, writing about the plant in the *American Academy of Science* in 1785, claimed to have cured himself of asthma by its use.[38] This was followed by an article in 1787 which incorrectly ascribed astringent properties to the plant. According to pharmacist John Uri Lloyd, this occurred when the author confused the properties of lobelia inflata with those of a related plant known as lobelia syphilitica.[39(p184)] Several decades later, James Thacher, in his *American New Dispensatory,* published in 1817, attributed its introduction to the Penobscot Indians in New England. Morris Mattson in his *American Vegetable Practice* (1841) also reported that lobelia inflata was used by the Penobscot Indians and as a domestic remedy by the people of New England long before its discovery by Samuel Thomson. However, valid these conflicting claims might be, Thomson employed lobelia as early as 1773 to produce vomiting and popularized the plant as a medicinal agent. By 1791, he used it regularly for colic, rheumatism, scarlet fever, erysipelas, dropsy, and other complaints in his practice which spanned Vermont, New Hampshire, New York, and Massachusetts.[40(pp519–521),41] The many preparations of lobelia included the following:

1. Infusion (drachm to half pint of water): Used for emetic purposes, to secure full relaxation in rheumatic or convulsive situations, or for dislocations.
2. Extract (bruising the green herb and macerating it with diluted alcohol): Used to create a relaxing influence in febrile and acute rheumatic situations; sometimes used as a plaster for irritation of the spine.
3. Fluid Extract (lobelia herb macerated in alcohol and acetic acid): Used frequently as an expectorant and nauseant.
4. Tincture (crushed lobelia herb, including the seeds, and diluted alcohol): Used in cases of acute pleurisy, pneumonia, rheumatism, and spasmodic croup.
5. Acetous Tincture (lobelia seeds, well ground, with distilled vinegar and diluted alcohol): Acts on the respiratory organs as a relaxant and stimulant, promoting rapid expectoration and relaxing spasms.
6. Acetous Syiru (acetous tincture dissolved in white sugar): Employed for same situations as acetous tincture.
7. Oxymel, Honey of Lobelia (tincture of bruised lobelia herb in cider vinegar and clarified honey): Used for dry and irritable coughs; less stimulating and more soothing than the acetous preparations.
8. Oil (pulverized seed with sulphuric ether): Given in five drop doses as an emetic. Lozenges (acetous tincture and white sugar): A relaxing expectorant for irritable coughs.
9. Lozenges (acetous tincture and white sugar): A relaxing expectorant for irritable coughs.
10. Compound Tincture of Lobelia and Capsicum, Antispasmodic Tincture, Thomson's Third Preparation (lobelia seeds and capsicum, cypripedium, and compound tincture of myrrh): Used as powerful stimulating and relaxing compound; arouses the stomach, the circulation, and the nervous system.
11. Balsam of Honey (tincture of lobelia, essence of anise and of sassafras, and clarified honey): Effective expectorant and antispasmodic in whooping-cough and dryness of the air passages.
12. Compound Pills (lobelia seeds, cypripedium, asarum, and softened extract of boneset): Used as a mild nauseant and expectorant; valuable in nervousness, mild hysteria, neuralgia, nervous headache, and sleeplessness.
13. Stomach Pill (lobelia seeds, apocynum, hydrastis and capsicum): Used for chronic atony of the stomach and in cases of dropsy and atonic forms of digestion.
14. Suppositories (lobelia seeds, simple cerate, and pulverized gum Arabic): Used for all acute pains of pelvic region and lower bowels, and especially for restlessness, chronic ovaritis, sciatica, neuralgia, and rheumatism of the womb.[40(pp543–545),41]

Regular medical journals published numerous accounts of the effects of lobelia. Parke, Davis and Company reported in 1893 that it was a vaso-motor poison and referred to several convictions for manslaughter. Much of this discussion had resulted from the notoriety of a murder trial in 1809 when Thomson was tried before the Supreme Court in Salem, Massachusetts, for the murder of Ezra Lovett, Jr, by poisoning with lobelia. Although Thomson was acquitted, the case was subsequently cited in most allopathic texts to document and stereotype the drug's dangerous effects. In explaining these instances of alleged poisoning, the physios emphasized the possibility for impurities, raised questions of whether the seeds or leaves had been used, and suggested that the constitution of the patient might not have been assessed carefully in judging the size of the dose. Despite negative publicity, lobelia remained the most important medicine of the Thomsonians and physios.[42]

## Physio-pharmacy

The early botanics refused to purchase their medicines from pharmacists, fearing adulteration with mineral poisons and objecting on democratic grounds to the secrecy involved in the use of Latin in prescription-writing. More importantly, however, botanics wished to control their own drug trade which meant either making their own medicines or purchasing them from their own firms. Among the early

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Fld. Ext. Solidago Comp.—Prof. Davidson's make.
Fld. Ext. Geum Album—Prof. Davidson's formula.
Fld. Ext. Composition—Thomson's Formula.
Physio-medical C. C. Pill—Prof. Hasty's Formula.
Physio-medical C. C. Pill—Stimson's manufacture.
Po. Composition—Thomson's Formula.
Po. Spice Bitters.
Po. Populus Comp.—Cook's Formula.
Anti-bilious Comp.—Prof. Anthony's Formula.
Neutralizing Mixture—Prof. Anthony's Formula.
Bedford's Sore Throat Mixture.
Bedford's Pile Suppositories.
Prof. Anthony's Cath. Pills.
Tinct. Lobelia Comp. (3d prep.).
Tinct. Myrrh Comp. [No. 6]—Thomson's Formula.
Oil Lobelia—Prof. Davidson's make.
Oil Capsicum—Prof. Davidson's make.
Salicylate of Soda. Free from carbolic acid—Schieffellins.

Just received a fresh supply of Syrup Juglans made from the green bark by Prof. Davidson. It is full strength and well made, a pint of the syrup representing a pound of the bark and warranted to give satisfaction.

We handle Wm. S. Merrell's Fluid Extracts, Syrups, Elixirs, Reisinoids, etc.

FIGURE 4. Advertisement for drugs from a physio-medical drug course, 1890.[16]

botanical pharmacists was John Thomson (son of Samuel Thomson) who owned a wholesale and retail house in New York City for users of herbal medicines; Godfrey Myer and Company of Columbus, Ohio; Ward Sears and Company of Baltimore; John Burns Milford Thomsonian Depot in New Hampshire; Westerfield Pharmaceutical Company of Dayton, Ohio; and the New England Thomsonian Depot of D. L. Hale in Boston.[22]

Following the decline of the Old Thomsonians, the physios lacked sufficient numbers to sustain their own drug manufacturing firms. Instead they relied on the good will of the eclectic pharmaceutical industry which advertised in physio-medical journals and offered a long line of "concentrated" preparations for reform and "new school" physicians. Among them, the products of the eclectic pharmacist John Uri Lloyd of Cincinnati were highly favored by physios everywhere. Physios also purchased their "concentrated tinctures" from B. Keith and Company, of New York City; F. D. Hill and Company in Cincinnati; Jacob S. Merrell of St Louis; Coolidge and Adams of New York; and a physio-medical druggist named Bedford in Indianapolis (Fig 4).[27(p146)] Parke, Davis, and Company of Detroit, Michigan, introduced a number of botanic remedies which were praised by the physios as sanative, efficient, and valuable. These included coto bark used as an astringent in diarrhea and dysentery; tonga, a Fijian remedy for neuralgia; and lippia Mexicana, and expectorant. Abbott Alkaloidal Company of East Ravenswood Park, Chicago, also advertised its medicines in physio journals as did the William S. Merrell Chemical Company (eclectic) of Cincinnati which sold "specific tinctures" along with corn silk, saw palmetto, black haw, echinecea, black cohosh, cactus, passion flower, cotton root bark, fringe tree, and stone root.[43,44]

The physios also praised the pharmaceutical firm of Eli Lilly and Company of Indiana because of the care of its employees took in selecting drugs that were pure and fresh.[45] "Honesty, industry, and energy has made Mr Lilly the pill man of the country," remarked the editor of the *Physio-Medical Journal* in 1881. Lilly sold a number of sugar coated herbal pills to the physio-medicals, including their Ague Physio-Medical, Apocynin Compound, Cohosh Compound, Lobelia Compound, and Podophyllin Compound.[46]

However grateful the physios were to the industrial pharmacist for the sale of botanic medicines, they never fully accepted the absence of companies devoted exclusively to their own medicinal needs. This remained a long-standing embarrassment as well as a serious impediment to their growth in the 19th century. Many physios simply refused to compromise on their principles, preferring instead to prepare their own medicines. "But I may save your money, and time, and patients, and make your own preparations from the drugs that you have handled yourself," advised Melville C. Keith, MD, in 1887.[27(p146)]

The gathering and preservation of medicinal herbs, roots, and barks required knowledge of the proper seasons, judicious selection, and careful processing. Annual roots which grew from seed each year were gathered just before flowering; biennial roots were gathered in the fall of the first year, or early in the spring of the second. Triennial roots were collected in the fall of the second year, or spring of the third year; while perennial roots were collected either in the fall after the leaves and tops began to die, or in the spring before they began to grown. After the roots were collected and before they dried, they had to be washed and trimmed of extraneous material. Roots could not remain long in water because of the danger of losing essential virtues. After washing, the roots were cut into small pieces and spread out to dry in an airy place or in sunshine. Again, care was taken to prevent their becoming wet. When dry, they were packed in jars, boxes, or barrels according to their quantity and placed in a dry, airy room. Leaves were fathered at the time of flowering since they were at their peak then. They were dried with the same precautions as roots, and preserved in a similar manner. Barks were gathered in spring or all, carefully dried, and preserved in a fashion similar to roots and herbs. Flowers were collected when about to open from the bud, or in a state of full perfection, in dry weather, and carefully and quickly dried in shade, and preserved as the others.[23(pp409–411),47(pp58,59)]

## Germ Theory

The germ theory of disease causation brought a period of excitement to the 1880s and 1890s. Robert Koch's (1843–1919) description in 1876 of the life-history of the bacillus of anthrax elevated germ theory to a scientific basis. His discovery of the *Mycobacterium tuberculosis* and his identifi-

cation of the cholera bacillus in 1882, and the findings by scientists in subsequent years challenged many of medicine's long held beliefs by linking a specific organism with a specific disease. Koch's "postulates" for the diagnosis of disease became the anchor of bacteriology and, despite the confusing basis upon which his evidence rested set doctors and scientists scurrying to embrace the theory, adapt it to older theories, or oppose it as contrary to the principles of medicine.[48–51]

"It is a strange fact," remarked M. Hermance, MD, writing in the *Physio-Medical Journal* in 1895, "that physicians of all schools, except the physio-medical, have always held to some erroneous theory as to what constitutes disease and its causes." Across the profession, medical scientists were beginning to replace the erroneous malarial theory of disease with an equally erroneous germ theory. Before long, he predicted, those same scientists would be suggested that malaria was an undiscovered microbe. Hermance argued that the bacillin tuberculosis which regulars had discovered to be the cause of tuberculosis was, in fact, the condition rather than the cause of the condition. "I have come to the conclusion," he wrote, "that instead of microbes, bacilli or whatever name they may be called, being the cause of disease, they are in and of themselves harmless, but the menstrum in which they are developed and live, constitutes the poisonous element which is capable of producing the disease in others, if the disease is not of a contagious nature." For the physios, this meant that anything that deprived the organs of their ability to perform normal functions became the cause of disease.[52(pp37,42)]

Hermance was not unlike the majority of practicing physios who continued to believe that the most rational explanation of disease causation had come from John Thomson's work on Asiatic cholera, published some sixty years earlier. Thomson attributed Asiatic cholera to the "unusual destruction of animal and vegetable matter during violent and sudden changes in the weather," and the "excess of nitrous or morbid gas that was extracted by the power of heat from the decaying mass during the summer weather."[52(pp94,97,100,101)] Even after 60 years, Hermance insisted that Thomson's theory was the most sensible ever advanced to explain the cause of cholera and was surely a fuller explanation than the microbe theory then in vogue. He further believed that Thomson's explanation applied as well to germ theory, namely, that "all the microscopical animalcula ever found in the excretions or fluids of the body in a person diseased are the result of disease, and not the cause of it."[52(p104)]

The physios continued in the main to be "bug cranks," believing that bacteria was "a good thing to have in a wound when they live by their own pablum." J. M. Thurston of the Physio-Medical College of Indiana admitted to having experimented with antiseptics but found they were too strong. Instead, he reverted to the use of Thomson's Rheumatic Drops (known popularly as No 6), arguing that the "best antiseptic is vital force."[53(p163)] There could never be too high an importance placed on the vital vigor preparatory for the ordeal of surgery. Excessive catharsis, or any form of depletion, would detract from the vital force in the tissue-unit. In this regard, the physios preached their own special brand of conservative surgery.[21(p303)]

Overall, the physios took exception to the germ theory, calling Koch the "great German Baccilio-Manic" and a "would-be scientist."[54] More specifically, they criticized germ theory because it lacked a working hypothesis based on the immutable laws of physiology. Until medicine returned to a more rational foundation, all of its vaunted progress and advanced methods, including bacteriology, would remain but "a splendid conglomerate of experimental concrete facts" and aimless empirical applications.[21(pp8,9)] Most physios concurred with the comment made in 1907 by a professor at the Physio-Medical College of Indiana that "the so-called 'disease germ' is a monumental medical bugbear, it is the greatest romanticism of the age."[32(p150)]

In spite of frequent reference to bacteria, tissue-units, bioplasm, and other more modern terminology, the physio-medicalists continued to rely on the regimens handed down by Samuel Thomson and other early advocates of herbal medicines, including naturalist Constantine Smaltz Rafinesque (1784–1841), physician James Thatcher (1754–1844), botanist Jacob Bigelow (1786–1879), and physician and naturalist Benjamin Smith Barton (1766–1815). This meant the importance of maintaining an "aseptic state" for the gastro-intestinal tract with the use of sodium salicylate, potassium chlorate, potassium nitrate, acid borate, acid citric, and acid tannic. The most popular vegetable antiseptics included baptisia, oleum cinnamomum triturated with sugar of milk or boric acid, and erythroxylon coca.[21(p106)] The physios also employed mints, balms, lobelias, vapor-baths, spongings of water, and other sanative means, including electricity and magnetism, to "loosen the tissues, open the emunctories and make a way of escape to any and every deleterious matter that may exist in the system." This was a system based on "simplicity, truthfulness, and safety"[55]

## Retrospect

The physios were especially strong in Ohio, Indiana, Illinois, and Iowa, with additional followings in Texas, Oregon, and Washington. At their peak, probably no more than 2,500 physicians were practicing this form of medicine at any one time. Even this number is inflated since the national organization, formed in 1883, claimed only 150 members. According to an eclectic survey in 1894, the regulars numbered 72,028; the eclectics, 10,292; the homeopaths, 9,648; and the physios, 1,553.[56] On average, physio-medical colleges graduated 21.6 physicians annually between 1881 and 1890. Of the state societies, Indiana was the oldest, having organized in 1863; others were in Ohio, Illinois, Iowa, Michigan, and Washington.[22(p152)] In 1900, the *Ohio Medical Directory* listed 1,162 sectarians practicing in the state. This amounted to nearly 19% of all physicians; of that number, 769 were homeopaths, 342 were eclectics, 41 were physio-medicalists, and 7 were minor cultists. By 1905, the percentage of sectarians had declined to 17% and, by 1917, they represented only 13% of the practicing physicians in the state. In 1938, there were fewer than 160 sectarians practicing in Ohio, or 1.75% of the total number of practicing physicians.[57]

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this is a more specific term, it also falls under the more general category of "gunshot," which refers to any "shot fired from a gun or just the firing of a gun," as defined in Webster's dictionary.[2]

Supporting this view, the *Index Medicus* has a heading only for gunshot wound but not for shotgun wound,[3] this last term being considered a subtype of the first.

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## Health Fraud Primer

**What is health fraud?** Health fraud is the promotion of useless or unproven remedies, for profit, usually by falsely representing that they will "cure" or aid in the cure of various diseases and problems.

**Who are the victims of health fraud?** Approximately 40 million Americans use fraudulent products each year. No one is immune. Its victims range from small infants to the elderly.

**What are the costs of health fraud?** Americans spend an estimated $30 billion annually on worthless and often harmful products and treatments, but there are emotional and physical costs as well. One in every ten people who use fraudulent remedies is harmed by side effects. Others abandon legitimate treatments, often with tragic results.

**What is a "quack"?** A quack is a person who pretends to be able to cure a disease or health problem. Some quacks believe their own claims. A charlatan is a quack who knows his or her claim is false. Quacks tend to oversimplify, and pay more attention to the person's psychological need rather than the physical problem.

**What are the most common forms of health fraud?** According to the FDA, the most common forms of health fraud are fraudulent arthritis cures; spurious cancer clinics; bogus AIDS cures; instant weight-loss schemes; fraudulent sexual aids; quack appearance modifiers; and false nutritional schemes.

**What is the best protection against health fraud?** The best protection against health fraud is to become a well-informed and skeptical consumer of health products, devices and treatments.

**How can a fraudulent claim be recognized?** When considering an unknown product or service, look for these key phrases: "Quick and Easy Cure;" "Scientific Breakthrough;" "Natural Ingredients;" "Computerized Diagnosis;" and, "It Really Works!"

**Who can help?** If you think you've been taken in by a quack, contact the regional office of the US Food and Drug Administration, the US Postal Service (if the product was ordered or received by mail), the State Attorney General's office, the State Consumer Protection Board, or the State Health Department.

**What is the most important thing to remember about health fraud?** The most important thing to remember is: If it sounds too good to be true, it probably is!

# Tarnished folk heroes in the battle against AIDS

*Acceptable Risks.* By Jonothan Kwitny. 466 pp. New York, Poseidon Press, 1992. $24.95 (hardcover)

Jonothan Kwitny presents two tarnished folk heroes of the acquired immunodeficiency syndrome (AIDS) power revolution, Martin Delancy and Jim Corti, who with a network of associates accomplished three feats. The first was to help develop and accelerate the gray markets in anti-HIV drugs by buying illegally and selling to individuals and later to groups and buyers' clubs. The second was to pressure the Food and Drug Administration (FDA) to approve some drugs earlier than planned. The third was to force the FDA to compromise enforcement against their drug operations and renegade research projects.

The gray markets and drug underground accomplished little, except to allay fears and to instill a degree of hope. The second, shaking FDA's tree to allow expanded and accelerated access through legitimate channels was a plus, although it did not satisfy Delaney. The third, calling off enforcement against gray marketeers was either a con or a masterful piece of lobbying, or both. Kwitny pumps all three feats as major social advances. In the world according to Kwitny, his protagonists are freedom fighters, and the antagonists are egotistical bureaucratic dysfunctionaries.

The book jacket states, "The explosive politics of life vs profit in America—how two courageous men fought the FDA to save thousands of AIDS patients, and changed the drug industry forever." If this sounds like puffery, it nevertheless reverberates throughout the book. The facts are that most of the drugs the heroes supplied are ineffective. None has cured AIDS, few have prolonged life, and those were already near approval. Even prophylactic aerosolized pentamidine, over which Kwitny and Delaney fussed, was rapidly supplanted by safer and cheaper drugs.

Kwitny is a reporter whose previous works explore intrigue and conspiracies, CIA and the drug trade, and the like. *Acceptable Risks*, comes off as a morality play—an unlikely contest of heroes and villains, undercover operations, games of wit and outwit, polities and economic self-interest, on the tragic background of AIDS and the gay community. Delaney and Corti are the "good guys" and FDA and responsible medical researchers are "bad guys" (terms used in this book).

*"Risks"* describes several episodes in Delaney's and Corti's association. They first crossed while both ran contraband ribavirin from Mexican pharmacies to United States buyers, making end runs around border inspectors and airport customs agents. Their next foray was shipping loads of low molecular weight dextran from Japan to the United States, with Corti again outwitting both Japanese authorities and US Customs. The last two Delaney projects were the renegade compound Q study and the underground sale of DDC. In these, we see Delaney as master lobbyist, power broker, and manipulator of officials.

There are meetings with former FDA Commissioner Frank Young, C. Boyden Gray (then VP Bush's closes advisor), and cross-country telephone calls with researchers Robert Gallo and Anthony Fauci. No question that everyone in the AIDS scene knows Martin Delaney.

Among others given bad press is Ellen Cooper, MD, of the FDA for attempting to assure proof of safety and effectiveness before approval of drugs. The principle is challenged by Delaney. In answer to the criticism that uncontrolled drug availability would ruin research projects (subjects in drug research must adhere to the protocol and not cheat on what they take,) Delaney claims that if experimental drugs were freely available, research projects would attract the more reliable volunteers. Who but Delaney, Kwitny, and friends could believe that?

Derision of the bad guys extends to their clothing. FDA's Frank Young has a penchant for white Public Health Service Uniforms. Donald Abrams of the San Francisco AIDS Consortium and the San Francisco General AIDS research team is fond of striped shirts, large paisley bow ties, and running shoes, but Martin Delaney wears a conservative dark gray business suit and striped tie. The book raises such irrelevancies to high political significance.

The book does not record lives saved or even days lived longer through the efforts of its heroes, but we are left a legacy of unequal enforcement of the law with which we will all have to deal later.

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