LAETRILE (B-17)
PANGAMIC ACID (B-15)
MEGAVITAMIN THERAPY
DIETS & VITAMINS

... gives 16 tips on how to spot food quacks; how to evaluate what is nutrition; what is a vitamin; what is a proper diet; nutritional anemias; the organic food fallacy; and legal recourses for victims of nutrition fraud!
Victor Herbert, M.D., J.D., is Chief of the Hematology and Nutrition Laboratory, Bronx VA Medical Center and Professor of Medicine at State University of New York Downstate Medical Center.

A native of New York, Dr. Herbert, after serving in World War II as a paratrooper, received his B.S. in chemistry in 1948, M.D. in 1952, and J.D. in 1974, all at Columbia University. He has taught at four major medical schools.

A member of numerous scientific societies, he has published over 400 papers. He received the 1972 McCollum Award of the American Society for Clinical Nutrition in recognition of his outstanding research in nutrition. He has testified several times before Congress on health and nutrition subjects, is Chairman of the Committee on Life Sciences of the American Bar Association, and has served as medical-legal expert for the U.S. Government and several State governments.

President of the American Society for Clinical Nutrition, he is the only person in the world listed in both World Who's Who in Science and Who's Who in American Law.

Do you believe Adelle Davis' suggestions that if you follow her nutrition advice, you won't get cancer?

Did you know that Adelle Davis died of cancer?

Do you believe that "more is better" for vitamins?

Do you know that large doses of almost any vitamin can be harmful?

Do you believe laetrile-promoting Georgia Congressman Larry McDonald successfully defended the laetrile malpractice suit brought against him?

Did you know his lawyers paid the widow $30,000 to forbear from pursuing the suit, as stated in the article "McDonald Pays, Widow Drops Case" in the June 28, 1979 Atlanta Constitution?

Do you believe that eating enzymes or taking them by enema or by injection helps fight cancer?

Do you know that the enzymes we eat are destroyed by acid and enzymes in our stomach and intestine, and therefore are worthless against any cancer; that rectally given enzymes can do no good and only harm, and that injected enzymes can produce fatal anaphylaxis (allergic reaction)?

Do you believe that "vitamin B15" (pangamic acid; pangamate) is the "miracle vitamin"?

Did you know that "B15" and "pangamate" are trade-names created by the same twice-convicted criminal who created the multi-billion-dollar laetrile industry, and that the allegations of nutritional value are at best deceptive and misleading and at worst downright fraudulent?

To protect yourself against nutrition cultism and quackery, you should realize that what is true about nutrition is not sensational and what is sensational isn't true. Nutrition is a science and not black magic.

The overlap of cultism and quackery, the allure of quackery, and the playing off of specious logic against the logic of science are discussed in this book, as is the worthlessness of anecdotal and testimonial claims.
NUTRITION CULTISM

FACTS AND FICTIONS
To those I cherish; that they may not fall victim to the gurus, the hucksters, or the arrogance of ignorance.
NUTRITION CULTISM
FACTS AND FICTIONS

VICTOR HERBERT, M.D., J.D.

Chief, Hematology and Nutrition Laboratory, Bronx VA Medical Center; Professor of Medicine, State University of New York Downstate Medical Center.
# CONTENTS

**FOREWORD**

*Stephen Barrett, M.D.*

**INTRODUCTION**

*Victor Herbert, M.D., J.D.*

**PART I. NUTRITION CULTISM**

LAETRILE: THE CULT OF CYANIDE—PROMOTING POISON FOR PROFIT

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry</td>
<td>15</td>
</tr>
<tr>
<td>The laetrile cult and the billion dollar laetrile industry</td>
<td>19</td>
</tr>
<tr>
<td>Cyanide poisoning from laetrile and apricot kernels</td>
<td>23</td>
</tr>
<tr>
<td>Laboratory diagnosis of poisoning</td>
<td>28</td>
</tr>
<tr>
<td>Clinical signs of poisoning</td>
<td>29</td>
</tr>
<tr>
<td>Factors affecting toxicity</td>
<td>32</td>
</tr>
<tr>
<td>Worthlessness of anecdotal and testimonial claims</td>
<td>33</td>
</tr>
<tr>
<td>The placebo effect</td>
<td>35</td>
</tr>
<tr>
<td>Laetrile is a fake “cancer cure”</td>
<td>38</td>
</tr>
<tr>
<td>The specious “freedom of choice” and “terminal cancer” arguments</td>
<td>41</td>
</tr>
<tr>
<td>Laetriles may cause cancer</td>
<td>42</td>
</tr>
<tr>
<td>Nutrition quackery as murder</td>
<td>43</td>
</tr>
<tr>
<td>The Allure of Quackery: Specious Logic vs. the Logic of Science; The Overlap of Cultism and Quackery</td>
<td>43</td>
</tr>
<tr>
<td>Agencies for complaints against quackery</td>
<td>47</td>
</tr>
<tr>
<td>Conclusion</td>
<td>49</td>
</tr>
<tr>
<td>Epilog</td>
<td>51</td>
</tr>
<tr>
<td>The Chad Green Case: Cyanide poisoning from laetrile and vitamin A poisoning from emulsified vitamin A</td>
<td>52</td>
</tr>
<tr>
<td>Laetrile industry promoters: The National Health Federation, the Committee for Freedom of Choice, and the “metabolic doctors”</td>
<td>55</td>
</tr>
<tr>
<td>Lethal effects of cult propaganda</td>
<td>59</td>
</tr>
</tbody>
</table>

**THE HEALTH HUSTLERS**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>The “Basic Four” of Good Nutrition</td>
<td>75</td>
</tr>
<tr>
<td>The Health Hustlers are usually charlatans and quacks</td>
<td>78</td>
</tr>
<tr>
<td>Recognizing the Quack—Sixteen Tips</td>
<td>79</td>
</tr>
<tr>
<td>The Weakness of the Law</td>
<td>88</td>
</tr>
<tr>
<td>Recommended Reading</td>
<td>91</td>
</tr>
</tbody>
</table>
THE DESTRUCTIVE VEGETARIAN “NUTRITIONAL AND METABOLIC ANTINEOPLASTIC DIET” OF LAETRILE PROONENTS 93
A Defense of “Metabolic” Cancer Diets 99
The Holes in the Defense of “Metabolic” Diets 102
PANGAMIC ACID (“Vitamin B-15”) 107
CAN B₁₅ (PANGAMATE) CAUSE CANCER.? 119
THE RATIONALE OF MASSIVE-DOSE VITAMIN THERAPY (Megavitamin Therapy: Hot Fictions vs. Cold Facts) 121
When is massive-dose vitamin therapy rational? 121
Dangers of massive-dose vitamin therapy 123
FACTS AND FICTIONS ABOUT MEGAVITAMIN THERAPY 129
THE VITAMIN CRAZE 141

PART II. ETHICAL MEDICINE
Acquiring New Information While Retaining Old Ethics 151
Medical, Legal and Ethical Considerations in the Use of Drugs having Undesirable Side Effects 161
Fat, Cholesterol and Free Scientific Inquiry 170

PART III. NUTRITION FACTS
WHAT IS A VITAMIN? 171
Recommended dietary allowances for vitamins 174
IN DEFENSE OF THE CHOLESTEROL REPORT 177
WATER SOLUBLE VITAMINS: DIAGNOSING DEFICIENCIES 179
SUMMARY OF “NUTRITIONAL ANEMIAS” 188
NUTRITIONAL ANEMIAS 189
AMA CONCEPTS OF NUTRITION AND HEALTH 199
FOOD, NUTRITION AND A DEFAMATORY ATTACK ON SCIENTISTS 206
TOWARD HEALTHFUL DIETS—NATIONAL ACADEMY OF SCIENCES 207
Members of Food and Nutrition Board 207
Introduction 208
Quest for guidelines toward healthful diets 209
Obesity 211
Cardiovascular disease 213
Hypertension 216
Cancer 218
Diabetes mellitus 219
Decision-making in public health 220
COMMENTARY ON “TOWARD HEALTHFUL DIETS”: MARK HEGSTED 224
INDEX 226
The modern food quack is a supersalesman. He plays on your fears. He caters to your hopes. And once he has you, he keeps you coming back for more... and more... and more. Seldom do his victims realize how often or how skillfully they are being cheated. Does the mother who feels good as she hands her child a vitamin think to ask herself whether he really needs it? Does the buyer of "organic" foods pause to ask whether they are actually better than—or even different from—conventional foods? Do subscribers to health food publications realize that articles are often slanted to stimulate business for their advertisers? Not usually.

Most people think that quackery is easy to spot. But it isn't. The modern quack wears a cloak of science. He talks in "scientific" terms. He writes with scientific references. And he is introduced on talk shows as the "scientist ahead of his time." The very word "quack" helps his camouflage by making us think of an outlandish character selling snake oil from the back of a covered wagon—and of course no intelligent person would buy snake oil nowadays, would he?

Well, maybe snake oil isn't selling so well lately. But vitamin pills? "Organic" foods? The latest diet book? Bee pollen? Tonics? Or a B-12 shot to pep you up? Business is booming for the food quack. His annual take is in the billions! What sells is not the quality of his product, but his ability to influence his audience. To those in pain, he promises relief. To the incurable, he offers hope. To the nutrition-conscious, he says, "Make sure you have enough." To a public worried about pollution, he says, "Buy natural." To one and all, he promises better health and a longer life. The modern quack has learned to reach people emotionally on the level that counts most.

During a recent trip, an attractive young airline stewardess told me she was taking more than 20 vitamin pills a day. "I used to feel run-down all the time," she said, "but now I feel really great!" "Yes," I replied, "but there's no scientific evidence that extra vitamins can do that. Why not take the pills one month on, one month off, to see whether they really help you or whether it's just a coincidence. After all, $300 a year is a lot of money to be wasting." "Look, doctor," she said. "I don't care what you say. I KNOW the pills are helping me."

How did the food quack convert this bright young lady into a true believer? First, an appeal to her curiosity persuaded her to "try and see." Then an appeal to her vanity convinced her to disregard scientific evidence in favor of personal experience—to "think for herself."
Sincerity is a powerful asset in the quack's approach. This was demonstrated most dramatically at the 1977 FDA hearings on laetrile. As a government witness, I was struck by the apparent deep conviction of the movement's leaders that they could save the world from cancer. Although no scientific evidence exists to show that laetrile works, many people who believe it has saved their lives have convinced state legislators to "legalize" it. Although many users have wasted their life's savings or have died as a result of using laetrile instead of effective treatment, proponents argue that someone "who will die anyway" should be allowed to use it. Viewed by itself, this freedom of choice argument can be very persuasive. What the food quack really wants, however, is freedom from government interference with his work.

The quack tries to boost his image by attacking science. Doctors, he tells us, are "butchers" and "poisoners." Scientific farmers, he says, are "poisoners" and "polluters." Government agencies, instead of protecting us, are "conspiring" with organized medicine and the food industry. And anyone who speaks out against quackery is accused of being part of the conspiracy.

To be sure, food safety and environmental protection are important issues in our society. But rather than approach them logically, the food quack exaggerates and oversimplifies. To promote "organic" foods, he lumps all additives into one class and attacks them as poisonous. He doesn't mention how natural toxicants are prevented or destroyed by modern food technology. Nor does he let on that many additives are naturally occurring substances. While warning against preservatives, he is careful not to mention that an ounce of Swiss cheese, which you might eat in a sandwich, contains the amount of calcium propionate used to preserve two loaves of bread. And while warning against monosodium glutamate (MSG), he won't tell you that wheat germ is a major natural source of that substance.

Sugar has been subjected to particularly vicious attack, being (falsely) blamed for most of the world's ailments. But the quack does more than warn us against imaginary poisons. He also sells "antidotes" for real ones. Care for some vitamin C to reduce the danger of smoking? Or some vitamin E to combat air pollutants? See your local salesman.

The food quack's most serious form of poisonmongering has been his attack on water fluoridation. Although fluoridation's safety is established beyond scientific doubt, well-planned scare campaigns have persuaded thousands of communities not to adjust the fluoride content of their water to prevent cavities. Millions of innocent children have suffered as a result!

Yes, business is booming for the food quack: vitamin B-15, hair analysis, systems to "balance our body chemistry," cults to give our lives new mean-
ing, "new" diets for our arthritis. His product list is endless.

Can we combat this supersalesman? Can’t people be helped to learn more mature ways to handle their health problems? Isn’t there a way to arouse public indignation against the food quack?

There must be, for nobody really wants to be hurt or cheated. There must be a way to help people see the quack for what he really is—a thief who takes advantage of human weaknesses.

This book will help. Informed citizens can resist a supersalesman.

Stephen Barrett, M.D.
Chairman, Board of Directors
Lehigh Valley Committee
Against Health Fraud, Inc.
Allentown, Pa.

March, 1980
Do you believe Adelle Davis’ suggestions that if you follow her nutrition advice, you won’t get cancer?
Did you know that Adelle Davis died of cancer?

Do you believe the Shute brothers’ claims that megadoses of vitamin E protect you against heart attacks, and the Rodale Press (Prevention Magazine) claims that their advice can prevent heart attacks and death until well past 75?
Did you know that one of the Shute brothers had a triple coronary bypass at Vancouver General Hospital in Canada, and that Prevention’s J.I. Rodale died of a heart attack at 72 while taping a Dick Cavett TV show?

Do you believe Linus Pauling’s claims that megadoses of vitamin C prevent colds and cancer?
Did you know that Prof. Pauling gets colds, as do we all, as reporters at one of his New York news conferences observed firsthand, and that, according to the June 11, 1979 Barron’s Magazine, the former director of the Linus Pauling Institute, Arthur B. Robinson, is currently suing Pauling and his associates for $25.5 million, and is alleging, among other things, that research at the Pauling Institute suggested that “at the equivalent human doses recommended by Pauling for everyday good health—vitamin C actually led to an increase in the incidence and severity of skin cancer in mice.”

Do you believe the claims that megadoses of vitamin A are good for you?
Did you know that Medical World News reported in 1979 that Adelle Davis’ estate settled out of court for $150,000 a suit brought by the parents of a child whose bone growth was crippled when they followed the “Let’s Have Healthy Children” recommendations of megadoses of vitamin A?
Do you believe that emulsified vitamin A in megadoses is less toxic than megadoses of standard forms of vitamin A?
Did you know that emulsified vitamin A is actually more toxic than the standard forms, and that only 15,000 International Units (IU) of emulsified vitamin A taken three times daily over a period of several months was toxic to Chad Green’s liver?

Do you believe that “more is better” for vitamins?
Do you know that large doses of almost any vitamin can be harmful?
Do you believe that “sugar is bad for you,” “fat and cholesterol are bad for you,” and that heart disease is a worsening epidemic in the United States?

Did you know that if you ate no sugar, your liver would make it because your body needs it, and if you ate no fat or cholesterol, your liver would make them because your body needs them? Did you know that the 1979 Centennial Edition of the Statistical Abstract of the United States (U.S. Government Printing Office, $9.00 paperback) says that by 1977 the death rate from the #1 killer heart disease had fallen to 322 per 100,000 from the 362 per 100,000 in 1970, and the life expectancy of Americans rose slightly from 1975 to 1977? The (nonsensational) facts as opposed to the sensational fictions about diet and the killer diseases are presented in the December 1979 issue of the American Journal of Clinical Nutrition, in the “Report of the Task Force on the Evidence Relating Six Dietary Factors to the National Health.” These diseases are related to overconsumption rather than to “bad” foods.

Do you believe that eating enzymes or taking them by enema or by injection helps fight cancer?

Do you know that the enzymes we eat are destroyed by acid and enzymes in our stomach and intestine, and therefore are worthless against any cancer; that rectally given enzymes can do no good and only harm, and that injected enzymes can produce fatal anaphylaxis (allergic reaction)?

Do you believe that laetrile helps against cancer and is harmless?

Did you know that laetrile is 6% cyanide by weight, and therefore always kills normal cells whenever it kills cancer cells, that it produces chronic cyanide poisoning in everyone who takes it, as measured by plasma and blood cyanide levels and urine thiocyanate and that, according to Medical World News (November 12, 1979), Chad Green’s blood was replaced with embalming fluid before an American pathologist could get to Tijuana to secure blood to determine whether Chad had died of cyanide poisoning? The November 25, 1979 Boston Sunday Globe carried a page one item on “The Selling of Chad’s Story,” subtitled, “It’s worth a million,’ say parents,” and the next day the Globe provided further background on Chad’s father and his current promotion of laetrile.

Do you believe that “vitamin B₁₅” (pangamic acid; pangamate) is the “miracle vitamin”?

Did you know that “B₁₅” and “pangamate” are trade-names created by the same twice-convicted criminal who created the multi-billion-dollar laetrile industry, and that the allegations of nutritional value are at best deceptive and misleading and at worst downright fraudulent? Did you know that there is evidence that most, if not all, of the “B₁₅” sold in America contains
either dichloroacetate (DCA), a nerve, eye, and gonad poison in rats and dogs, and a mutagen, or contains dimethylglycine (DMG), a waste product of choline breakdown which has been shown to destroy the kidneys of methyl-depleted pregnant rats, produce congenital deformities in their offspring, and be transformed into a mutagen when mixed with nitrite (such as is present in human saliva), it also is transformed in the temperature and pH conditions of the normal human stomach into a substance reported to be toxic to the nerves of rabbits and chickens, and to produce a sharp drop in the blood pressure of dogs?

Do you believe Prevention Magazine is a source of reliable nutrition information?

Did you know that the January 1980 issue of Consumer Reports indicates that Prevention Magazine takes in almost two million dollars a month in advertising revenue from “nutrition” promoters whose ads appear separate from, but in the same issue as, deceptive and misleading articles which, if incorporated into the ads, could cause the sellers to be prosecuted for fraud or misbranding?

Do you actually believe Prevention Magazine’s “Hotline to Health” columnist, Carlton Fredericks, Ph.D.?

Did you know his Ph.D. was in the field of radio communications, and that he has a criminal conviction in 1945 for passing himself off as a health professional?

Do you believe that the National Health Federation is a consumer interest group promoting national health?

Did you know that seven of the leading figures of the National Health Federation have criminal convictions in relation to nutrition fraud? Did you know that the National Health Federation is characterized by the chairman of the Board of Directors of the Lehigh Valley Committee Against Health Fraud as “the unhealthy alliance; promoters fighting for the right to cheat. Victims fighting for the right to be cheated.”

Do you believe the Kurt Donsbach nutrition booklets sold in almost every health food store in the U.S.?

Did you know Donsbach has a criminal conviction for a nutrition fraud, and his “Ph.D. in Nutrition” is from Union University, a “diploma mill” “authorized” by California but not approved or accredited by that State?

Do you believe laetrile-promoting Georgia Congressman Larry McDonald successfully defended the laetrile malpractice suit brought against him?

Did you know his lawyers paid the widow $30,000 to forbear from pursuing the suit, as stated in the article “McDonald Pays, Widow Drops Case” in the June 20, 1979 Atlanta Constitution?
If you accepted any of the above beliefs and did not know the contrary facts outlined above and detailed in this book, then you have been brainwashed by the multi-billion dollar nutrition cultism industry—and this book may save your life, your health, and will certainly save your money. The nutrition cultism industry rakes in its billions via a 24-hour-a-day multi-million dollar advertising campaign; using all the media, it presents as if they were facts sensational anecdotes and testimonials, ranging from the scientifically worthless to the outright lie, backed by grandiose and impossible "I have seen thousands of cases where it worked" claims unsupported by any proof which separates cause and effect from coincidence or suggestibility.

The promoters of "health foods" also often promote and profit from literature making sensational health claims (which they do not make on the label of their products, because it is illegal to lie about nutrition on the label of a product, but legal to do so in books, magazines and on the air). To prevent the truth from coming out, they also frequently threaten suit against, and sometimes do sue responsible nutritionists who dare to speak out against nutrition frauds. Honest nutrition scientists adhere to codes such as the Code of Professional Responsibility of the American Society for Clinical Nutrition, which requires them to speak out against deceptive and misleading nutrition claims. If an alleged nutrition scientist is not a member of the American Society for Clinical Nutrition, or the American Institute of Nutrition, or one of the other member societies of the National Nutrition Consortium which has a Code of Professional Responsibility, that fact alone should make you wary. You should not be deceived by the list of "Institute," "Research," and "nutrition" organizations he (or she) belongs to; many of them he has created himself by sending $100 to his state capitol and thereby incorporating himself as the "World Nutrition Research Institute" or whatever.

To protect yourself against nutrition cultism and quackery, you should realize that what is true about nutrition is not sensational and what is sensational isn't true. Nutrition is a science and not black magic. You should know that the basis of good nutrition is moderation in all things, and that moderate amounts of carbohydrates, fats, proteins, vitamins and minerals are good for you, but that large amounts are bad for you. You should be aware of the hallmarks of nutrition quackery outlined in the chapter on "The Health Hustlers," in fact, you should read the whole new 1980 edition of The Health Robbers (Stickley Co., Philadelphia) which is strong medicine against the flourishing health quackery business.

When P.T. Barnum said, "There's a sucker born every minute," he could easily have been thinking of food cultism and nutrition quackery. Belief in the magical properties of food goes back to Eve and the magic apple. The first nutrition con man was Satan himself, in the form of the snake—the
The overlap of cultism and quackery, the allure of quackery, and the playing off of specious logic against the logic of science are discussed in this book, as is the worthlessness of anecdotal and testimonial claims (pages 33-34, 43-49).

Sensationalism and scare tactics are the hallmarks of all demagoguery. This is as true for the demagoguery that creates nutrition cults as it is for the demagoguery that creates other cults (pages 43-49).

The basic scientific axiom that no alleged nutrient is safe until demonstrated to be safe and efficacious until demonstrated to be efficacious can be said to have been enunciated when God told Adam not to eat that apple—and the first demagogue of nutrition cultism can be said to have been Satan, when he told Eve to go ahead and have Adam eat the apple. So it has been ever since, with one demagogue after another doing good for himself and harm to others by promoting one after another dangerous remedy as safe, and one after another worthless remedy as preventive and/or therapeutic.

Most of the “nutrition” advice given to the public in newspapers, magazines, radio, television and popular books ranges from deceptive and misleading to downright fraudulent. The media introduce as “nutrition experts” a number of popular figures whose only nutrition credentials may be criminal
convictions for nutrition fraud coupled with the charisma and amorality which allow them to make sensational claims and use the scare tactics that enchant the public to sell newspapers, magazines, air time, and products.

Nutrition is a science; it is not a religion. Those who ask, “What do you believe about this or that nutrition claim?” and those who state they “believe” this or that about nutrition are talking religion and not science. What nutrients can and cannot do in the human body is determined by the chemical structure of the nutrient and the specific biochemical reactions in the human body in which the chemical structure is capable of becoming involved. Nutrition science is largely a branch of biochemistry. Many of the happy fictions of nutrition cultism are flatly contrary to the scientific facts about what the given nutrient or food substance is capable of doing in the human biochemistry.

To provide the reader with a better understanding of the fundamental nutrition science concept of “moderation in all things,” against which to judge the “we have the answer” claims of nutrition cultism, the major nutrition statements of two national bodies are added to this text. They are the “AMA Concepts of Nutrition and Health,” formally adopted by the House of Delegates of the AMA and published in 1979 in the *Journal of the American Medical Association*, and “Towards Healthful Diets,” published in 1980 by the Food and Nutrition Board of the National Research Council of the National Academy of Sciences. Although not a member of the AMA, this author was invited by that organization to be one of the group of nutrition experts who helped in the development of the AMA nutrition paper; as a member of the Food and Nutrition Board, this author was involved in the preparation of “Toward Healthful Diets” for the National Academy of Sciences.

Nutrition cultism has cleverly profited from distorting the decision by millions of Americans to assume greater control over their own fate into a cry to abandon science and dependency on scientists, and prove their “independence,” “personal responsibility,” and “freedom of choice” by making decisions based on anecdote, fraud, and misrepresentations rather than making informed judgments.

We need to teach young people to ask, “How do we know the things that we know?” The fundamental sciences of logic and epistemology teach how to evaluate the validity of statements. These sciences should be basic teaching in our schools, but are not. We need to teach how belief can be rationally established.

In the realm of science, we know things because they prove to be so when subjected to testing. In science, claims are considered untrue until proved true in studies which separate cause and effect from coincidence. The “double blind controlled trial” is a classic such scientific study.

Unfortunately, in the real world, much of what people believe about nu-
Nutrition is false. This is because what people believe is based on acceptance as fact of deceptive and misleading information provided by magazines which promote nutrition quackery, such as *Prevention*, and organizations which promote nutrition quackery, such as the National Health Federation and the Committee for Freedom of Choice. The activities of these media experts promote the multi-billion-dollar industry of nutrition remedies ranging from the worthless to the downright dangerous and, occasionally, lethal. Hopefully, this book will serve as a partial antidote.

A word should be said about the penchant of the media to promote “debates” between responsible nutrition scientists and promoters of nutrition quackery, for the purpose of sensationalism but disguised as “giving a fair hearing to both sides.” Is it giving a “fair hearing to both sides” to invite a rapist to provide his side of the story, i.e., why rape is good? If not, then why is it appropriate to invite a rapist of the mind, i.e., a promoter of health quackery, to present his deceptions, distortions and misrepresentations as if they were fact? When the scientist points out these are lies, the lay audience, without the scientific background or time to delve into the scientific literature to ascertain who is telling the truth, simply concludes there is just a “difference of opinion” between two scientific equals (otherwise why would the talk-show host put the quack on?).

The February 1979 Forbes Magazine indicates Hoffmann-LaRoche is “vitamin wholesaler to the world,” controlling 60 to 70% of all vitamin sales in the free world, including the $400 million annual sales of wholesale vitamin C. They promote the development of middlemen distributorships, so that when you look at ten different brands of vitamin C on the shelf of your local “health food” store, and think they came from 10 different places, in fact, all ten are probably distributors who purchased vitamin C wholesale from Roche. This explains why Roche places ads promoting vitamins in hundreds of scientific journals and lay magazines all over the world, and why they have a “Vitamin Information Bureau” engaged in subtle distortion and misrepresentation to promote vitamin sales in the guise of performing a public service. Typical of their deceptive ads is their ever-popular “Are you a vitamin underachiever?” ad which tells you and your doctor that if you smoke, your blood vitamin C level is lower than if you do not smoke, and implying smokers need vitamin C supplements. The ad does not tell you or your doctor that those lower levels are still ten times above the deficiency level, and that there is no legitimate reason to take supplementary vitamin C because you smoke if you eat one fresh fruit or vegetable or drink fruit juice each day. Contrary to the false claim that “orange juice is just vitamin C,” orange juice is also potassium, folic acid, other vitamins and minerals, fiber, and carbohydrate.
Roche financially supports many persons who promote vitamin sales, gives $100,000 annually to the Linus Pauling Institute, and attacks those who publish scientific information adverse to Roche's vitamin interests, such as this writer. Persons who receive money from Roche often publish their attacks and claims without mentioning their financial support from Roche, thereby preventing the reader from recognizing the possibility of bias induced by financial support.

Moderation and variety are the keys to good nutrition. Any "nutrition" book hyped by claims of dietary "magic," "sensation" or "new discoveries revealed here for the first time" is nearly always a rip-off aimed at lining the author's pockets with book royalties.

No writer for a lay audience has any special insights into nutrition which are not known by a substantial part of the scientific community. Magic and sensational diets are nothing more than exaggerations of one facet of nutrition at the expense of another, often to the monetary (and sometimes health) detriment of the willing victims. Until Einstein's equation, \( E = mc^2 \) (Energy = mass times the speed of light squared), which may also be written (Calories = weight times the speed of light squared) is repealed, the only way to lose weight will be to eat each day less calories than you burn up, and the only way to gain weight is to eat each day more calories than you burn up. The average adult burns up approximately two-thirds of the calories he eats each day just to keep his body temperature normal. The other third of the calories we eat are burned up in our daily activities and exercise. Professional athletes exercise more, and therefore burn up more calories. The claim that athletes need more protein than non-athletes has no basis in human nutritional biochemistry, and is untrue. What athletes need are more calories in their diet to make up for those they burn up, and more water and electrolytes (salts) to make up for what they lose in perspiration.

A rough guide to appropriate body weight is that a five-foot tall woman should weigh 100 pounds and a five-foot tall man should weigh 106. For each inch over five feet tall, a woman should weigh an additional 5 pounds over the 100 pound baseline; for each inch over five feet tall, a man should weigh 6 pounds over the 106 pound baseline. In general, if you exceed this guideline by more than 20%, you are sufficiently overweight that you should lose weight.

The best evidence is that the claims that eliminating sugar, carbohydrates, and/or additives from the diet corrects behavior disorders and hyperactivity in children are based on coincidence rather than cause and effect. The child's behavior improves in part because the parents are saying in effect, "Look, you don't have to act up in order to get our attention. See how much attention we are giving you. We are building our whole lives
around your diet and changes in your diet.” The changes in behavior are induced by behavior modification, and not by changes in diet content.

Many otherwise intelligent people believe that the claims of Linus Pauling or other gurus of nutrition fads must have validity because “where there’s smoke, there’s fire.” It is just such specious logic that makes character assassination of people and ethnic groups by constant repetition of falsehoods so often successful. All one can say when one sees smoke is that one sees smoke. To determine what the smoke means requires skepticism and the common sense to adhere to the two fundamental canons regarding nutrition claims: no alleged nutrition remedy is safe until proved to be safe, or effective until proved to be effective.

Riding the crest of the wave of nutrition cultism to fame and fortune are the leaders of a number of “anyone can join” organizations created by “nutrition” hucksters. As pointed out in the chapter on “The Health Hustlers,” these organizations lend a specious aura of “legitimate scientific credentials” to the promoters of laetrile, pangamate, and other frauds.

Also lending authenticity to nutrition frauds are scientifically irresponsible sensationalist articles promoting such things as laetrile and B\textsubscript{15} in magazines like Prevention, New York, and Mother Jones, similarly irresponsible radio and television talk shows, and similarly irresponsible books promoting laetrile (“B\textsubscript{17}”) and pangamate (“B\textsubscript{15}”) as vitamins like the Nutrition Almanac and People’s Almanac.

The Nutrition Almanac is sold in health food stores throughout the country, making wild claims of magic value of such things as “B\textsubscript{15}”. These claims could lead to legal action for fraud if made on the label of the “pangamate” sold in the same stores, so the books are usually not on the same counter with the product. In February of 1980, NBC-TV aired a news segment showing this writer going into a GNC (General Nutrition Center) health food store with NBC-TV reporter Pamela Field, picking a bottle of their pangamate off the “B Vitamins” shelf, asking the manager what it was good for, and being referred by the manager to the Nutrition Almanac on sale on the store bookshelves. Lying about nutrition on the label of a product is illegal; lying about nutrition in books (or magazines, TV or newspapers) is different, and the hucksters take full advantage of this fact in ripping off the public.

There are many sound nutrition and diet books for the layman, such as those of Stare, Mayer, Dwyer, and others who teach nutrition at nationally accredited universities and have approved and accredited doctoral degrees in health sciences, rather than degrees from fly-by-night operations such as “diploma mills” like Union University and Donsbach University, authorized by California, but not approved or accredited by that state. However, books presenting sound nutrition sell much less well than those which sen-
sationalize and misrepresent. The public wants magic, not science. It does not want to know that nutrition is a science. It wants to hear about the latest magic cure, and doesn’t want to know it’s just another “snake oil” rip-off.

This book differs from most “nutrition” books for the public in three major ways:

1) The author has real scientific credentials in nutrition, rather than the phony nutrition credentials of most of the charismatic “doctors” (including a number of MDs whose licenses to practice have been restricted or lifted, or who have been repeatedly sued for negligence) who write for the public on nutrition and diets, and get rich on royalties from sensational claims undocumented in the only place where scientific truth and falsehood get separated—the peer-reviewed scientific literature.

2) Every chapter on nutrition written by the author was forged in the fire of peer review by competent nutrition scientists, passed that review, and was published in scientific journals indexed in the National Library of Medicine Medlars Search Computer.

3) It was written primarily for health professionals, but the author feels that everyone will benefit from reading it.

Do you believe the nutrition nonsense promoted by Richard Passwater, Ph.D? Did you know his Ph.D. is from Bernadean University (Las Vegas and Van Nuys), a mail-order correspondence school whose Ph.D. degrees are not acceptable in the scientific community because they do not represent the result of acceptable scientific training. According to their “Information Sheet (109),” for $240 they will make you a minister (ordination optional).
I. NUTRITION CULTISM

Laetrile: the cult of cyanide
Promoting poison for profit

On June 8, 1977, 11-month-old Elizabeth Hankin of Attica, New York, ate five tablets (2.5 g) of laetrile. She rapidly went into a coma from cyanide poisoning, and 3 days later she was dead.* Her Certificate of Death read, “Immediate cause of death: Extensive anoxic (lack of oxygen) brain damage, due to subacute cyanide poisoning, due to ingestion of amygdalin. Ingested laetrile tablets in her home.” The Certificate was signed by the Erie County Chief Medical Examiner, Dr. Judith Lehotay, who performed the autopsy.1 Faster death has been reported.160,161

In July 1977, three Los Angeles physicians sent to the Journal of the American Medical Association the case report of a 17½-year-old Los Angeles girl who drank 3½ ampoules (10.5 g) of laetrile. Within 10 minutes she was in a coma from cyanide poisoning and in 24 hours she was dead.2

Chemistry

Laetrile is amygdalin, a cyanogenetic glycoside3 naturally present as a toxicant (poison) in the kernels of apricot pits, a number of other stone fruits and nuts (almonds, macadamia nuts, etc.).4 Nature may have put it there to protect the plant against being eaten.5 Cyanogenetic glycosides (tradename “laetrile,” “nitrilosides,” and “vitamin B17” by laetrile proponents)6 are chemical substances made up of cyanide, aldehyde or ketone, and sugar. Laetrile consists of two parts glucose, one part benzaldehyde (itself mildly poisonous4), one part cyanide, and no parts vitamin3,6 (Fig. 1). The cyanide they contain is released (“generated”) as hydrogen cyanide (prussic acid) by hydrolysis in the presence of the enzyme β-glucosidase, or heat, or mineral acids3,4 or megadoses of ascorbic acid, especially in the presence of blood.6a

The released hydrogen cyanide (hydrocyanic acid, HCN) is a colorless, weak acid that boils at 25.5 °C (well below body temperature) to become a gas.7 The almond oil odor (“bitter almond odor,” “odor of fresh macaroons”) of crushed apricot kernels is associated with the release of the gas.

---

*Supported in part by the Medical Research Service of the Veterans Administration and in part by United States Public Health Service Grant AM 20526.
*Her father, who was taking the laetrile for his cancer, died in the ensuing year.
Fig. 1. Laetrile with a capital “L” is a synthetic substance that has never been marketed, and the claimed method of synthesis of it by Krebs was never reproduced. The “natural” substance closest to it is prunasin, which differs only in having a “-CH₂OH” replacing the “-COOH”. Laetrile with a lower case “l” is amygdalin, the product marketed by laetrile promoters. The popular term “laetriles” is a synonym for “cyanogenetic glycosides.”

The gas is so penetrating a poison that victims have died within 2 minutes after ingestion of 300 mg hydrocyanic acid in aqueous solution, an amount obtainable from 2½ ounces of some varieties of bitter apricot kernels mixed with saliva or from a sixth of an ounce of laetrile mixed with saliva and vegetables containing β-glucosidase, a plant enzyme.

The false claim by laetrile promoters (cited in Reference 5) that any dose of cyanide from food or laetrile is immediately detoxified to thiocyanate by rhodanese (mitochondrial sulfur transferase) is disproved by the fact of undetoxified cyanide measurable in the blood of persons poisoned by laetrile or apricot kernels and the further fact that thiocyanate is itself toxic to a lesser degree. While the liver and kidneys contain enough rhodanese to convert several kilograms of cyanide to thiocyanate in 15 minutes, very little of the enzyme is present in blood, and the limiting factor in detoxification-
Laetrile: Cult of Cyanide

Laetrile with a capital “L” is the trademark for the product Krebs claims to have synthesized once upon a time and which has just one instead of two parts glucose in addition to one part benzaldehyde and one part cyanide. In his 1977 “Laetrile Fact Sheet,” laetrile promoter Dean Burk* states “laetrile is on the H.E.W.-F.D.A. GRAS (generally recognized as safe) list... under the heading of natural extractive from bitter almond, apricot or peach kernels...” The statement is false, since the “almond bitter (free from prussic acid)” on the GRAS list is an oil extract that is essentially benzaldehyde, with residual traces of cyanide removed.

Laetrile is 6% cyanide by weight. Its promoters allege that cyanide in minute quantities and in the “proper food forms,” instead of being a deadly poison, actually is an essential component (the mythical “vitamin B_{17}”) of normal body chemistry. It is poison, is not a component of normal body chemistry, and its only effect on body chemistry is to harm it. There is no vitamin B_{17}; B_{17} is a trade-name created for laetrile by a laetrile promoter. A vitamin is an organic nutrient functioning to facilitate an essential biochemical reaction, necessary in small amounts from food to sustain life, and lack of which produces a specific deficiency disease which is corrected by supplying the vitamin. Cyanide has no value in sustaining human life. In small amounts it injures, in larger amounts it maims, and in still larger amounts, it kills. No law prevents promoters from trade-naming nutritionally worthless pangamate as “B_{15}” or poisonous laetrile as “B_{17}.” They practice the snake oil medicine of the 19th century. To paraphrase

*A Ph.D. biochemist who, before his retirement at age 70 in 1974, was head of the then small four-person Cytochemistry Section of the Laboratory of Biochemistry of the National Cancer Institute. Since 1974, as head of the Dean Burk Foundation, despite his lack of credentials as a clinical nutritionist or in cancer treatment, he has promoted various questionable remedies, such as laetrile, “vitamin B_{13},” and “vitamin B_{5},” alleging on specious grounds that they are vitamins. (See “A brief on foods and vitamins,” by Dean Burk, published in June 1975 by the McNaughton Foundation, and sold by various promoters of laetrile.) (Address of McNaughton Foundation: Box B17, San Ysidro, California; just across the border from Tijuana.) McNaughton, who has a criminal conviction for stock fraud, established the CytoPharma laetrile manufacturing plant in Tijuana, of which Contreras became co-owner. (See opinion upholding criminal convictions and sentences, including fines and 3 years’ probation of defrocked physician John Richardson, Ralph Bowman, Frank Salaman, and Committee for Freedom of Choice President Robert Bradford for conspiracy to smuggle laetrile, U.S.A. v. Richardson, Bowman, Salaman and Bradford, #77-2203, -2204, -2262, -2268. United States Court of Appeals for the Ninth Circuit, filed October 20, 1978.) McNaughton also has a criminal conviction for conspiracy to facilitate transportation of smuggled merchandise and was placed on 2 years’ probation (U.S.A. v. Andrew McNaughton, #76-0488, United States District Court of California). As an expert witness, Dr. Burk indicated his definition of a vitamin included many food substances and minerals; when the word “vitamin” was created, the substances specifically excluded from the definition were carbohydrates, fats, proteins, minerals, and water. It is a perfect example of the abuse of words by laetrile promoters in deceptive and misleading ways, and violates the Federal Rule of Evidence which says that words shall have their ordinary (dictionary or encyclopedia) meaning.
Closing brief for the People\textsuperscript{119} by Asst. D.A. Carol Hehmeyer noted: Testimony of State Department of Health Investigator J.R. Jackson that “Most of the correspondence for purchase of laetrile was addressed to E.T. Krebs, Jr., Malvina Cassese, or to the Krebs Foundation. The mail order business was conducted out of 1348 South Van Ness…during that search, money was found hidden in a can…Mr. Krebs had initially refused to open the can but the investigator insisted and discovered the large stack of money…there were quarters in the Krebs mansion for R.L. McNaughton, for Wynn Westover, and for Dean Burk (see “Chemistry” section footnote). He identified each one of these people as leading figures in the laetrile conspiracy...The literature propounded laetrile as a cure or treatment for cancer...Testimony of Tamara Zema that her husband contracted a 95% surgically curable cancer but she was “persuaded by Dr. Krebs that she should use laetrile for her husband instead of surgery...He told her that it is normal for the spots of cancer or the lumps to get larger before they get smaller during laetrile treatment...she accompanied her husband to Dr. Richardson’s office when he went there for treatment. He received vitamin B\textsubscript{15} with the laetrile. She brought one of the vitamin B\textsubscript{15} bottles into court...That bottle bears the label Krebs Laboratories...the bottle of B\textsubscript{15} cost $15.00. She stated that she paid over $3000 to Dr. Richardson for her husband's treatment in an amount over $200, and the money was all for pills...Inspector Jim Eddington testified about...Krebs...$12,705 in cash...hidden in a cache in the ceiling. It was in 12 bundles which were dated February and June of 1975...sales records...indicate that between February 5, 1975 through December 1, 1975, $10,310 passed from Mr. Bradford to Mr. Krebs for the B\textsubscript{15}...there were three probationary searches...on each occasion there were empty barrels of calcium gluconate...These were all 200 pound drums...Undercover agent Don Cooper testified that...“it was a hush when Mr. Krebs would enter the room, and he was treated by his guests as a sort of 'sage'...there was another meeting at 1348 South Van Ness which was attended by Mr. Cooper, Mr. Malone, Dr. Parker, Mr. Bradford, Mr. Newkirk, Frank Salaman's wife, Dr. Dean Burk, Malvina Cassese and Mr. McNaughton were all present...During that visit to the mansion, Mr. Cooper noted that Dr. Dean Burk had a room in the mansion, apparently permanently. He heard a great deal of discussion about laetrile. The people also discussed McNaughton's laetrile factories in various countries...A local B\textsubscript{15} laboratory” was discussed...Mr. Krebs...talked about a new clinic in Mexico. He also talked about smuggling arrests and discussed his theories as to who the informant was that made those arrests possible...In the testimony of Dean Burk...“tested his definition of a vitamin would include many food substances and minerals...He admitted that he does have a permanent “bed” at the 1348 South Van Ness mansion owned by E.T. Krebs, Jr....He stated that he testifies “a lot” for his friends...Andrew McNaughton “admitted that his laetrile foundation up in Canada had been started with the assistance of some Mafia-related money sixteen years ago. He also admitted that he frequently stays with Mr. Krebs when he comes to San Francisco...Mr. Krebs testified that he has never ever made any money from laetrile...he at no time mentioned any source of income which would explain his...mansion...car...elaborate meals...secretary...trips...thousands and thousands of dollars in cash which were located on two separate occasions during probationary searches. In each instance, the large sums of money were hidden on the premises...With respect to his doctorate from the American Christian College\textsuperscript{169a} Mr. Krebs admitted that this particular college has no science department. The doctorate was, of course, in science. He stated that he gave a speech at this particular college, and that this was the reason that he received the honorary degree...Mr. Krebs is listed as a Doctor in the 1975 phone book...and the 1976...He has allowed and encouraged himself to be touted and proclaimed as a person of knowledge and wisdom, whose authority can be relied upon. He is not that...his educational history, the record of his criminal activities, his own testimony...show him to be an irresponsible and greedy man—motivated by a love of acclaim, as well as by a love of money...Where does the money which supports this unemployed man come from? B\textsubscript{15}?!!! Laetrile!!!!!!” Judge O’Gara stated Krebs, “wants us to believe he has a messianic belief in the value of laetrile as a retardant in the cancer area. It's one thing if a man wants to be a prophet of a far-out cause, but Krebs profited at the expense of a very vulnerable group—cancer victims and their relatives.” The judge stated “there is overwhelming evidence produced during the probation hearing that shows laetrile at its best is useless....”\textsuperscript{118} The original
Laetrile: Cult of Cyanide

Abraham Flexner and Harvard biochemist L. J. Henderson, "It was not until after World War I that a random patient with a random illness seeing a random doctor had a random chance of profiting from the encounter."

Typical of the scientifically bizarre reasoning of laetrile promoters is their claim that laetrile must be a vitamin because vitamin B₁₂ also contains cyanide. There is no cyanide in functional vitamin B₁₂. Cyanide is added to one of the pharmaceutical forms of vitamin B₁₂ to stabilize it as cyanocobalamin. A daily 1 µg dose of cyanocobalamin not only contains well below one millionth the amount of cyanide in a daily 1 g dose of laetrile, but the cyanide, which is metabolically worthless, must be removed before vitamin B₁₂ can function in human nutrition.

An ironic fact is that vitamin B₁₂, in hydroxocobalamin form, can be used in large doses as a continuous intravenous infusion to prevent cyanide poisoning from concomitantly administered nitroprusside. It acts by "soaking up" the cyanide before the cyanide binds to cytochrome oxidase. It may also be good treatment (with oxygen and diuretics, for the pulmonary edema) for acute cyanide poisoning; in truly massive doses of 1.8 g vitamin B₁₂ per 100 mg of cyanide. About 25 mg hydroxocobalamin (1347 daltons) should neutralize about 1 mg sodium nitroprusside (269 daltons; 5 cyanide radicals per molecule). (See "Epilog" below.)

The laetrile cult and the billion dollar laetrile industry

The word "cult" is used in this review in the dictionary meaning of "any system for treating human sickness that originated by one usually claiming to have sole insight into the nature of disease, and that employs methods generally regarded as being unorthodox and unscientific." Nutrition cultists are recognized by their statement, "I believe in..." rather than, "The scientific nutrition evidence is..." They are recognized at public meetings concerning nutrition when they ask speakers, "Do you believe in..." rather than, "What is the scientific nutrition evidence that..." To "believe in" something regarding nutrition is to engage in cult talk. Either there is scientific evidence or there is not.

Cults relating to health have existed throughout history. For centuries there was the Cult of the Unicorn Horn, claiming mysterious health powers of the powdered horn, which brought huge sums to those who purveyed it. A century ago, when scientific medicine was still in its infancy, there...
was the Cult of Arsenic. This purported remedy was so widely used by physicians that it became the basis for the Cult of Homeopathy. Homeopathy sprang up using only trace doses of arsenic to reduce the side effects from this remedy. Since patients who got trace doses of arsenic did better than those who got larger doses, homeopathy globalized the concept to a general belief that one should always use doses of treatment so small that they were worthless, because that brought out the true worth of the drug. What was actually going on, of course, was that large doses of arsenic did harm, and using smaller doses did less harm.

Down through the centuries, quacks and faith-healers have created cults of followers, who accept with religious fervor the bizarre teachings of their mentors, who usually become rich in the process. These cults spring in part from "magical thinking," which Piaget studied in children, which is still present in many adults, and which can be reactivated by fear of cancer or other dread diseases. 20

The Laetrile Cult is perhaps the most bizarre, ruthless, deceptive, misleading and dangerous health cult to come along in this century. Laetrile is not supported as of value by a single scientist recognized in the scientific community as a currently reliable source of information about cancer or about nutrition. 5,8,10,21-29 Its support comes from self-styled cancer and nutrition experts rewarded by backers who profit from such promotions, such as the Committee for Freedom of Choice in Cancer Therapy (some of whose leading figures have had criminal convictions)* and the National Health Federation (seven of whose leading figures have had criminal convictions in relation to health fraud). 30 Individual proponents have allegedly taken in millions of dollars from it, 5,30-34 it is a billion dollar a year industry, 5,30-34 an estimated hundred thousand cancer patients (at least 50,000 in the United States) are fanatically supporting it even as it shortens their lives, 5,36 and state legislatures are supporting it because they are counting votes instead of lives. 34

More than half of cult supporters, the "cancer underground," are characterized by a unique ideological tetralogy: belief in vitamins as a panacea, hostility to scientific medicine, right wing politics, and religious fundamentalism. 35 Many laetrile profiteers and their victims are John Birch Society members. 31,37,38 Attorneys fighting the cult should avoid judges and jurors with such characteristics, the first two of which suggest inability to separate anecdote from science; and the last two often indicating a proclivity to accept without evaluation or question conclusory pronouncements of simple solutions to complex problems. Such judges in several states have rendered pro-cult decisions, by giving fabrication, anecdote, and deceptive and misleading testimony by laetrile promoters the same weight as scientific evidence. The totalitarian mentality, be it right- or left-wing, appears to favor the promulgation of nutrition quackery, as witness the support by the Russian political
Laetrile: Cult of Cyanide

apparatus of the fraudulent “vitamin B₁₅.”

The laetrile empire is a highly organized and lucrative industry using sophisticated computerized technology, levels of funding undreamed of by the “snake oil salesmen” of old, with enormous impact on federal, state and local levels of government. It has the ability by push-button to generate avalanches of mail, massive funding for candidates supporting laetrile. It has an interlocking network of direct mail, an interlocking network with other organizations promoting health quackery, exerts unrelenting pressures on elected officials, and is not above smearing and threatening responsible scientists who dare to challenge it. For example, the Coalition for Alternative Therapies and the National Health Federation publish a monthly newspaper called “Public Scrutiny” which, in its November 1, 1978 issue, smeared this reviewer, falsely claiming he makes “attacks on nutrition,” “lies a lot,” “distorts the truth,” and (frightening exhortation) “needs to be exorcized.” Suing for defamation is costly and unworkable, since it results in heavy legal expense, years in court, and a final judgment which usually merely slaps the defendant’s wrist. In the case of Scott v. McDonald, in which this reviewer was “of counsel” to the lawyers for the Scott family, he was told by an anonymous telephone caller, “If you show up in court Monday morning, you’re a dead man.”

“Freedom of Choice in Cancer Therapy” is the laetrile industry’s slogan, as clever and deceptive a slogan as ever mounted on a multimillion dollar budget by a Madison Avenue advertising agency, with sophisticated experts in mass psychology preparing the literature. A major voice for the laetrile industry is the Committee for Freedom of Choice in Cancer Therapy, whose Scientific Director, Ernst Krebs, Jr., flunked out of medical school, is a convicted criminal, and called himself “Doctor” in the San Francisco telephone book by dint of an honorary doctorate from American Christian College in Tulsa, Oklahoma, which was not empowered by the State of Oklahoma to grant the degree. The masthead page of the Freedom of Choice monthly magazine, “The Choice,” lists a number of promoters who appear to have become multimillionaires in that industry among its officers, consultants, and contributors. A number of them have had criminal convictions variously for fraud, conspiracy, smuggling, and probation violation in connection with their lucrative activities; documentation of the brushes with the law of Krebs, Bradford, Richardson, McNaughton and others are available from the Food and Drug Administration. Thousands of dollars were found concealed in various parts of Krebs’ castle in San Francisco during raids by the authorities.

The December 1976 issue of “The Choice” notes that “McDonald… legislative consultant to the Committee for Freedom of Choice in Cancer Therapy…” was rewarded by re-election to a second term in the United
States Congress with the help of "a radio-television blitz in the Atlanta area by . . . committee spokesmen." The laetrile industry backs its promoters with apparently unlimited funds. It sells not only products but also services, publications, meetings, and conventions.

Laetrile-promoter and Congressman (from Georgia) McDonald and the multibillion dollar health quackery industry\(^{36}\) are so financially and politically powerful that their "open season on the consumer" Symms bill (H.R. 54) to repeal the hard-won "proof of efficacy" requirement of the Kefauver amendments of 1962 (which arose out of the Kefauver hearings into horrendous consumer frauds) is supported by over 100 congressmen. The bill, under the euphemism "Medical Freedom of Choice," eliminates rationality from therapeutics and legitimizes every snake oil salesman who ever double-talked a widow out of her life savings. To quote Consumer Reports\(^{34}\): "the 'Medical Freedom of Choice' bill has no place among the laws of the land. It would turn the clock back to a time when purveyors of worthless nostrums could prey freely on an unprotected public, exploiting the fears of the sick and the desperation of the dying."

The interlocking nature of the laetrile empire of lucrative books, filmstrips, meetings, services, tests, and goods was illustrated in the McDonald malpractice trial.\(^{38,40}\) According to uncontroverted testimony, McDonald required his patients to have read the Kittler book, to see the Griffin filmstrip (at a meeting). Scott paid $1,000 cash (laetrile is usually sold only for cash, which can't be traced) for a money order to Heinsohn's Tennessee outfit\(^5\) for 3 weeks of Tijuana laetrile to be mailed to Scott c/o McDonald, McDonald required Scott to make out a check to Richardson in California for a test to be done by Navarro in Manila, and Scott ran up thousands of dollars in hospital bills in the defendant hospital while getting intravenous laetrile there.

No doctor treating cancer with legitimate therapy can take in the more than $100,000/month taken in by some laetrile promoters\(^5,31-33\) with their emotionally charged word-salad doubletalk (evasive and ambiguous language) of "cancer control," "nutritional therapy," "alternative therapy," "metabolic therapy," "holistic therapy," "unconventional therapy," "nontoxic therapy," "terminally ill," "food supplement," and "freedom of choice." These euphemisms may be characterized as the "code phrases of quackery," since in no case is the phrase as used by quackery promoters an honest description; they have stripped it of its dictionary meaning. The millionaire promoters behind laetrile\(^5,31-33\) claim they oppose the evil demon of "orthodox medicine" (by which they mean scientific medicine) and support the good fairy of "unorthodox medicine" (by which they mean unscientific medicine).\(^5,39\) Interestingly, the word "orthodox" comes from the Greek word for "straight," "upright," "correct," and means "sound or cor-
rect in opinion or doctrine."  What they oppose is scientific medicine; the term “orthodox medicine” is used by them so they may characterize themselves as “unorthodox” rather than “unscientific.” While taking in millions of dollars from their gullible victims, they can afford to joke. Page 2 of the December 1976 issue of “The Choice” carried a cartoon captioned: “Orthodox medicine has no known cure for your condition. I could recommend a good quack.”

Cyanide poisoning from laetrile and apricot kernels

Laetriles have been known to be poisonous since antiquity. Professor J. Ross drew attention to the 1895 book by Blyth which contains the lines: “The Egyptians knew prussic acid as extracted in a dilute state from certain plants, among the chief of which was certainly the peach; on a papyrus preserved at the Louvre, M. Duteil read, ‘Prone Not the Name of I.A.O. under the Penalty of the Peach.’ in which dark threat, without doubt, lurks the meaning that those who revealed the religious mysteries of the priests were put to death by waters distilled from the peach.” Laetriles were used as a suicide poison in ancient Rome, according to Blyth: “From the Egyptians the knowledge of the deadly drink appears to have passed to the Romans. At the trial of Antipater, Verus brought a potion derived from Egypt, which has been intended to destroy Herod; this was essayed on a criminal; he died at once. In the reign of Tiberius, a Roman knight, accused of high treason, swallowed a poison, and fell dead at the feet of the senators; in both cases the rapidity of action appears to point to prussic acid.”

Contrary to the popular belief that all foods are safe no matter how much of them we eat, many foods contain poisons in small quantities. In fact, the National Academy of Sciences in Washington, D.C. publishes a large book entitled “Toxicants Occurring Naturally in Foods,” which describes the various poisons found in small quantities in different foods. Chapter 14, on the cyanogenic glycosides, describes the many compounds that yield hydrogen cyanide on treatment with acid or appropriate enzymes. It notes that more than a thousand species of plants release varying quantities of cyanide when tissues of the plant are crushed or otherwise disrupted. The first substance listed in the table of cyanogenetic glycosides is amygdalin, which is the scientific name, since 1830, for the substance Krebs more than a century later trade-named laetrile, and which sold even better after he also trade-named it “vitamin B17,” despite its not being a vitamin and being nutritionally worthless. It is found in significant quantities in the pits not only of apricots, but also of apples, cherries, peaches, pears, and plums, and in almonds.

Bitter apricot kernels are little “cyanide pellets” because of their millions of subcellular organelles containing amygdalin and millions of other organ-
ellles (lysosomes) containing β-glucosidase. The cyanide is "safe" as long as the apricot kernel is uncrushed, because it is tightly bound to the benzaldehyde of amygdalin. When an apricot kernel is crushed (by a blender, or the teeth, or anything else) the amygdalin and β-glucosidase make contact and cyanide is generated. The amount of cyanide generated is directly proportional to thoroughness of chewing the kernel. The process of cyanide release from an apricot kernel is analogous to dropping a sodium or potassium cyanide pellet (these salts of cyanide are highly water soluble solids) into water or acid, the means of "gas chamber" executions in California and genocidal mass killings by the Hitler regime during World War II. Ironically, various leaders of the Third Reich, including Himmler and Goering, ultimately committed suicide by biting into, and thereby crushing, cyanide pellets.

Cyanide is rapidly absorbed from the intestine and diffuses throughout the body, knocking out respiration in normal cells and to a lesser extent in cancer cells, combining with and completely inhibiting the enzyme cytochrome oxidase at a concentration of only $10^{-8}$ M cyanide. Because the lethal dose of cyanide taken orally for humans is between a half and 3½ millionths of a pound per pound of body weight, and because cyanide is rapidly breathed out of the body or detoxified within the body, up to about 10 of some varieties of bitter apricot kernels can be eaten without acute toxicity by adults, but 25 kernels of other varieties could be lethal eaten at once. Twenty-five to 35 average variety bitter apricot kernels eaten over 1 or 2 hours would be likely to produce nonfatal symptoms of cyanide toxicity: headache, dizziness, nausea, drowsiness, sharp fall in blood pressure, difficulty breathing, damage to heart action, and possible convulsions or coma. The Merck Index lists 50 to 60 mg as the average fatal dose of cyanide; if the entire 60 mg cyanide content of 1 g laetrile was released before giving it to a patient, it could be lethal. Human autopsy studies showed the minimum lethal absorbed dose of cyanide to be 0.5 mg HCN/kg of body weight, the average absorbed dose in people killed by cyanide was 1.4 mg/kg of body weight at the time of death.

Sollman notes the lethal dose of absolute HCN (a liquid) is about 0.05 g; that of dilute hydrocyanic acid would be about 2.5 g; 50 to 60 average bitter almond seeds would be fatal. For some cultivars (varieties), one gm of cherry kernels yields 1.7 mg hydrocyanic acid; 1 g bitter almond pulp yields 2.5 mg hydrocyanic acid. One apricot kernel weighs about 0.5 g and contains about 0.5 to 2 mg cyanide. In one study, kernels of five cultivars (varieties) of apricots showed cyanide contents of $11.7 \pm 0.5$ to $177.1 \pm 11.1$ mg/100 g but only one cultivar had less than $132.5 \pm 9$ mg/100 g and it was the only one tasting sweet rather than bitter. (Bitterness can be measured in the laboratory by measuring cyanide or benzaldehyde content.) The kernels that poisoned a Connecticut lady in 1978 contained 409 mg cyanide/100 g moist
Laetrile: Cult of Cyanide

weight. Her blood cyanide on hospitalization was 3.2 mg/liter. Testimony on September 13, 1978, in the State of New York Department of Agriculture and Markets Food Seizure S-19091 was that the seized health food store apricot kernels contained 391 mg cyanide/100 g. The kernels each weighed about 0.5 g, so a lethal dose (50 mg cyanide) for an adult was about 25 kernels weighing less than ½ ounce! Respondent's attorney offered to eat one to "prove" they were harmless, but refused to eat 10 crushed with a mortar and pestle. (It is a ploy of laetrile promoters to gulp apricot kernels to "prove" their safety, knowing that unchewed kernels, like pebbles, pass out in the stool without releasing their cyanide.) Respondent's attorney alleged apricot kernels were "safe" because macadamia nuts were "safe" and also contained amygdalin, but failed to point out that the amygdalin (and cyanide) content of the nuts was less than 5% that of respondent's kernels. Testimony in the hearing was that the "ordinary use" of health food store apricot kernels was as recommended by "Prevention" magazine, the "bible" of health food faddists, whose apricot kernel recipe produced cyanide poisoning. The alleged strength of many preparations may be weakened by decomposition or slow absorption due to various factors, accounting in part for the variability of symptoms. Sollman gives a thorough account of the symptoms of acute and chronic cyanide poisoning as known in 1957, including chronic cachexia and visceral and nervous degenerations, and Drill's Pharmacology, an excellent account through 1970.

The cult of cyanide has its own cookbooks. According to the May 10, 1977 issue of the Thousand Oaks (California) News Chronicle, "Little Cyanide Cookbook" authoress DeSpain, "a Thousand Oaks nutritionist (and health food store owner) who advocates the banned drug laetrile in cancer treatment, fell victim to her own enthusiasm" and was hospitalized with acute cyanide poisoning from 25 apricot kernels she had ground to a powder, toasted, mixed with honey, and eaten. The May 11, 1977 State of California Food and Drug Fraud Unit report stated "June DeSpain in comatose condition on arrival...immediate treatment of subject on 5-2-77...intensive care one night...almost died...hospital stay two days...more concerned about her business than her health...doesn't want people to know how sick she really was." The vast majority of hospitalizations from cyanide poisoning from apricot kernels are not reported in the medical literature. Hospitals rarely report them. Some of them can be found in the Food and Drug Administration files as "consumer complaint/injury" reports (Examples: cyanide poisoning reports X098-450 and X059-818, involving "health food" sellers in Minnesota, Washington, and Oregon in 1976 and 1977). Some others may be found in the files of local Poison Control Centers and Medical Examiners.

Because of the dangers of cyanide, foods containing it are generally processed to reduce or remove the cyanide prior to their being eaten, and/or
heated to destroy the enzyme that could release the cyanide. For example, almonds and macadamia nuts are often roasted or smoked to reduce their cyanide content and destroy their \( \beta \)-glucosidase before their being eaten. The almond paste used to make marzipan and other almond-flavored candies is processed to remove all of its cyanide before it is used. The air of work areas where benzoaldehyde (almond flavor) is prepared from apricot pits may contain toxic levels of cyanide.\(^7\) Laetrile promoters put on "demonstrations" of the "safety" of apricot kernels by either gulping them whole so as not to crush them and release the enzyme, or secretly preroasting them to destroy the enzyme. In the 1978 Atlanta laetrile malpractice case, defendant McDonald refused to eat apricot kernels offered to him with a mortar and pestle to crush them\(^{38,50}\); respondent's attorney Rothblatt similarly refused such an offer in the 1978 New York apricot seizure case described above.

Laetrile is unique because, unlike all foods containing cyanide, which are processed to remove cyanide before their being eaten, laetrile is processed from food to concentrate the cyanide.

Dr. Jerry Lewis, of the University of California, Davis, School of Medicine, published in July 1977 a review of a number of cases of amygdalin and apricot kernel poisoning.\(^8\) His review included four cases of cyanide poisoning reported from France following eating amygdalin; two fatal cases and seven nonfatal cases of cyanide poisoning at the Children's Hospital in Ankara, Turkey, after eating apricot kernels; and a fatal case from Germany of cyanide poisoning after eating amygdalin. Professor Joseph Ross observed in November 1977 the death from apparent cyanide poisoning of a Hollywood figure who came to the University of California at Los Angeles Center for the Health Sciences emergency room shortly after having been given intravenous laetrile (personal communication).

The California Bureau of Communicable Disease Control has reported cyanide poisoning in Los Angeles from following a recipe for apricot kernel milkshakes\(^{51}\): "A man and his wife purchased a two-pound bag of apricot kernels at a local health food store. They soaked some 30 kernels with dried apricots in distilled water overnight, and the following day pureed the ingredients in a blender. The resulting concoction was bitter and took some effort to swallow. About an hour after drinking the mixture the wife complained of abdominal discomfort, rapid heartbeat, and feeling strange. She drank some water and vomited. Within minutes of his wife's onset, the husband became symptomatic also and complained of headache, light-headedness, tachycardia, a generally strange sensation, and impaired vision, 'as if looking through frosted glass.' He felt impending doom. They were rushed to the emergency room of a nearby hospital. Vomiting was successfully induced and after several hours of observation, they were released. For the next three days, the husband complained of insomnia and
tinnitus. The wife had diarrhea which abated in one day.”

The California Bureau of Communicable Disease Control also reported cyanide poisoning in a San Diego County man who had eaten 48 apricot kernels. He used 48 kernels roasted for 10 minutes and milk and honey in the preparation of milkshakes, following a recipe in the magazine, “Prevention”. An hour later, he developed forceful vomiting, headache, flushing, heavy perspiration, dizziness, and faintness. The local emergency room induced forceful vomiting with ipecac, bringing up kernel fragments. The Bureau also reported the case of a 56-year-old woman in Redwood City who ate a “handful” of apricot kernels purchased at a “Nutrition Center” and within 30 minutes developed headache, tachycardia, lightheadedness, flushing, and generalized weakness. She was seen at the emergency room of a local hospital where ipecac was used to induce vomiting; the vomitus had a cyanide content of 1.7 µg/ml.

Even the proponents of laetrile admitted a variety of toxic effects of the drug, including low blood pressure, itching, bleeding into the urine and intestine, fever, inflammation of the nerves, vomiting, dizziness, blue skin, and headache.

One of Dr. Lewis’ patients, who had been to the Contreras Clinic in Tijuana, reported that several patients at the Clinic had serious reactions to laetrile injections, including diarrhea, vomiting, and high fevers. Another of Dr. Lewis’ patients, who had also been to the Contreras Clinic, told him that she too experienced nausea when taking oral laetrile. In December 1977, Dr. V. Herbert and photographer M. Herbert visited and photographed the Soto Clinic (Clinica Cydel) in Tijuana and tape recorded a conversation with a patient and her husband, who stated that it was only after her first injection of laetrile that she was told, “it makes you sick for a week,” and indeed she was unable to keep any food down for a week after the first injection. She also stated that it was an “all cash business; they take no checks” and that her family pooled their life savings for her 3 weeks at the clinic. The Committee for Freedom of Choice in Cancer Therapy had its laetrile literature in the lobby of the Clinica Cydel, and the Clinic brochure lists the Committee as its official American agent. (These documents and others were turned over by Dr. Herbert to a United States Attorney in San Diego in December, 1977.)

There is evidence that although it may not be as bad as thalidomide, laetrile may have bad effects on a developing fetus, since it appeared to produce kidney defects in some rat fetuses and hydrocephalus in others. Yet it is promoted to everyone, including pregnant women, as a “cancer preventative.”

There is also evidence that laetriles in the diet can produce goiters, from the inhibition of iodine uptake by the thyroid due to the thiocyanate produced by the body in detoxifying the cyanide; and 1 to 10% of a
million Zaire nationals are affected with cretinism and mental retardation from it.\textsuperscript{43,55} (See Epilog below.)

**Laboratory diagnosis of poisoning**

The 11-month-old girl, Elizabeth Hankin, who was killed by laetrile, ate approximately five tablets of it (labeled as 500 mg each) on June 8, 1977. Within 30 minutes, she began to vomit, became listless, had difficulty breathing, and later went into a coma from cyanide brain damage, and died 3 days later from that brain damage.\textsuperscript{1,9} As was to be expected because of the rapid absorption of cyanide from the intestinal tract, the blood cyanide level was very high when it was measured shortly after she took the laetrile. Also, as was to be expected because of the rapidity with which cyanide exhaled from the body, there was almost no cyanide left in her body tissues when she died 3 days later. It is characteristic of cyanide poisoning that the blood levels are high immediately after taking the poison, but after the poison and the invariable lactic acidosis of major cyanide poisoning\textsuperscript{7,17} has done its damage to the brain and other tissues, the cyanide is rapidly detoxified and some of it is exhaled.\textsuperscript{56}

Every patient who takes laetrile should have a plasma and blood cyanide (for acute cyanide poisoning) and plasma thiocyanate and 24-hour urine thiocyanate (for chronic cyanide and thiocyanate poisoning) determination at least every 2 weeks, because of the erratic degree of chronic and acute poisoning due to the various factors each day which result in different degrees of release of cyanide each day from identical oral and/or intravenous doses of laetrile,\textsuperscript{3,6a,8,10,22,53} and different rapidity of conversion of cyanide to thiocyanate. The daily industry excretion in the urine is 0.5-3 mg thiocyanate.\textsuperscript{57} Any blood cyanide level in excess of 0.2 µg/ml of blood suggests a toxic reaction, but because of tight binding to cytochrome oxidase, serious poisoning may occur with only modest blood levels, especially several hours after poisoning.\textsuperscript{58} Normal values are less than 0.2 µg/ml.\textsuperscript{59} Levels of 0.1 to 0.15 µg/ml may occur in normal persons from cigarette smoking, pollution by industrial cyanide wastes, and food sources. Fatal cyanide poisoning has been reported with blood levels greater than 3 µg/ml.\textsuperscript{17} About ¾ of the cyanide in a blood sample is in the red cells, to the hemoglobin of which cyanide tightly binds.\textsuperscript{7,60} Highest cyanide concentrations are found in the spleen.\textsuperscript{61} Blood levels dissipate rapidly in vivo and in vitro.\textsuperscript{19} Normal Nigerians\textsuperscript{53} have plasma thiocyanate levels in the range of 2.9 ± 0.02 µmole/100 ml; and urine thiocyanate levels in the range of 0.6 ± 0.04 µmole/kg body weight per 24 hours. Patients with ataxic neuropathy have plasma levels in the range of 11.3 ± 0.2 and urine levels in the range of 2.4 ± 0.1.\textsuperscript{53} Since the molecular weight of HSCN is 59, 2.9 µmole/100 ml = 0.17 mg/100 ml and 11.3 µmole/100 ml = 0.67 mg/100 ml.
In addition, a plasma and blood cyanide and plasma thiocyanate determination should be made immediately upon appearance of hypotension, an obvious indicator of poisoning from hydrogen cyanide (prussic acid) released from nitroprusside or laetrile given intravenously, or on appearance of any other sign of cyanide poisoning. Cyanide levels must be drawn immediately because this evidence dissipates rapidly; thiocyanate persists longer.

When the 10th Circuit in 1978 in Rutherford v. U.S.A. authorized intravenous laetrile for terminal cancer patients, it should have required that each intravenous injection of laetrile running into a patient's vein should be sampled for free cyanide. It would appear to be negligence not to make such samplings and to immediately determine blood cyanide on the appearance of hypotension or any other symptom of cyanide poisoning from intravenous laetrile, as well as 24-hour urine thiocyanate determinations for chronic poisoning at intervals of at least once every 2 weeks for all patients on such a regimen. There was testimony that John Scott had hypotension on three mornings after a slow drip of intravenous laetrile given at about 2 A.M. This suggests there was either release of cyanide in the blood or free cyanide in the intravenous laetrile given, possibly due to deterioration of laetrile in its ampoules or mixing it in the iv with glucose and water and megadoses of vitamin C.

All 10 patients of a New Jersey surgeon given intravenous laetrile got hypotension, presumably from free cyanide (see "epilog").

Clinical signs of poisoning

The 17½-year-old girl killed by laetrile in Los Angeles drank 3½ ampoules of it (10½ g) in her home. Within 10 minutes, she developed headache, dizziness, collapse, convulsions, and coma. The paramedics were called to her home and put her on a respirator at the nearest hospital, but she died 24 hours later. Ironically, autopsy showed that the conventional surgery she previously had at Kaiser-Permanente in Los Angeles had removed all parts of her brain tumor. Her subsequent trip to Mexico gave her laetrile and laetrile gave her an untimely death.

Hypotension occurred in all ten patients given laetrile intravenously by a New Jersey surgeon, now deceased, who provided no data on whether the laetrile shortened the lives of his patients. Other symptoms suggesting poisoning from intravenous cyanide, and calling for immediate determination of plasma and blood cyanide and plasma thiocyanate, are nausea, vomiting, diarrhea, headache, palpitations, muscular twitching, restlessness, and sweating. Thiocyanate may accumulate; particularly during prolonged laetrile infusion in patients with renal insufficiency. Blood thiocyanate levels should be determined after 48 hours in such patients, and more frequently in patients with renal failure. Three weeks of cyanide could produce hypothyroidism from excessive thiocyanate accumulation. In
some patients who have recovered from cyanide poisoning, complaints of weakness, fatigue, insomnia, and cardiac distress occasionally continue for months. Repeated episodes of acute poisoning may be followed by polymorphous chronic illness, which may appear as encephalopathy, extrapyramidal signs mimicking parkinsonism; may resemble poliomyelitis; or there may be periodic excitement and violence.

Chronic cyanide intoxication from laetriles in the diet has produced in Africa thousands of cases of slowly progressing neurologic damage with blindness (bilateral optic atrophy), nerve deafness, and myelopathy, with muscle weakness in a demyelinating syndrome of toxic ataxic neuropathy and variants of it. In these patients, whose staple diet includes bitter cassava (manioc), a plant root food containing a laetrile, plasma levels of thiocyanate, plasma cyanide, and urine thiocyanate are high, and an increased frequency of goiter is observed. Small amounts of cyanide may be oxidized to CO₂ via cyanate, and cyanate is neurotoxic. This may help explain the neurotoxicity of cyanide. Cyanate toxicity in man includes not only hypoxia-like damage to the nervous system (drowsiness, diminished vision, severe debilitating peripheral neuropathy with muscle weakness, gait disturbance with foot drop, electroencephalogram changes with possible diffuse encephalopathy, demyelination, paresthesias), but also marked weight loss, cataracts (which may appear months or years after exposure), and greater susceptibility to bacterial infection (with reduced titer of the third component complement (C₃)), and impaired humoral antibody production.

Hard on the heels of the two most recent deaths from laetrile was further evidence in the United States that doses not large enough to kill may still be toxic. Dr. Frederick Smith and his colleagues at Georgetown University School of Medicine in Washington, D.C., had the opportunity to study two patients who had been given laetrile by others. Both had serious reactions to the laetrile. One of them was a woman who developed generalized discomfort, with nausea, backache, headache, abdominal cramps, and a fever to 102 F. with diffuse rash most prominent on her abdomen. (Dermatitis occurs frequently in industrial workers chronically exposed to cyanide solutions. She had been taking 6 g laetrile weekly intravenously and oral laetrile as one 500 mg tablet three times a day. When her laetrile was stopped, her temperature became normal, and her rash and abdominal cramps went away within 2 days. When she resumed taking laetrile, she was readmitted to the hospital with the exact same symptoms that laetrile had previously given her: headache, nausea, abdominal cramps, rash and fever to 102 F. When laetrile was discontinued, the fever, rash, and abdominal discomfort again went away within 48 hours.

The other Washington patient was a 46-year-old man who had been taking one 500-mg laetrile tablet daily since September 1976, and came into
Georgetown University Hospital in March of 1977 with a 1-week history of progressive neuromuscular symptoms, including severe drooping of the eyelids and muscle weakness in the arms and legs. Within 48 hours after stopping laetrile, his drooping eyelids and muscle weakness improved dramatically and went away completely in 6 days. The cases reported by Dr. Smith and his associates suggest laetrile tablets or injections produce a similar type of poisoning to that produced by the laetrile in cassava.

The Merck Index lists the human toxicity of cyanide from laetrile (or any other source) as: from high doses, tachypnea, dyspnea, paralysis, unconsciousness, convulsions, and respiratory arrest; from lesser doses, headache, vertigo, nausea and vomiting, and from chronic exposure over long periods, fatigue, and weakness. Lassitude, insomnia, cardiac discomfort, anemia, skin eruption, and ocular and auditory disturbances may also occur. In the McDonald case, there was expert testimony from Professor Jerry Lewis (who wrote Reference 8), that the hospital record gave evidence of seven separate episodes of acute cyanide poisoning of deceased John Scott by laetrile given orally (nausea, vomiting, diarrhea) or intravenously (hypotension) by defendant laetrile doctor McDonald, plus testimony of progressive fatigue and weakness, consistent with chronic cyanide poisoning.

The vegetarian diet given by laetrile proponents assures the patients of greater cyanide poisoning because plants are the main sources of the enzyme which releases cyanide from laetrile.

For every person dramatically killed by cyanide poisoning, there may be thousands chronically poisoned by low concentrations of it, and suffering insidious loss of appetite, weight loss, cachexia, and mental deterioration. Rhodanese and sulfur in the body "detoxify" cyanide to thiocyanate, which itself is toxic and can produce weakness, nausea, vomiting, diarrhea, skin eruptions, arthralgia, palpitations, precordial pain, muscle cramps, facial edema, nephrosis, hepatic necrosis, anemia, depressed thyroid function, irritability, blurred vision, tinnitus, motor aphasia, hallucinations, and delirium. The public conception of cyanide poisoning as always acutely lethal arises from the use of cyanide in homicides and suicides.

Cyanide poisoning in a child may produce bizarre behavior which parents may describe as "acting like an animal." A 3½-year-old girl poisoned by apricot kernels exhibited "disorientation and confusion, vertigo and restlessness. She reportedly tried to drive her tricycle into a wall and to chew on a red flower, which she assumed was a lollipop." The odor of cyanide is widely believed to be easily detected. However, there are gross genetically determined differences in the olfactory perception of cyanide by different persons. In one study, only six of 19 physicians recognized cyanide when they smelled it, and five of 30 detected no
smell at all when confronted by a sample of sodium sulfate containing essence of almond.\textsuperscript{17}

In patients taking laetrile “some deaths ascribed to cancer, particularly in debilitated patients, may have been due or accelerated by cyanide from the drug.”\textsuperscript{9} Laetrile may cause neurological signs and symptoms erroneously attributed to a suspected or actual brain metastasis but in fact due to the laetrile. These signs are curable by stopping the laetrile\textsuperscript{9,70} rather than increasing it and producing neuromuscular weakness and ptosis.\textsuperscript{70} The case against “nontoxic” laetrile grows daily.\textsuperscript{56}

**Factors affecting toxicity**

As a poison, laetrile is much more toxic when taken by mouth than when injected. Gastric juice may release some cyanide from laetrile. The enzymes which split off the 6% cyanide from the rest of the laetrile molecule are found in many plant foods, and to a small extent in intestinal bacteria and possibly intestine epithelial cells.\textsuperscript{6,8,22} Human feces were reported to hydrolyze 45.2\% of amygdalin as compared to only 0.47\% for mouse feces and none for monkey feces.\textsuperscript{75} These enzymes are not absorbed from the intestine into the blood stream, and thus the releasing of cyanide from laetrile occurs largely in the intestine,\textsuperscript{6,8,22} including the colon.\textsuperscript{75}

The toxicity of the cyanogenic glycosides (laetriles) is influenced by actual cyanide concentration, which varies widely.\textsuperscript{76} Cyanide concentration depends on the size of the bolus of cyanide; thus 25 apricot kernels chewed and eaten as one mouthful could be lethal, but the same 25 kernels chewed one every ½ hour may produce no visible symptoms. As Olson\textsuperscript{77} noted, if 50 ppm of cyanide in air are inhaled by human subjects, the rate of detoxification to thiocyanate is equivalent to the rate of intake, and the subject shows no obvious acute ill effects. Under these conditions, 720 mg can be metabolized in 24 hours.\textsuperscript{77} Chronic poisoning from thiocyanate would still have to be reckoned with from long-term same conditions.

Laetrile tablets and injections may contain as little as 0\textsuperscript{78} to 55\%\textsuperscript{10,79,79a} of the amount claimed on the label, with 10 to 80\% being the usual range.\textsuperscript{10} Ampoule solutions contain the D and L epimers in 1:1 ratio and often contain 2.7 to 6.8\% isopropanol.\textsuperscript{79,79a} Tablets have only the D epimer.\textsuperscript{79,79a} Other factors affecting toxicity are: amount and type of plant products and other foods ingested; size of patient; how long and well the food is Waring-blended, chopped, or chewed before swallowing; factors in the stomach and intestine affecting the stability of the cyanide-releasing enzymes in eaten plant food; and the ability of the patient to detoxify the cyanide. Conn\textsuperscript{78} and Lewis\textsuperscript{8,9} have pointed out that among the plant foods that can assure cyanide poisoning from ingesting them with oral laetrile are sweet almonds, mushrooms, lettuce, carrots, green peppers, celery, bean sprouts, peaches, and plums.
Worthlessness of anecdotal and testimonial claims

Anecdotal evidence is a narrative account lacking necessary scientific evidence to establish the facts alleged. Testimonials are emotional statements citing personal experience by persons unqualified by scientific training and expertise to separate cause and effect from coincidence. On investigation, every case of cancer "cure" from laetrile falls into one of the following four categories: never had cancer, cancer in remission unrelated to laetrile; cancer progressing; patient dead.

In 1977, United States District Court Judge John Reynolds (former Governor of Wisconsin) put a laetrile factory out of business in the case of the United States of America v. Mosinee Research Corporation and United States Pharmaceuticals, Inc. His decision was upheld, as was his injunction against U.S. Pharmaceuticals of Manitowoc, Wisconsin, in 1978 by the United States 7th Circuit Court of Appeals in Chicago. Three of his important Findings of Fact were: "Due to the presence therein of cyanide, a poisonous and deleterious substance, amygdalin is potentially harmful and ordinarily injurious to health," and "Due to the presence of cyanide, amygdalin is unfit for consumption as a food by human beings," and "The promotion or sale of amygdalin for any food or drug use constitutes a fraud on the consuming public." Among his Conclusions of Law was, "amygdalin in any form contains cyanide, a poisonous and deleterious substance which is ordinarily injurious to health and otherwise unfit for food."

Perhaps his most important judicial decision was to reaffirm that the uncontrolled studies of laetrile by its proponents are worthless. Specifically, he held as a Finding of Fact that, "anecdotal and testimonial evidence as to cures or effects of treatments on cancer victims as described by lay persons, or persons possessing either an M.D. or Ph.D., but who are not qualified by scientific training and experience as experts in the field of cancer therapy, is not probative or substantial evidence of the safety and efficacy of cancer treatments." Judge Reynolds held as a Conclusion of Law, "The testimony of lay witnesses as to the existence of cancer and the safety and efficacy of an alleged cancer treatment based on their personal experience with the treatment is entitled to no weight and is therefore inadmissible as irrelevant and non-probative evidence." As precedents for this Conclusion of Law, Judge Reynolds cited a number of legal sources.

At several 1977 and 1978 National Health Federation conventions promoting nutrition quackery, and in several court cases involving laetrile, stunning results against cancer with laetrile were purported to have been obtained by Harold Manner of Loyola University and David Rubin of Israel. As is typical of laetrile claims, these were not submitted to scientific scrutiny by publication in the scientific literature, and laetrile promoters falsely claimed legitimate scientists were ignoring "the facts" because of a
conspiracy against any possible cure. The reality was that investigation of
the Manner claims by this reviewer and others revealed that he was digest-
ing mammary tumors in mice by injecting digestive enzymes (a German
quack cancer remedy called Wobe Mugos) directly into the tumors, and
then irrelevantly claiming in these mice “complete regression of cancer by
laetrile, enzymes, and vitamin A.” Further information regarding Manner’s
claims appears in the “Epilog”. Many laetrile quacks inject Wobe Mugos
into their patient’s tumors, which is equivalent in barbarism to injecting
Adolph’s meat tenderizer. Both have the plant enzyme papain as an active
ingredient. Fatal anaphylaxis is a risk of such injections.

The information on Rubin as of late 1978 was that the “Israel Medical
Research Foundation” of which he was Medical Director had never done
clinical research and was out of business, all 45 patients to whom he gave
laetrile in 1976 and 1977 were dead in 1978, and he was working in a Ti-
juana laetrile operation for which the Committee for Freedom of Choice in
Cancer Therapy was the official American agent.83

Because of the public’s inability to separate anecdote from fact, scientists
do not come off very well against quacks on radio and television talk shows.
The scientist is limited to speaking the truth, the quack is not, and most
moderators are solely interested in entertaining the audience, where spec-
tacular scientifically unsound claims do better than cold facts. Some talk
shows will only give air time to personalities known to make such spectacular
claims.90 Responsible nutritionists often refuse to appear in the same forum
with quacks, because it lends prestige to the quack, who is falsely presented as
a scientist of equal stature engaged in legitimate scientific controversy.83a

A typical example of a worthless testimonial is the affidavit laetrile
promoters attempt to obtain from the next of kin of patients who die from
cyanide poisoning from laetrile, attesting laetrile did not kill the patient.
Loved ones, feeling involved in the death, attempt to expiate their feelings
of guilt by willingly signing such affidavits, which are worthless as evidence
since they are self-serving documents which not only fly in the face of the
medical facts (the clinical and laboratory evidence of cyanide poisoning),
but the persons signing lack the clinical and laboratory knowledge to eval-
uate the medical facts.

As psychiatrist Hilde Bruch has pointed out,20 patients turn to quacks
because they offer hope and, often by “nutrition” gimmicks in which the
patient can participate, make the patient feel involved in, and in control of,
his own therapy. Those who feel hapless, helpless, and hopeless are easy
marks for the quack. To avoid driving patients into the arms of such per-
sons, physicians should never give up hope, never tell the patient there is
nothing that can be done, and should involve the patient in his therapy so
he has some sense of mastery of the situation.20
The placebo effect

Frequently on beginning any treatment, a patient will have a sense of improved well-being, improved appetite, and reduced pain. This phenomenon is so well-recognized by physicians that it has an established name—the “placebo effect” (the name means “I will please”). Competent physicians recognize this effect as having nothing to do with the medication given per se; quacks and less competent physicians take credit for it as the effect of the drug rather than what it is—psychological effect, or the effect of suggestion (which can generate neuroendocrine changes). For this reason, there has been no testimony in favor of giving people laetrile by any medical scientists recognized by the scientific community as a source of reliable information about cancer or nutrition, and all such testimonials have been from anecdotalists.

Scientific failure does not prevent political success. Quack remedies will survive as long as they are lucrative and laymen and legislators ignore the scientific dictum that every chemical is harmful until proved safe, and fail to realize that the placebo effect is a powerful therapeutic tool “on the average about one-half to two-thirds as powerful as morphine in the usual dose in relieving severe pain.” Placebos may induce endorphin release.

Since cyanide and thiocyanate are neurotoxic, it is possible that as the patient is progressively debilitated, blinded, and deafened by laetrile, his sensory nerves may also be damaged so that he feels less pain. However, many analgesics and narcotics offer surer pain relief without slowly destroying the patient.

Since the “placebo effect” occurs with a harmless “sugar pill,” giving a poisonous “food supplement” like laetrile to achieve it is irresponsible, and can be the legitimate basis for a malpractice claim by a victimized patient or his next of kin, or for a charge of murder by the state. (See the McDonald case and “Nutrition Quackery as Murder,” below.)

Laetrile is a fake “cancer cure”

The claim that cyanide from laetrile concentrates in cancer tissue because such tissue has more β-glucosidase and/or less rhodanese than normal tissue flies in the face of the fact that neither of these claims is true and furthermore, cyanide is freely diffusible.

Laetrile is the chemical amygdalin, and therefore laetrile therapy is chemotherapy. All cancer chemotherapy poisons some normal cells as well as some cancer cells. Responsible chemotherapy kills more cancer cells than normal cells; laetrile, like other irresponsible chemotherapy, only kills cancer cells in doses which also kill the patient.
Dr. Lewis has pointed out that the acute toxicity of laetrile in tumor-bearing animals is much greater than in animals without tumors. This would suggest that the worse the patient's cancer the more toxic laetrile will be for the patient. Cyanide poisoning has been demonstrated in normal dogs when fed laetrile.

Laetrile is a fraud as a cancer cure. So held United States District Court Judge John Reynolds in July 1977. Judge Reynolds held as a Finding of Fact that the promotion or sale of laetrile for any food or drug use constitutes a fraud on the consuming public. Irving Lerner, Past President of the Minnesota Division of the American Cancer Society, testified that he had examined reports of 23 studies of laetrile conducted at such institutions as Yale University, the University of California, and Sloan-Kettering Memorial Institute in New York. In each of these institutions, laetrile was found to have no effect on tumors. He further testified that the theories of laetrile action on cancer cited by proponents of laetrile were pure scientific carelessness and error. He pointed out that when laetrile was injected intravenously it was absolutely useless and excreted in the urine, and that when it is swallowed, either nothing happens or something bad happens, depending on how much cyanide is released from the dose. He testified to having seen patients who stopped conventional cancer treatment—which was effective—and went on to die of cancer after switching to laetrile. He testified the use of laetrile was cruel because it involved proposing a treatment with no hope of effectiveness to replace treatment which has hope.

Dr. Lewis testified that the claims of value of laetrile against cancer made by the lucrative laetrile-promoting "fringe" clinics such as those of Contreras and Soto in Mexico, Nieper and the Janker clinic in Germany, Navarro in the Philippines, and Ransberger and the Fairfield Clinic in Montego Bay, were worthless. Laetrile promoters and their attorneys are generally armed with reams of deceptive and misleading writings, provided by the laetrile industry's most active lucrative promotional literature sources, including the McNaughton Foundation (see footnote in "Chemistry" section, also footnote to Reference 119; see also References 121 and 122) and American Media, as well as letters touting laetrile from the lucrative laetrile mills in Tijuana, Manila, Germany and Vienna, and the island of Jamaica. This material ranges from anecdotal and worthless to blatantly false, and because of its hearsay nature, was not allowed into evidence by Judge Reynolds. Documents on these various laetrile mills are available from the Food and Drug Administration and make fascinating reading, since many of them also promote a wide variety of other quack remedies, from cell injections to coffee and enzyme enemas.

The laetrile industry has a crew of "laetrile doctors," many of them previously lauded in, or listed on the masthead page of "The Choice." Some
are outright quacks and others are licensed physicians on the lucrative fringe of organized medicine, all selling hope—for a price. This crew flies around the country passing themselves off on gullible audiences, judges, and juries as legitimate scientific experts on nutrition and cancer. Most of them are charismatic masters of the art of deceptive and misleading exposition and are snake oil salesmen of classic stripe. Their credibility is usually easily impeachable by an attorney with the foresight to secure their documents from the Food and Drug Administration, since their background often includes brushes with the law in relation to health quackery, often with more indictments than convictions. For this reason, a frequent legal tactic of the laetrile industry is to spring one of their crew as a “surprise witness” so there will be no time to learn his background to discredit him. Attorneys fighting laetrile quackery who do not secure pretrial agreement that there will be no surprise “expert” witness risk fighting a flying circus!

The promoters of laetrile falsely claim that the drug is legal and freely prescribed in many countries (for example, in the exploitation book World Without Cancer—the Story of Vitamin B₁₇). However, Dr. Sherwood Lawrence, Executive Secretary for the Cancer Advisory Council of the Department of Health of the State of California contacted the Secretary of Health, or equivalent, of Israel, Australia, Greece, Belgium, the United Kingdom, and India, and learned that laetrile was not only illegal, but that no applications had been made to legalize it.²¹ ²² Even in Mexico, the direct selling of laetrile to the general public was prohibited, and both of the Tijuana sellers of laetrile were under federal injunction by the Mexican Government.

Laetrile mill operators fake credibility by using letters from responsible medical scientists asking for their data as “proof” that they too are respected cancer scientists, and by submitting abstracts (summaries) to reputable scientific meetings. However, their abstracts present irresponsible conclusions unjustifiable by the data, and therefore are scientifically worthless.

Despite a letter from Guy Newell⁸⁸ of the National Cancer Institute to 385,000 physicians and 70,000 allied health professionals, and additional letters to many persons who were self-proclaimed laetrile prescribers or users in the United States, asking for reports of beneficial effects on tumors in any case at all by laetrile, only two cases of alleged remission and 4 of alleged partial remission passed initial screening, and progression of cancer was reported in over 1000 cases.⁸⁹ The “partial remissions” in the laetrile group (four of 68) were statistically not significantly greater than in the “no treatment” group (one of 24), and the two complete remissions could have been incorrect or falsified data or spontaneous remission.⁸⁹ No effort was made to visit the alleged two completely remitted patients to determine if they even existed, much less to determine if the data were valid.

Failure of laetrile in this study in which only positive results were solic-
ited and no information on adverse effects of laetrile was sought is damning (two alleged complete remissions out of over 50,000 Americans taking laetrile), as is the recent report of studies in which the life span of cancer patients has been halved by taking laetrile, due to the combined effects of lack of proper medical care and chronic cyanide poisoning.

On adequate investigation, every claimed “cancer cure” by laetrile proves to fall in one of four categories:

1. Patient never had cancer. Quacks tell many people they have cancer (but often fail to prove it by biopsy), and then “cure” the cancer that was never there with laetrile.

2. Patient had cancer cured by proper therapy (like Mr. Rutherford) but then claims laetrile brought about the cure.

3. Patient has currently asymptomatic progressing cancer, and believes laetrile has produced a remission (like Joey Hofbauer).

4. Patient dead (like John Scott 2 months after U.S. Congressman McDonald claimed in the John Birch Society magazine that Scott’s cancer was “controlled” by laetrile).

In 1976, a crusading new book about unscrupulous medical con men who steal money and sometimes kill people was published. It is *The Health Robbers: How to Protect Your Money and Your Life*, edited by Stephen Barrett, M.D., of the Lehigh Valley Committee Against Health Fraud and the Committee on Quackery of the Pennsylvania Medical Society, and Gilda Knight of the American Institute of Nutrition. Its first chapter, by Dr. Sidney Arje (former Vice President of the American Cancer Society), deals with “The cruellest killers: exploiting cancer victims.” It points out that through the years, hundreds of worthless drugs have been promoted for cancer prevention or cure, but laetrile leads the list of all forms of cancer quackery. It notes that in the 25 years laetrile has been promoted, not a single case has been published in the scientific literature in which it was proved useful against cancer, but “cancer quackery is big business, with an estimated yearly income in the billions. It is also a cruel business for its customers come in deadly fear.” Barrett, an editor of the book, subsequently collected $500 and an apology from a promoter of questionable therapy who slandered him.

Laetrile doctor John Richardson had his license to practice medicine in California revoked in 1976, after a hearing before the California Board of Medical Quality Assurance, partly because he “personally and his agents, advised and discouraged Helen B. Schneck, Kapitan P. Zema, Paul Olsen, and Margaret Baldock from seeking conventional cancer therapy.” Four of the seven patients whose records were reviewed by the California Board either paid or were asked to pay $2000 each for a course of laetrile treatments. In May 1977, Dr. Richardson was convicted of
conspiracy to smuggle laetrile into the United States and fined $20,000.\textsuperscript{5,31,120} This would appear trivial to him, because, according to the Assistant United States Attorney who prosecuted the case, Richardson took in $2.8 million from January 1973 to March of 1976.\textsuperscript{5,31} Less trivial may be the lawsuits filed against him by the spouse of deceased laetrile patient Zema, and by another laetrile patient. As noted below, a 42-year-old patient of his clinic subsequently died from cyanide poisoning from laetrile and apricot kernels, a mixture his book warns against, but does not say produces cyanide poisoning.\textsuperscript{72}

Richardson will probably take in more money with his 1977 lay press book, “Laetrile Case Histories,” written with Mrs. Griffin, a nurse who is the wife of the author of another laetrile exploitation book, “World Without Cancer.” (An interesting statement on page xxii of the Bantam edition of \textit{Laetrile Case Histories} was that reputed Mafia figure “Bayonne Joe” Zicarelli of New Jersey provided $130,000 to the McNaughton Foundation to promote laetrile. Subsequent to that financial transaction, but presumably unrelated to it, laetrile was legalized by New Jersey.) Both books were published by American Media, the lucrative laetrile exploitation literature house,\textsuperscript{48} of which Mr. Griffin is President. Case histories are worthless unless they can successfully survive the cross-examination by experts which they can get from outside reviewers when submitted to responsible scientific journals. This is why literature promoting health quackery is published only in the lay press and in fringe journals, which do not have submitted articles pass through outside expert nonpartisan reviewers before acceptance. The Richardson book case reports are too scanty and case follow-ups too brief to be of any scientific worth. The “metabolic therapy” and “corrective diet for patients with neoplastic disease” which the Richardson book describes is not only nutrition nonsense, but also nutritionally dangerous.\textsuperscript{71,72} The unsophisticated layman may believe it because he has not the scientific basis to separate science from anecdote and fact from fiction.\textsuperscript{13,21} “Nontoxic therapy” and “metabolic therapy” for cancer are double-talk phrases used by self-styled “nutritionists” and outright quacks to “con” the gullible. Cyanide is neither “nontoxic” nor “metabolic” therapy and to so describe it is so obscene and without redeeming value as to be nutrition pornography, as witness the death from cyanide poisoning of the victim who got her laetrile from the Richardson clinic and ate it with apricot kernels.\textsuperscript{160,161}

The antidote to the deceptive and misleading Richardson book is \textit{You Can Fight Cancer and Win}, by New York Times writer Jane Brody and American Cancer Society Senior Vice-President Dr. Arthur Holleb.\textsuperscript{24} This excellent book dispels the irrational fears and ignorant mystification about cancer and shows that in many cases it can be prevented, modified, or cured by the genuine medical advances of recent years. \textit{It records that 1½ million cancer patients are alive today from surgery, radiation, and chemotherapy who would be dead if on laetrile.}
Laetrile promoter McDonald had indicated in an article in "American Opinion" magazine in January 1974\textsuperscript{37} that his patient John Scott's cancer was "controlled" by laetrile, yet Scott died with untreated cancer two months later.\textsuperscript{38} In 1978, as a defendant on trial for malpractice in connection with Scott's death, McDonald admitted in the witness box that laetrile could be poisonous,\textsuperscript{90} and although he admitted he gave Scott laetrile, he denied he was treating Scott's cancer and said he had no intention of doing so.\textsuperscript{38,40} His hometown Atlanta jury's verdict was against him for $15,000.\textsuperscript{38} Yet the John Birch Society's "American Opinion" bookstores in 1978 were still selling offprints of the article at 20¢ each (12¢ each for 1000 or more), with no notification to the buyer that the implication that Scott was cured by laetrile was false, no indication that laetrile could be poisonous, and no indication it was worthless against cancer. As noted earlier, many laetrile profiteers and their victims are John Birch Society members. Most "metabolic doctors" have their patients sign forms consenting that they understand laetrile is not a cancer cure but "nutritional and metabolic support." These deceptive and misleading "consent forms" by the laetrile industry appear meant to exculpate the "metabolic doctor" when his patient dies of untreated cancer. At his trial, McDonald claimed Scott did not want his cancer to be treated. This is the standard defense of "metabolic" doctors charged with negligence in the deaths of their patients.

There was testimony in Scott v. McDonald\textsuperscript{38} of living fungus cultured from an ampoule of laetrile found in defendant hospital,\textsuperscript{168} and question was raised about possible pulmonary fungus infection being misdiagnosed as metastatic cancer.\textsuperscript{38}

In the 1978 trial, McDonald did not contest the testimony of the widow Scott and her son Dan that he wanted "a $200 suit if I cure him and a $2 tie if I don't," and that he then indicated he had cured Scott by having the Scotts (who lived in Birmingham) open a charge account at Muse's men's shop in Atlanta and picked out a $300 suit for himself. McDonald's legal team contented themselves with pointing out to the jury that the Scotts had paid Muse's only the majority of the $300 due for the suit by the time John Scott died, but declined to pay the balance due for the cure after the patient died.\textsuperscript{38} The jury awarded $15,000 to the widow Scott, but McDonald's lawyers then paid her $30,000 to allow court records to be changed to a final judgment in favor of McDonald (Atlanta Constitution, June 20, 1979).

Those who promote laetrile claim that it is "nontoxic therapy" which "corrects the body chemistry" and "supplies vitamin B\textsubscript{17}, the cancer preventing vitamin." They are either misguided or unscrupulous, according to testimony in Federal Court in July 1977.\textsuperscript{21} The claims are contrary to fact.\textsuperscript{5,6,10,21} As United States Senator Edward Kennedy stated at the end of the laetrile
hearings he chaired, in which he heard extensive testimony from laetrile promoters Krebs, Bradford, Richardson, and Halstead, “There isn’t a scintilla of evidence that it provides any sense of hope in terms of curing or preventing cancer... there’s been wholesale profiteering in terms of this substance... gross malpractice and a number of individuals who... appeared here today, in terms of the distribution of it.” Representative Terrence McCarthy (Edgartown) of the Massachusetts legislature was quoted as stating: “The people selling laetrile are crooks, liars, and thieves... Anyone who votes for laetrile is helping to organize mass murder.”

The specious “freedom of choice” and “terminal cancer” arguments

Senator Edward Kennedy has noted that, “The elimination of useless treatment is a valid federal role. It is a humanitarian role. It reduces the burden on cancer patients and their families and allows them to exercise their freedom of choice on the basis of informed judgments among viable alternatives.”

The “freedom of choice” argument of the proponents of laetrile ignores the fact that, for freedom, choice must be informed. There is no freedom of choice when the chooser is not informed that a worthless poison like laetrile is worthless and poisonous. Under our Constitution, freedom of choice does not run to freedom to use fear of cancer and of effective therapy to poison people with a drug that has no redeeming features in order to get rich. There is no “right to shout ‘fire!’ in a crowded theater.”

In July 1978, The United States Court of Appeals for the 10th Circuit, in the case of Rutherford v. U.S.A., ruled that “safety” and “effectiveness” have no meaning when considered in the context of a patient “terminally ill.” Ironically, the phrase “terminally ill” had no meaning in the case of plaintiff Rutherford, a healthy propagandist for laetrile legalization, not known to have cancer at the time of the lower or upper court decision, apparently having years earlier been cured of a polypoid adenocarcinoma of the colon by cauterization after the edema subsided. Such tumors rarely metastasize, and local removal of the polyp is virtually always curative.

The court upheld administration of laetrile (intravenously only) to persons certified by a licensed medical practitioner to be “terminally ill” of cancer. The phrase “terminally ill” was not adequately defined, and it was left to any unscrupulous or misguided physician to declare by affidavit that anyone to whom he chose to give laetrile, including patients previously cured by conventional therapy such as Rutherford, was “terminally ill.” Presumably the Court rejected oral laetrile (effectively outlawing laetrile tablets and capsules) because, while it approved worthless and possibly harmful therapy in such cases, it would not go so far as to authorize gross cyanide poisoning. The disturbing 10th Circuit decision depriving “terminal” cancer patients of the right to safe and effective drugs is being appealed by the
United States of America to the Supreme Court\textsuperscript{92,94} and is counter to the 7th Circuit 1978 decision in U.S.A. v. Mosinee (U.S. Pharmaceuticals of Manitowoc, Wisc.)\textsuperscript{21,80} as well as other court decisions.\textsuperscript{93} Death from so-called "terminal" blood cancers is often due to a bleeding tendency associated with thrombocytopenia. Recent evidence suggests cyanide may precipitate more severe thrombocytopenia.\textsuperscript{94a}

Expert testimony in July 1977 in Judge Reynolds' court\textsuperscript{21} confirmed that all of the claims of relief of pain and other cancer symptoms, and of slowing or "curing" cancer by laetrile were based on the gullibility of the victims and, in some cases, ignorance by their doctors that the natural history of cancer is that it frequently progresses by halts and starts rather than relentlessly, and that many people with "terminal cancer" live many years. It is unjust to use the phrase "terminal cancer," which distorts the truth about cancer in an era when so much can be offered to treat successfully or even cure these patients.\textsuperscript{95} "Terminal cancer" is a poor synonym for "incurable cancer,"\textsuperscript{95} also often a wrongly used phrase. Anything a patient takes when his cancer, in the course of its natural history, goes into a "halt" phase will erroneously get the credit for the "halt."\textsuperscript{92} In addition, spontaneous regression of cancer has been reported in nearly 200 patients.\textsuperscript{96}

In January 1979, the United States Supreme Court agreed to hear the government's appeal from the Rutherford v. U.S.A. decision\textsuperscript{92} in which the 10th Circuit held that terminal cancer patients had no right to safe or efficacious drugs, and therefore could be given intravenous laetrile if a physician signed a "Bohanon affidavit" that the patient was terminally ill with cancer. On June 18, 1979, the U.S. Supreme Court reversed the 10th Circuit by 9-0 in the case of Rutherford v. U.S.A.,\textsuperscript{21} and in February, 1980, the 10th Circuit reversed pro-laetrile judge Bohanon, holding patients had no constitutional "freedom of choice" to take drugs the FDA had not approved, including poisons like laetrile, because the government had a proper interest in protecting citizens. Shortly earlier, California laetrile-promoting physician Privitera had gone to jail after the U.S. Supreme Court refused to hear his appeal.

Laetriles may cause cancer

The final irony in the laetrile story is that laetriles may actually cause cancer. Five lines of evidence suggest this possibility: laetriles are goitrogenic,\textsuperscript{54,55} and such goiters are precancerous lesions,\textsuperscript{43} mutagenic,\textsuperscript{8,97} give a positive Ames test,\textsuperscript{11} a patient with cancer developed a second cancer while being "treated" with laetrile;\textsuperscript{98} and cyanate, an oxidation product of cyanide reduces the ability of mice to reject tumor inocula.\textsuperscript{69} The happy fiction by laetrile proponents that Hunzas (Hunzakuts) "do not get cancer because they eat apricot kernels" was shattered two decades ago by the unhappy fact that autopsy reports showed that Hunzas got cancer.\textsuperscript{5,99}
H. L. Mencken noted that, "For every complex problem, there is a simple solution—and it is wrong."

**Nutrition quackery as murder**

There is precedent in appropriate cases for a murder charge against laetrile purveyors. A California chiropractor, Marvin Phillips, was convicted of second degree murder and imprisoned for shortening the life of a cancer victim by making money via false promises. It is a situation the law calls felony murder. He maliciously induced the prevention of surgery necessary to save the life of 8-year-old cancer victim Linda Epping, by representing that surgery would not cure her cancer but his treatment could, by "chemical balancing" with food supplements. The promoters of laetrile call it a food supplement. When Linda died, assistant D.A. John Miner of Los Angeles got a murder conviction despite the defendant's employment of famed Melvin Belli as one of his attorneys. Dr. Phillips was sentenced to state prison for the term prescribed by law, and the United States Supreme Court refused to hear his appeal.

In his article on "The Phillips Case—A New Dimension in Murder", John Miner concludes that: "Medical quackery is a peculiarly vicious social evil. It preys on those who, because of ignorance or wishful thinking, are left defenseless against the glib promises of cures of everything from pimples to terminal cancer. Inevitably, the quack takes the lives of those unfortunate who...are talked out of getting the proper medical treatment needed to cure or alleviate their illness. Until the Phillips case, the most the quack had to fear was a theft conviction, and if they were unlucky, as much as a year in prison.” The affirmation of Phillips’ conviction for murder by the highest court of California, and the refusal of the Supreme Court to review the case, means the law has forged its strongest weapon to strike down the quack. Justice needs that weapon. The doctor-patient relationship is based on the moral principles of truth, fairness and keeping of promises. Using ineffective drugs in life-threatening diseases gives up realistic hope and betrays the patient. The patient does not want laetrile—he wants to live.

A frightening fact is that anyone wishing to murder a devotee of the laetrile cult need only feed him all at once a half-dozen freshly crushed sweet almonds, macadamia nuts, or apricot kernels (to supply β-glucosidase) plus about a gram of pure laetrile (not the usual adulterated stuff, which is 0 to 80% of what it says on the label). A gram of pure laetrile contains 60 mg of cyanide, and the Merck Index lists 50 to 60 mg as the average fatal dose of cyanide. The crushed apricot kernels found in the stomach of Jo Anne Fye at her autopsy suggested she died from simultaneously eating a gram of laetrile plus crushed apricot kernels.

The allure of quackery: specious logic versus the logic of science; the overlap of cultism and quackery
Patients are most susceptible to quack remedies when they feel helpless, not in control of their therapy, or without hope.\textsuperscript{19,20} Nutrition quackery feeds on specious slogans and beliefs which appeal to needs for control of one's own destiny and of the environment,\textsuperscript{26,161,102} such as the sophistic concept that natural is good and synthetic is bad.\textsuperscript{30} This need for control is accompanied by lack of respect for knowledge, repudiation of knowledge, and perception of established experts as hated paternal authority figures, whereas promoters of quackery are seen as courageous, independent persons with the foresight to penetrate the fakery of the establishment. Those most vulnerable to nutrition quackery are unable to perceive the difference between a genuine authority and expert, i.e., someone who has earned, by disciplined controlled study, scientific training, and experience, the right to make a judgment, and persons who do not follow the basic scientific canons\textsuperscript{13,103} for evaluating medical information, and thus are not authorities and have not earned the right to be classified as experts. Many lay persons are blind to the difference between creative originality and intemperate rebelliousness, and unable to recognize the many characteristics which, taken together, define nutrition quackery.\textsuperscript{83a,104,105,105a}

Mandell\textsuperscript{169} considers Harvey Cleckley's book "The Mask of Sanity" a classical psychiatric explanation of certain cult gurus. He notes they are "...apparently sane, often dynamic...almost always seductive...impress others with their sincere motives and positive intentions and wind up causing great institutional and personal harm. With an unexplainable capacity to engender trust, even in experienced and cynical observers, these people create chaos...the single most powerful diagnostic test was his own willingness to cash their checks...Charm, a quick sensitivity to the unspoken needs of others, and a certain flexibility with the facts are woven into a personal charisma that entrances." They are confidence men per excellence. "Cleckley speaks of the psychopath's immunity from anxiety, extraordinary poise, sense of well-being, and remorselessness. The people around usually think, "He's found it." "The ambivalence of living, the good and bad of everything there is, is painful internal dialogue until the shaman and his magic encourage metaphysical surrender and the induction of unity."\textsuperscript{169}

"The two sides of the brain, especially the neural circuits that are our emotions, are specialized in their functions..." The survival side with speech capacity analyzes incoming data for potential dangers (Freud's force for life, Eros); the pleasure side is intuitive and insatiable for stimulation (Freud's force for death, Thanatos). When the conscious discipline of the survival side fails to brake the natural impulses of the pleasure side, we have Jim Jones and His People's Temple of Jonestown,\textsuperscript{169} or the gurus of laetrile, the cult of cyanide.

Specious logic is typical of the hypothetical questions posed by health quacks. For example:

1. How can you say my remedy doesn't work if you don't personally use
it? (Answer: those who do not profit from history are condemned to repeat it.) Attorneys for laetrile interests ask opposing experts: Do you use laetrile, doctor? If not, how can you say it doesn’t work?

2. Since useful drugs can be toxic, why isn’t my drug justifiable? (Answer: possible efficacy is the only justification for possible toxicity.)

3. Big doses of anything are harmful, so isn’t my drug as good as anything else? (Answer: Comparison of possible harms without comparing efficacy is specious. The only valid comparison is of both efficacy and harm.)

Bills promoting nutrition quackery frequently pass legislatures because the promoters are better organized than “organized medicine.” They control magazines and organizations nationwide in scope. They hold “revival”-type meetings exhorting their followers to be at the legislature during the debate and vote. At the legislature, they set up a command post, fill every seat, buttonhole every legislator, and place their propaganda on each legislator’s desk. Thus, legislators are buried under an avalanche of proponents and the bill often prevails.

Promoters of quackery frequently pounce on a legitimate scientific word or phrase, empty it of its dictionary meaning while retaining its emotional impact, and then use it as a deceptive and misleading “code phrase” in pseudoscientific jargon which impresses the gullible. Examples of such often-abused phrases are “nutritional therapy,” “metabolic therapy,” “holistic therapy,” “alternative therapy,” and “nontoxic therapy.” The modern quack represents himself as a scientist.

The Harvard Medical School Health Letter notes four basic scientific canons for evaluating medical information:

1. Does it go beyond “personal observation” to stand the test of scrutiny and criticism by other scientists, i.e., is it a study or a story? Is it science or anecdote?

2. Was it compared for effectiveness in controlled studies to other treatments and to suggestibility or to the “doing of nothing,” i.e., to a placebo? What is the natural history of the disorder in the absence of therapy? Was the observed result cause and effect, or coincidence due to the natural history of the disorder?

3. Has it been proved safe? Safe compared to what? Is the risk justified? What is the risk:benefit ratio? (Note that if there is no benefit, the risk:benefit ratio is infinity, which is not tolerable.)

4. The burden of proof is on those who propose doing or giving something, especially if it involves a remedy or procedure not well established in medical practice.

Valid weapons against disease are forged in the crucible of these canons, and products which fail to meet these canons either disappear or become quack remedies.

To protect patients from worthless and possibly harmful remedies for which the unscrupulous make miraculous claims, physicians should never lose pa-
tience or give up hope, never tell a patient his condition has no legitimate basis or is hopeless, and always involve the patient in his own therapy.

Vickery and Fries\textsuperscript{106} suggest 4 questions the consumer should ask himself to avoid medical fraud:

1. \textit{What is the motive of the marketer?} (If his hourly gross exceeds $100 per professional, watch out.)

2. \textit{What are the claims made?} (Vague? Misleading? Testimonials? The question is not has it ever allegedly helped anyone. The question is: Is it \textit{likely} to help \textit{you}? It is characteristic of health quackery to make "shifting claims." That is, as the facts slowly catch up with claim "A", quacks shift to claim "B". This is now occurring with laetrile. As the facts are now overwhelming that laetrile is worthless against cancer, the promoters say, "Sure. It's worthless \textit{alone}. You have to use our whole program of nutritional and metabolic therapy\textsuperscript{72} to cure cancer." Of course, the new claim, like the old, is unsupported by valid evaluation such as double-blind control studies. As usual, the quack's position is not, "Here is proof I'm right," but rather "Prove I'm wrong." No matter which "nutritional and metabolic program" of quackery is added to laetrile, when it proves useless against cancer, the quack will simply shift to claim "C"—"You used the wrong quantity of one or more of the "nutritional and metabolic agents," or "You didn't give the enzyme enemas the right way." The claims are infinitely shifting, based in quicksand rather than data, and thus the quack stays in business.

3. \textit{Do experts in the field use it?} (Do cancer doctors use laetrile when their mother, spouse, or child has cancer? What organizations endorse it?)

4. \textit{Does it make sense?} (False cures have false rationales.) Specious or sound?

History professor John Duffy noted that, "A fact frequently overlooked is that in any day and age a good part of medical practice falls into the categories of folk medicine, self-medication, and quackery. For the vast majority of people, sickness represents a serious economic threat, and their first impulse is to try a folk or proprietary medicine or some practical home technique..." "One can only wonder which is most amazing—the greed and callousness of the quacks or the gullibility of their clientele."

The long and continuing story of health quackery in the United States has been well told by history professor James Harvey Young.\textsuperscript{108}

The Consumers Union book, \textit{The Medicine Show}\textsuperscript{109} points out that "The AMA, whose Bureau of Investigation has been a clearinghouse for information about quacks and quackery for fifty years, has suggested certain guidelines for spotting a quack. Beware, it warns, if self-styled medical experts use a special or secret machine or formula they claim can cure disease; if they guarantee a quick cure; if they advertise or use case histories or testimonials to promote their cures; if they clamor constantly for medical inves-
tigation and recognition; if they claim representatives of organized medi­
cine are persecuting them or are afraid of their competition; or if they tell
you that surgery, X-rays, or drugs will cause more harm than good.”

“If, after applying these rules, you still have doubts about a treatment or
cure suggested to you by an advertisement, a book, a friend, or a relative,
you can obtain helpful answers to questions from a variety of public service
organizations. (Most of these organizations appreciate being notified of
questionable activity in their areas of special interest.) Some of the reliable
places to try are:

The Food and Drug Administration District Offices, as listed under
Health, and Human Services in telephone directories of the cities where
they are located, or its national office, Rockville, Md. 20857.

The Federal Trade Commission, Bureau of Consumer Protection, Wash­
ington, D.C. 20580—for complaints about misleading advertising.

The United States Postal Service, 475 L’Enfant Plaza, N.W., Washington,
D.C. 20206—for information and complaints about mail-order products.


The American Medical Association, Bureau of Investigation, 535 North
Dearborn Street, Chicago, Ill. 60610.

The American Cancer Society, Committee on Unproven Methods, 777
Third Avenue, New York, N.Y. 10017.

Your state or local health department, medical society, or food and drug
enforcement agency.”

The *Medicine Show* goes on to state109: “The vigor shown by the AMA in
pursuing outright quacks has not been matched by equal energy and dili­
genoe in unmasking questionable practitioners who operate under the cloak
of official licensure. In this area the AMA has been virtually derelict. Al­
though machinery exists for depriving physicians who are incompetents or
charlatans of their right to practice medicine, the procedures are so cumber­
some that they are seldom invoked. The authority to hear charges and,
theoretically, to revoke licenses is delegated to state and county medical
societies. These bodies are usually content merely to reprimand a physician
brought up on charges. The physician, duly reprimanded, is then permitted
to resume normal practice.”

“This kind of wrist slapping does little to upgrade the quality of medical
care. The traditional image of the doctor as an inviolate guardian of health
care has changed in recent years more because of the misconduct of a few
physicians than because of any pervasive flaw in the medical profession as a
whole. Consumers Union believes that more stringent penalties for abuses
of medical privileges are needed, as well as more responsibility on the part
of state and county medical societies.”
Some of the “questionable practitioners who operate under the cloak of official licensure” are part of the “flying circus” of laetrile promoters who travel around the country speaking to gullible audiences and appearing in various court cases involving laetrile, using their M.D. degree to impress the gullible into believing that laetrile is “nutritional and metabolic therapy.”

The allure of quackery was recently garishly illustrated by People’s Temple cult leader Jim Jones, who reportedly was a faith healer who “cured” parishioners by the “Filipino psychic surgeon” trick of appearing to remove tumors while actually “removing” a palmed chicken innard. According to the New York Times for November 21, 1978, he killed about 900 of his parishioners in Guyana, South America by a suicide method in which “cyanide was dumped into a large soup kettle, and the liquid was fed first to the babies, then to the children old enough to drink it themselves, and finally swallowed by the adults, many of whom were older people who had turned their Social Security checks and their lives over to the custody of Mr. Jones.” About Jim Jones, former cult Planning Commission member Wanda Johnson was quoted in the November 21, 1978 New York Times as saying, “I was struck with his charisma, his power; he spoke beautifully; he seemed so benevolent… Once I became a member of the inner circle, I realized he was a madman, completely insane.”

Like other quacks, Jones used letters of reply from responsible public figures, thanking him for his letter, as a means to vouch for his own integrity. According to the Times, “A physician, Lawrence Schacht, prepared the cyanide punch” taken by about 900 People’s Temple cult members who “took their drinks, put their arms around each other, had convulsions, and died within five minutes.” Cult leader Jim Jones “died of a bullet wound in the head.” The poison punch was purple Flavour-aide laced with potassium cyanide.

When quackery and cultism overlap, as in the case of laetrile, the allure of quackery takes on grotesque proportions. Boston psychiatrist and student of cultism, John Clark noted in the November 21, 1978 Associated Press story on why the People’s Temple cultists committed suicide, that “People who go into cults are in a state of mind that does not allow outside information to enter. They feel safe, cozy. They can talk their own language to each other. It is reinforced by their opposition to all outside reality—an ‘us and they’ mentality. There is no room for ambiguity in groups like these.”

Boyce Rensenberger of the New York Times, in its November 22, 1978 issue, discussed the fanatical devotion to their leaders and fears of the outside world fundamental to many cults. He quoted Yale psychiatrist and authority on brain washing, Robert Jay Lifton, as noting that when the present looks frightening, there is often a cry for a return to absolute simplicity in the rules of living. People seek to return to a past of perfect harmony that never was. When they find their fundamentalist principles threatened by the outside world, believers have many times chosen suicide
as a way of immortalizing their purpose. Dr. Lifton indicated the increasing rootlessness of American society was spawning new cults, most fundamentalist in nature, at a striking rate.

Laetrile, the cult of cyanide, is just such a cult, with alarming similarities to the People's Temple. Both cults are headquartered in California, which, with its many rootless transplanted people from other areas, is fertile soil. Both breed on fear and fanaticism. Paranoia pervades the atmosphere of both. The followers of both are impervious to outside reality and information. They are intolerant of outsiders and submissive to their leaders.

Followers of both cults run the risk of their loved ones dying of cyanide poisoning. Operating out of San Francisco, Ernst Krebs is the "guru" of the laetrile cult, as Jim Jones, operating out of San Francisco, was of the People's Temple cult. Unlike Jones, Krebs is a convicted criminal.119 Followers of both cults pour their money and their lives into the coffers of the cult. Both appeal particularly to the elderly, are fundamentalist, anti-establishment, and politically extreme (one to the left, the other to the right). Cults and quackery go hand-in-hand.20,83a

Professor Harold Morowitz of Yale105a suggests that young people are vulnerable to irrational food cults because we do not teach students how to evaluate the validity of statements, i.e., epistemology and logic. We need to teach them to ask, "How do we know the things that we know?" They should know the methodology for evaluating the validity of statements such as, "Laetrile cures cancer. Laetrile is harmless." We need to teach them how belief can be rationally established. This section indicates the type of evaluatory questions students should be taught to ask regarding health and nutrition, so that they become capable of separating the specious from the sound. Self-righteous certainty about the validity of nutrition fads is the province of the smugly ignorant.105a

Conclusion

Figure 2 is the warning notice which in November, 1977 was mailed to every doctor111 and a total of nearly one million health professionals in the United States26,111 placing them on notice that laetrile is worthless, poisonous, and often contaminated with fungus and insect parts.79 It may also contain free cyanide released by deterioration of laetrile. Thus no American doctor using laetrile can invoke the defense of ignorance or confuse anecdote with science. Legalization of laetrile will not protect physicians against charges of malpractice or homicide. Many narcotics are legal, but physicians remain liable for malpractice or homicide in relation to their use.

The alleged value of laetrile is clearly a myth112 and a fraud.23,27 It is not for scientists to beg for the data of every new snake-oil promoter of laetrile who claims that the century-old quack cancer remedy now "works"; it is for the promoters to submit their data for publication in the crucible of the
Cancer patients and their families are warned that:

**LAETRILE IS WORTHLESS**

Whether sold as a drug (amygdalin) or as a "vitamin" (B-17), laetrile is worthless in the prevention, treatment or cure of cancer. The substance has no therapeutic or nutritional value.

**LAETRILE IS DANGEROUS**

Laetrile can be fatal for cancer patients who delay or give up regular medical treatment and take laetrile instead. Laetrile contains cyanide and can cause poisoning and death when taken by mouth. One infant is known dead of cyanide poisoning after swallowing fewer than five laetrile tablets. At least 16 other deaths have been documented from ingestion of laetrile ingredients (apricot and similar fruit pits). Laetrile is especially hazardous if the injection form is taken by mouth. This can cause sudden death.

**LAETRILE MAY BE CONTAMINATED**

Laetrile is not routinely subject to FDA inspection for quality and purity as are all other drugs. Analysis has shown some laetrile to contain toxic contaminants. Ampules of laetrile for injection have been found with mold and other adulterants which can be dangerous when injected.

Those who persist in the use of laetrile or its ingredients should:
- Be prepared to deal promptly with acute cyanide poisoning if the oral product is used. Vigorous medical treatment must be started immediately or death can result.
- Watch for early symptoms of chronic cyanide poisoning, including weakness in the arms and legs and disorders of the nervous system.
- Keep the drug out of reach of children.

For full details about the hazards of laetrile, see your family physician or a cancer specialist, or write the Food and Drug Administration, HFG-20, 5600 Fishers Lane, Rockville, Maryland 20857.

Donald Kennedy
Commissioner of Food and Drugs

Peer-reviewed scientific literature, where it can be subjected to validity testing. It is in this crucible that the steel of truth is separated from the dross of error. Since the time of the pharaohs, when laetriles were first used for execution by cyanide poisoning, they have failed every test of validity except as agents of debility and death.

The legal position of the United States and Canada is that laetrile is quackery. The cyanide in it is deadly. The quack says "anything I do is safe and effective until you can prove otherwise." The basic
rule of medical science is that it is for the proponent to prove safety and efficacy; and any therapy is unsafe and ineffective until proved otherwise. To have any other rule is to risk the health and lives of millions. Laetrile violates the primary ethical rule of medicine—"above all, do no harm."81,116

A number of leaders of the laetrile cult, including Ernst Krebs, Jr., Andrew McNaughton, John Richardson, and Robert Bradford are convicted criminals.117-122 However, their charisma still sustains the laetrile industry, a role facilitated by their being on probation rather than in jail. Each has a foundation named for him. Such foundations provide a layer of protection from the law and from aggrieved victims who must "pierce the corporate veil," and lend prestige in the eyes of the gullible.

Scientific medicine uses many medicinal agents derived from plants.123-125 Unsafe and ineffective remedies like laetrile are not among them.3 Scientific medicine does not reject the "natural"; it rejects quackery.

EPILOG

Recent data suggest the partial detoxification of cyanide to thiocyanate may not be as rapid as previously believed.126 Thiocyanate may partially convert back to cyanide.127 While the total daily excretion in urine of adults in industry is 0.5 to 3 mg thiocyanate,57 for nonsmoking adults generally, it averages 0.65 mg KSCN/24 hours,128,126 or 0.5 mg -SCN, although smokers may urinate a mean of 10 mg KSCN/24 hours.128,129 Nonsmoking adults may average 0.54 mg/100 ml KSCN in their serum and smokers 1.52 mg/100 ml.128,129 "If a proven nonsmoker has serum values of 1.5 to 2 mg% or above, which is the normal range of the smoker, then he should be regarded as overexposed ...(as should be regarded a smoker with a)... serum thiocyanate of 3 mg% or above."129 "Any increase of urinary thiocyanate output above 2 mg/24 hours should be regarded as indicating too great an absorption..."129 In adult smokers, "only increases or urinary thiocyanate above 16 mg/24 hours should be regarded as dangerous."129 In one laboratory, 10 adult nonsmokers had mean levels of 3.6 ± 0.9 µmole thiocyanate/100 ml of plasma (2.2 ± 0.5 µg/ml), and 20 smokers had mean levels of 6.5 ± 1.7 µmole/100 ml (4 ± 1 µg/ml).130 Each laboratory should run its own control values, since values vary from one laboratory to another; perhaps the most important diagnostic information is that either plasma or urine levels approximately four times normal for the laboratory may mean serious toxicity if sustained.53

It has been suggested that Leber's hereditary optic atrophy and tobacco amblyopia are both due to defects in the partial detoxification of cyanide to thiocyanate.130 Smokers with such defects should have high plasma cyanide levels, but they have the same plasma thiocyanate levels as nonsmokers.130,167

A level in excess of 0.2 µg cyanide per milliliter of blood suggests acute cyanide poisoning.58,59,126 Since about three-fourths of blood cyanide is in the
cells,\textsuperscript{7,60,131} a value greater than 0.1 \( \mu g \) cyanide per milliliter of plasma would suggest acute cyanide poisoning (assuming a hematocrit of 50). In acute fatal cyanide poisoning, levels of 0.26 to 3.1 mg cyanide per 100 ml of blood occur.\textsuperscript{131a} Fatal subacute poisoning was associated with a level of 0.29 \( \mu g \) cyanide per ml of serum 3 hours after ingestion.\textsuperscript{1} Vesey et al.\textsuperscript{131} suggest the amount of cyanide in plasma rather than in red cells is the critical factor in cyanide intoxication, and that the fatal concentration is between 10 and 20 \( \mu m o l e \) HCN per liter plasma (0.27 to 0.54 \( \mu g \) HCN per ml plasma).

The finding that human feces hydrolyze amygdalin\textsuperscript{75a} raises the possibility of insidious cyanide poisoning one or two days after ingestion of amygdalin, when ingested material reaches the colon and the released cyanide is absorbed by diffusion. In 1978, the pediatric literature* recorded the near-death of a child from cyanide poisoning from a laetrile enema. On page 6 of the March-April 1979 issue of the laetrile industry magazine “Choice,” a leader of that industry “warned that pure amygdalin...in enemas can produce toxic cyanide release and that by administering injectable laetrile as an enema it is possible that one person has died and that several cases of toxicity have occurred.” A similar phenomenon may occur if injected laetrile is excreted in the bile. Human tumor cells do not release cyanide from laetrile,\textsuperscript{29,132} but human liver can, to a very small degree release cyanide from prunasin.\textsuperscript{6,29,132} A number of studies in the first half of this century tested cyanide as a cancer chemotherapy agent, but it always proved to have too narrow a therapeutic ratio (i.e., toxicity to tumor: toxicity to host) to be of clinical value.\textsuperscript{133}

In the body, cyanide \((-C \equiv N)\) is converted to not only the lesser poison, thiocyanate \((-SCN)\), but also the lesser poison, cyanate \((-OCN)\), so it may also be desirable to measure blood cyanate\textsuperscript{134} when assessing cyanide poisoning.

**The Chad Green Case: Cyanide poisoning from laetrile and vitamin A poisoning from emulsified vitamin A**

This reviewer was a medical-legal consultant to the Commonwealth of Massachusetts in the Chad Green case.\textsuperscript{135} Chad was a 3-year-old acute lymphocytic leukemia victim who had been placed within the legal custody of the State after his parents had allowed relapse by stopping the chemotherapy that put him in remission without significant side effects. Under court order, a second remission without significant side effects was

brought about with chemotherapy. After September, 1978, when the physician giving Chad chemotherapy learned that he was getting the so-called “metabolic therapy” of the laetrile cult at home, Chad had plasma thiocyanate levels of 2.7 and 1.1 mg/100 ml measured at Massachusetts General Hospital, as compared to levels of 0 in each of four children on chemotherapy not taking laetrile. His parents stated his laetrile dose was 250 mg twice daily, but only 80 mg amygdalin was found in the 24-hour urine collected by Court order in January, 1979, suggesting that the drug had either been stopped prior to the start of the urine collection or was so adulterated as to be about 22% of label content, since about 70% of an oral dose of amygdalin appears in the urine in 24 hours. However, residual cyanide from prior doses was still so great that Chad had 0.22 µg cyanide per milliliter of plasma, a plasma thiocyanate of 1.8 mg/100 ml and a total urine thiocyanate of 24.3 mg (1.43 mg –SCN/kg body weight/24 hr) compared to two other children on chemotherapy not taking laetrile, who had 8.5 mg (0.25 mg/kg per 24 hr) and 9.2 mg (0.51 mg/kg per 24 hr), respectively. These two children were in the hospital, exposed to frequent tobacco smoke and possibly various low cyanide sources in their diets. It should be noted that Chad’s plasma cyanide was only 0.07 µg lower than that of a fatally poisoned infant.

These laboratory evidences of chronic cyanide poisoning suggested that his intermittent symptomatology of irritability, insomnia, and abdominal distress (and possibly other symptoms) on the “laetrile metabolic diet” were due to episodic cyanide poisoning associated with the variable blood levels of cyanide and thiocyanate of persons taking laetrile, due to the variable release and absorption of cyanide from laetrile, and the varying actual amygdalin content of the tablets labeled “500 mg”. His blood and urine data were in the range of Nigerians with ataxic neuropathy associated with laetrile in their diets, supporting the possibility that he would also gradually deteriorate over the years from cyanide poisoning if he continued taking laetrile. Headaches, nausea, perspiration, and flushing are frequent in children with low grade cyanide poisoning. Typical symptoms of chronic exposure to cyanide are hoarseness, conjunctivitis, anorexia, weight loss, weakness, and an altered mental status. A 3-year-old poisoned by apricot kernels repeatedly rammed her tricycle into a wall and sucked on a red flower thinking it was a lollipop. Cyanide can make a child act like a “wild animal.”

He was getting at home 15,000 IU of “emulsified vitamin A” thrice daily. “Emulsified vitamin A” is considered a prohibited new drug by the Food and Drug Administration, because of lack of adequate evidence of safety or efficacy, but it is the preferred product of the laetrile cult. Dr. John Truman testified that over a 3-month period, the “emulsified vitamin A” produced
serial rises in Chad's plasma vitamin A levels from the 0.67 µg/ml normal mean to 6.8, which is in the toxicity range of tenfold normal, along with parallel serial rises in SGOT, suggesting probably liver damage from deposition of toxic quantities of vitamin A in his liver. Laetrile cult folk hero Harold Manner recommends that cancer patients receive "metabolic therapy" including 300,000 I.U. of "emulsified vitamin A" daily, on page 165 of his 1978 cult book "The Death of Cancer."

On January 23, 1979, Judge Guy Volterra ordered that the health-threatening "nutritional and metabolic therapy" with laetrile, vitamin A, and enemas of digestive enzymes be stopped, and that Massachusetts General Hospital be allowed to do periodic tests on Chad to check for cyanide and vitamin A poisoning. There had been testimony that the enzyme enemas could digest the colon's protective coat, allowing toxic substances to enter the blood, and, in addition, daily enemas in a 3-year-old boy could produce emotional problems that could be severe in his later life. Mrs. Green stated, "We have the constitutional right to believe whom we wish to believe," and the parents then fled the State with Chad, as have other disciples of the laetrile cult when states challenge laetrile therapy, and took him to Contreras' laetrile clinic in Tijuana, which contains the retail outlet in Mexico for the Kem laetrile factory founded by Contreras. They stated they were getting financial support from the National Health Federation.

In October, 1979, Chad died suddenly in Tijuana, in a manner suggesting possible acute cyanide poisoning. Medical World News reported that when an American pathologist arrived in Tijuana to secure blood to determine if it contained a lethal amount of cyanide, he was informed that by error all of Chad's blood had been replaced with embalming fluid. In November, 1979, the Boston Globe reported that Chad's parents had refused $100,000 for his story and were holding out for $1,000,000. The laetrile industry reported that Chad's father was now traveling the U.S. for them promoting laetrile.

In "The Origins of Totalitarianism," Hannah Arendt noted that the feelings of rootlessness, loneliness, and despair in modern society cause people feeling adrift in anarchy to seek connectedness via a disciplined set of rules, consistent even to the point of absurdity. Psychoanalyst Erich Fromm, in his book, "Escape from Freedom," described the desire to replace the complexity of real life and the uncertainties of democratic choices by a nearly childish existence in totalitarianism, in which the cult and its leaders supply all rules and all answers, and the disciple meets his psychobiological need for relatedness by absorbing himself to the cult without true connectedness. The cultist abandons his own personality and adopts that of the cult, becoming an automaton, reciting what he has been taught (Fromm's "automaton conformity"). This lack of reality orientation at the heart of the cult makes its members dangerous to themselves and others. "Heavenly
lying” (i.e., lying to further cult goals—the end justifies the means—) is a feature of many extreme cults.

**Laetrile Industry Promoters: The National Health Federation, the Committee for Freedom of Choice, and “metabolic doctors.”**

This fanaticism of cultists is illustrated in the Green case, in which the parents, disciples in the cult, and Contreras and Halstead, leaders in both the cult and the laetrile industry, all indicated in court that they favored continuing the chemotherapy (which might get the judge to lift the protective order), but as soon as the judge ordered cessation of the laetrile due to the evidence of cyanide poisoning, the Greens fled to Contreras’ laetrile clinic in Mexico. The judge issued warrants for their arrest on contempt charges, but they indicated they would stay in Mexico, where they were getting financial support from the National Health Federation, they stated.

Funding for the Greens’ legal battles appears to have come from the laetrile industry, as appears to be the case for legal battles of other disciples of the cult of cyanide. The laetrile industry magazine, “Choice,” in full page ads, secured funding for the Greens’ “life and death battle with the courts and medical orthodoxy,” and their lawyer, John Graham, was an officer in the laetrile industry-promoting National Health Federation whose General Counsel, Kirkpatrick Dilling, frequently represents both the laetrile industry and disciples of the laetrile cult in their respective battles. Mr. Dilling is listed in the monthly Bulletin of the National Health Federation as one of the seven “paid Federation staff.” The respectable (i.e., orthodox) pharmaceutical industry has no machinery comparable to that which the laetrile industry mobilizes for the legal battles of nutrition cultism. *The Health Robbers* notes that then Chairman Kurt W. Donsbach and Vice-Chairman V. Earl Irons of the Board of Governors of the National Health Federation have criminal convictions for nutrition fraud, with the latter having once received a one-year prison sentence. Several other NHF Governors have been involved with the law in relation to nutrition frauds, and Emory Thurston received a criminal conviction and two years’ probation for selling laetrile and advising against surgery for cancer of the uterus: luckily the patient was an agent of the California Bureau of Food and Drug. Donsbach has a “Ph.D. in Nutrition” from Union University of Los Angeles, which is neither approved nor accredited by the State of California (but is “authorized” as apparently is almost any “diploma mill” in California), according to the State Office of Private, Post-Secondary Education.

A similar case was “reported” by Alan Stang in the January 1978 issue of “American Opinion,” the John Birch Society magazine. He recited the battle of the parents of 7-year-old leukemia victim Kimberly Cox against the “establishment” which was forcing chemotherapy on her, and how they
had to flee Wisconsin to get her to a doctor who “is one of the most beautiful human beings” Stang ever met. Typical of laetrile industry articles asserting the need for “freedom of choice in cancer therapy,” there was no mention of the outcome: in December 1977, Kimberly had been rushed by ambulance on the threshold of death—from bleeding due to relapsed leukemia wiping out the ability of her blood to clot—from the Contreras laetrile clinic in Tijuana to University Hospital in San Diego, for proper treatment including chemotherapy (Milwaukee Sentinel, December 7, 1977, and Milwaukee Journal, December 8, 1977). Once out of the hands of “metabolic” doctors, she was brought back into remission and continued on proper chemotherapy at the Marshfield Clinic in Wisconsin (Milwaukee Journal, June 4, 1978).

The Greens had presented to the court\textsuperscript{135} as their choice of physician for Chad two “metabolic physicians,” Ernesto Contreras of Tijuana and marine plant toxicologist and “chelation therapy”\textsuperscript{138} promoter Bruce Halstead\textsuperscript{72} of California. Contreras is reputedly a multimillionaire in connection with laetrile sales,\textsuperscript{33} and he and his laetrile factory were indicted by a United States attorney in San Diego, but only the factory was convicted on smuggling conspiracy charges.\textsuperscript{92a,120} Under cross-examination, both Contreras and Halstead stated that Chad was not terminally ill and that the chemotherapy being given at Massachusetts General Hospital was the proper therapy for his cancer and could cure him. However, each stated that if Chad became his patient, he would sign “Bohanon affidavits” swearing that Chad had terminal cancer so that Chad could continue to get laetrile.\textsuperscript{135} The Greens’ attorney, John Graham, a Governor of the laetrile-promoting National Health Federation,\textsuperscript{30} indicated to the court that in his opinion, the Rutherford decision included any cancer patient.\textsuperscript{135} Accepting this position would mean that anyone with a small skin cancer completely curable by local removal would be considered a “terminal cancer patient” and could get “Bohanon affidavits” and cyanide poisoning from laetrile.

When Attorney Brant\textsuperscript{135} split therapy effects into objective and subjective, Contreras admitted that only proper chemotherapy would objectively benefit Chad, and that placebo therapy could produce the same subjective “improvement in the quality of life” as he claimed could be produced by chemotherapy with laetrile and the destructive “nutritional and metabolic diet” of laetrile proponents.\textsuperscript{71,72}

Under cross-examination,\textsuperscript{135} Harold Manner of Loyola University, a folk hero of the laetrile cult,\textsuperscript{32} admitted that his laetrile industry-financed study claiming regression of mouse mammary tumors by laetrile, digestive enzymes and vitamin A did not include autopsies of his mice to determine if his enzyme injections were spreading cancer and that he claimed “remission” simply because the digestive enzymes digested the tissue into which
they were injected. He failed to do two other crucial controls: studies to ascertain if the digestive enzymes he used would digest normal as well as tumorous mouse mammary tissue, and studies to determine if laetrile, enzymes, and vitamin A shortened the lives of the mice so treated as compared to untreated mice.

Manner also admitted that his daughter was president of Mid West Nutrition, whose price list included laetrile and digestive enzymes, and that he was a consultant to two profitable laetrile-promoting enterprises in Illinois, and travelled widely to promote laetrile at profitable symposia organized by the laetrile industry. Like many laetrile promoters and cult leaders, Manner is an ingratiating and charming person whose misleading presentations are not easily seen through by the scientifically unsophisticated. His use of the word "remission" instead of "digestion" to describe what digestive enzymes do to mouse mammary cancer tissue is typical. Any tissue should be digested when injected with the Wobe-Mugos (German; prohibited for human use in the United States, according to the Food and Drug Administration) enzyme mixture used by Manner. It contains not only pancreatin, which digests carbohydrates, fats, and proteins but also many other digestive enzymes. Viokase (Viobin Corporation, Monticello, IL), the 4 N.F. (National Formulary) pancreatin used in our own gastroenterology research, will digest 100 times its own weight in protein, 150 times its own weight in starch and 450 times its own weight in fat. From studies of patients with chronic pancreatitis, it has been known for decades that pancreatic enzymes digest human tissue. Wobe-Mugos and similar digestive enzyme preparations could produce lethal anaphylactic shock if repeatedly injected into humans, but Manner recommended such injections on page 165 of his 1978 cult book, "The Death of Cancer," in a section entitled "Physician's Protocol."

Mr. Krebs calls himself "doctor" by dint of a 1973 honorary doctorate from American Christian College a small Bible college in Tulsa, Oklahoma. According to the Academic Affairs Office of the Oklahoma Regents, it was not accredited to award any doctoral degree, and was defunct as of the 1977 to 1978 academic year. An organization at American Christian College was reported in early 1978 by the Minneapolis District FDA Supervisor Investigator to have been established by Carey Reams, who "tells every patient 'I am a biophysicist and an ordained minister. I am not a medical doctor ... All I am doing is giving you a diet for your specific body chemistry and teaching you the health message contained in the Bible.'" (quote from Healthview Newsletter, which, via his parents, got into the Massachusetts General Hospital medical record of Chad Green, whose laetrile was from Krebs' operation). The FDA has information on Reams' brushes with the law in various states in relation to lucrative nutrition quackery.
Ernst Krebs (see footnote, beginning of section), the layman who is the guru of the cult of cyanide and the creator of the billion-dollar laetrile industry, is currently appealing the revocation of his probation, which followed his criminal conviction. In the Green case, the Greens and their attorney kept reciting the central dogma of the laetrile cult, which is the "Krebs theory." The theory holds that cancer is a nutritional deficiency disease due to lack of cyanide, for which the cure and prevention is cyanide provided by cyanogenetic glycosides ("laetriles"). The theory states that cyanide from laetriles is not released in the stomach or intestine but rather only when it gets into cells in the body, where it selectively destroys cancer cells but not normal cells, because only normal cells immediately detoxify cyanide to "harmless" thiocyanate. The theory further holds that the cure and prevention of cancer require a "nutritional" and "metabolic" therapy different from nutritional and metabolic therapy as understood by persons with scientific training and experience in human nutrition and human metabolism, but rather a bizarre array of dangerously large doses of digestive enzymes, vitamin A, vitamin C, and other cult "nutrition" measures. The cyanide cult ordains as "metabolic physicians" and "nutritional physicians" individuals who accept as fact the speculations of the Krebs theory. As oncologist (cancer specialist) Takao Ohnuma, M.D., Ph.D., of Mount Sinai School of Medicine in New York noted, the laetrile industry creates "metabolic physicians" in 2-day "workshops on metabolic therapy," which have "no good science; no patient histories or case data; no histology; not even chest x-rays or bone scans to illustrate the response to treatment." Most of the program deals "with the legal status of laetrile, its alleged nontoxicity, and its Keystone role in a 'holistic metabolic' regimen for treating cancer patients." Such would be expected of a cult whose guru is a layman (Krebs) who variously styles himself "physician", "biochemist", "Dr.", and "Ph.D." (see footnote above), after failing medical school.

A theory is a speculation, and as reviewed in the preceding pages and elsewhere, every facet of the Krebs theory has proven to be wrong when subjected to reality testing, as well as dangerous to health if followed. Even the minor concept of the Krebs hypothesis that laetrile is an active agent after parenteral administration by virtue of metabolism to HCN in vivo is wrong, because essentially 100% of injected laetrile is excreted unchanged, unless deteriorated so that it produced cyanide poisoning (vide supra).

Because of the doubtful insights of "clinical experience," it is only the systematic testing of hypotheses concerning the causes and treatments of disease, using the means provided by science and technology, which makes possible the validation of proposed cures. Science is the knowledge gained by such systematic study, i.e., by the scientific method.

That the laetrile cult and its priests, the "nutritional and metabolic physi-
cians” continue to thrive and wax rich is a tribute to their skills in politics, propaganda, and proselytizing, funded by the several million dollars they collect daily from disciples who, like members of other extreme cults, have escaped from reality to recite like automatons the litany of their cult as their highest truth. 34

Lethal Effects of Cult Propaganda

Lack of safety of alleged nutrients has always had difficulty overcoming fictional allegations of efficacy couched in nutrition cult terms. It took from the French Revolution to World War I for the fact that wormwood in absinthe slowly and inexorably destroyed the brain to overcome the fiction that absinthe was an aphrodisiac. When absinthe was finally outlawed in the United States in 1912, thousands had been destroyed by it, and New Orleans had been “the absinthe capital of the World.”

Several other pertinent articles relating to laetrile were recently published. 141-145

One of the shifting claims of the quackery industry is that benzaldehyde “may be” the active antineoplastic principle of laetrile. Some Japanese work claimed reduction in weight of tumors of mice injected with benzaldehyde extracted from figs, an anecdotal cancer remedy. 146 The studies were worthless because they presented no data on whether the benzaldehyde produced weight loss in all (not just cancer) tissues, or shortened the lives of the mice. Various aldehydes extracted from plants have been claimed to be carcinostatic since at least 1938, include citral and citronellal from lemon grass, 146 but none has been shown to possess a sufficient difference between the dose toxic to the tumor and the dose toxic to the patient to be of value in treating human cancer.

Although benzaldehyde is a poison in large doses, 4 and has not yet been evaluated for possible carcinogenicity by the Selection Subgroup of the Clearinghouse for Environmental Carcinogens, for flavoring uses in low doses it is GRAS (generally recognized as safe) (Food Chemical News, Dec. 11, 1978).

Thousands of chemicals kill cancer cells, but also unacceptably risk the life of the patient, because of the low therapeutic ratio of the drug (i.e., the dose which kills the tumor is too close to the dose which kills the patient). 170 Therapeutic ratio is determined in various ways, including “therapeutic trial in the test tube,” in which the ability of the chemical at a given dose to kill tumor cells versus its ability to kill normal cells is tested. 147-149 Only chemicals with therapeutic ratios high enough that they constitute acceptable risks can rationally be used to kill cancers in humans. Benzaldehyde 4 and cyanide 4 are both poisons with therapeutic ratios too low to be used in humans. As Dukes states 150: “No evidence appears to have become avail-
able that neoplastic tissue is more sensitive to cyanide than is healthy tissue, or possesses preferential mechanisms for enzymatic break down of amygdalin. A selective effect thus seems unlikely, and one would therefore expect that if Laetrile is given for long periods (as is recommended) and in sufficient doses to exert any effect at all, cyanide poisoning will result.

The effectiveness of laetrile propaganda on a gullible judge is illustrated in the New York “Custody of a Minor” case of 8-year-old Hodgkin’s disease victim Joseph Hofbauer, whose parents were disciples of the laetrile cult and whose doctor was “metabolic physician” Michael Schachter.

The following is documented in the pages of the Appendix on Appeal, referred to below as pages A-1 to A-363: Schachter, a psychiatrist (A-34) with little or no experience in proper treatment of cancer (A-142) and no specialty credentials in the science of nutrition (A-34), “teaches” both these subjects at laetrile industry “metabolic workshops,” and represents nutritionally and metabolically destructive therapy as “supportive” (A-34, A-157).

Dr. Schachter was apparently conducting human experimentation on Joseph using various dangerous and questionable remedies noted in the oncology text chapter on “Drugs, Cancer and Charlatans,” and in the American Cancer Society literature on cancer quackery. In addition to laetrile, these questionable remedies include Staphylococci phage lysate (A-150), once to twice daily digestive enzyme retention enemas (A-299), Progenitor cryptocides vaccine (A-310, A-317) and several other dangerous products promoted by the laetrile industry, including “B₁₅” (A-162), a product the FDA considers a prohibited food additive, and “emulsified vitamin A” (A-mulsin) (A-162, A-198) and Wobe-Mugos enzymes (A-162) which the FDA consider to be prohibited new drugs in the United States because acceptable proof of either safety or efficacy has not been submitted to the FDA. All of these appear to be in violation of New York State Law regarding human experimentation. Dr. Schachter was also giving Joseph dangerously large doses of vitamin C (A-317), a largely vegetarian diet (A-161, A-164-A-171) which increases cyanide poisoning from laetrile, and daily coffee retention enemas (A-168). He performed the bizarre and dangerous act of injecting digestive enzymes (possibly Wobe-Mugos) on two occasions into one of the nodes in Joseph’s neck (A-45, A-46, A-293). His human experimentation on Joey in part mimicked the uncontrolled and therefore worthless mouse experiments of laetrile promoter Harold Manner, who flew in to testify in the case. Schachter also carried out (and presumably charged for) extensive “food allergy testing” of Joey (A-215, A-290, A-291), using the “cytotoxicity” methodology (A-222-A-247) considered questionable to worthless by responsible authorities.

Joseph developed liver damage, found by liver function tests requested by the State (A-18, A-19), probably due to the megavitamin therapy with
up to 225,000 IU emulsified vitamin A. Dr. Schachter was giving Joseph daily intravenously (A-161). There were no plasma vitamin A levels to document the suspected poisoning (A-191, A-198), as competent medical practice would dictate. Megadoses of 225,000 IU of emulsified vitamin A were actually resumed without measuring plasma vitamin A level, because Schachter stated he believed (against the logic of the situation) that Hodgkin's disease caused the liver damage and vitamin A was treating it (A-283, A-292). Dr. Schachter sought advice regarding treatment of Joseph from laetrile industry leaders, including Dr. Hoefer-Janker, who Schachter referred to as a "world's expert on Hodgkin's disease" (A-283), and layman and convicted criminal Ernst Krebs (who Schachter referred to as an "expert on nutritionally and metabolically supportive therapy") (A-199), Dr. Marco Brown (Fairfield laetrile Medical Center, island of Jamaica) (A-199, A-201-A-203), and Dr. Donald Cole (A-161, A-216), a promoter of questionable cancer therapy. However, Dr. Schachter rejected advice from two radiotherapists and a hematologist, alleging that "None of the three consultants have had any experience with laetrile or the nutritional management of cancer patients. All of them admitted ignorance in this area..." (A-308). (The laetrile industry frequently uses the specious logic that only those who subject their own patients to laetrile are competent to judge it, and that no doctor can claim cyanide from laetrile poisons people unless he personally has poisoned people with it.)

Dr. Schachter had the Hofbauers sign a deceptive, misleading, and uninformative "informed consent" (A-141 to A-143, A-151, A-157-A-159), giving them almost no information on the dangers of his treatment program, which he elsewhere represented as "nontoxic" (A-137, A-160), not telling them he was engaging in human experimentation on Joey, and representing his treatment as "nutritional and metabolic support," where in fact it was otherwise. He appeared ignorant of the possibility that Joseph's "occasional nausea and abdominal cramps" (A-197) could be intermittent cyanide poisoning. He obtained no serum cyanide, blood cyanide, plasma thiocyanate or 24-hour urine thiocyanate tests for cyanide poisoning when these symptoms appeared, as competent medical practice would dictate in a patient receiving laetrile (A-44, A-45). The single tests the State of New York managed to obtain via legal process showed that Joseph had a serum cyanide of 0.14 µg/ml, but no detectable thiocyanate in his plasma, and a urine cyanide of 1.15 µg/ml and urine thiocyanate of 15 µg/ml. There was no amygdalin in his urine, suggesting the laetrile may have been stopped after the parents and Dr. Schachter were notified to make Joseph available for testing but before the blood and urine collection started, possibly in the hope that all laboratory evidence of cyanide poisoning would dissipate before the plasma and urine were collected.
Dr. Schachter gave Joseph daily 3 to 6 g intravenous injections of laetrile (A-150). There seems to be no sense and only danger in this procedure, because 100% of uncontaminated injected laetrile pours out unchanged in the urine,\(^{136}\) and the intravenous vitamin C he gave Joey could have increased cyanide release from laetrile.\(^{6a}\) No laetrile for human use is subjected to FDA standards for purity and safety. All laetrile for parenteral use appears to be adulterated and/or contaminated with fungus, insect parts, and/or other noxious and dangerous foreign matter,\(^{79,79a}\) as well as sometimes possibly deteriorated with free cyanide present in it.\(^{6a}\) There is no evidence in the Appendix on Appeal that Dr. Schachter had the laetrile he injected intravenously into Joey checked for content, deterioration, or foreign matter before injecting it.

Unlike Judge Volterra in the Green case,\(^{135}\) Judge Brown did not wait in the Hofbauer case\(^{151}\) for laboratory evidence that Joseph was being poisoned with cyanide from laetrile. He refused the State’s demand that Joseph’s Hodgkin’s disease be properly treated. He had numerous ex parte telephone conversations (A-369) with Dr. Schachter prior to his June, 1978 hearing of the Hofbauer case, and ex parte discussions with an unnamed “oncologist” confidante (A-369), but refused to have ex parte telephone conversations with experts with specialty credentials in hematology, oncology, or nutrition (A-368, A-369). The Judge received into the record (A-172-182, A-248-A-253, A-243-A-350, A-365) extensive literature promoting cancer quackery which Dr. Schachter appended to his “progress reports” on Joseph (A-365), and, despite his disclaimer (A-365), the judge was so thoroughly indoctrinated that he recited laetrile cult dogma as part of his June 28, 1978 Findings of Fact and Conclusions of Law. He accepted Dr. Schachter and the laetrile industry’s “flying circus” as experts, despite their lack of specialty credentials in the sciences of hematology, nutrition, and cancer treatment, rejected the evidence of all the scientific experts with such specialty credentials, and held that, “...respondents’ experts strongly indicated that the scientific development of metabolic therapy, including the use of vitamin A, vitamin C, proteolytic enzymes, Amygdalin (Laetrile), coffee retention enemas and enzyme retention enemas, is being suppressed by governmental and peer pressures....This court also finds that metabolic therapy has a place in our society, and, hopefully, its proponents are on the first rung of a ladder that will rid us of all forms of cancer.”\(^{171}\)

Judge Brown’s approval of Dr. Schachter’s experimentation on Joey may not have legalized that experimentation, since there is no evidence that Schachter met the precedent condition of compliance with the requirements of New York State law with respect to human experimentation.\(^{156}\) New York law implies that there be an IND (investigational new drug) application (none existed in 1978 for laetrile, B\(^{15}\), “emulsified vitamin A,” or
Laetrile: Cult of Cyanide

Wobe-Mugos), and other compliance with Article 24-A of the New York Public Health Law before any experimentation on a human. The law makes no exception from compliance with Article 24-A for court-approved human experimentation.

The cult of cyanide rejects proper treatment for curable cancer in favor of quack remedies, and thereby kills those who can be cured. Eighty percent of children with acute lymphocytic leukemia brought into remission are cured, the stopping of Chad Green’s chemotherapy caused his relapse. Stage I Hodgkin’s disease is curable with proper therapy in 95% of cases; Joseph Hofbauer’s Hodgkin’s disease is progressing unchecked. Both these children were exposed to acute and chronic cyanide poisoning from laetrile, vitamin A poisoning from “emulsified vitamin A,” and Joey also to possible anaphylactic shock from injections of digestive enzymes, and the dangers of a panoply of other questionable remedies.

The religious overtones of the cult of cyanide appear clear in the case of 5-year-old leukemia victim Nikki Decker, who, according to the White Plains Reporter-Dispatch of February 18, 1979, “has been taken by her parents to West Germany from her home in Gainesville, Florida, for treatment more consistent with their religious convictions,” even though “the girl’s doctor says the move will deprive the child of basic medical care,” and even though “unlike the Chad Green case in Massachusetts, Nikki’s parents won their case in court.” Parents of children with cancer feel particularly helpless and are particularly easy marks for the high-pressure laetrile cult recruiters, who have been alleged to pay hospital clerks per head for providing name, address, and telephone number of anyone diagnosed as having cancer, and then go after them hammer-and-tongs to “take laetrile or be cut, burned, and poisoned to death by the doctors.” A good mutual-support organization for parents of cancer victims is Candlelighters, affiliated with the American Cancer Society, and founded by attorney Grace Powers Monaco, herself the mother of a cancer victim.

On December 3, 1978, 42-year-old Jo Anne Pye died in the emergency room of Vesper Memorial Hospital, San Leandro, California, of cyanide poisoning from her daily oral dose of 1 g of laetrile, taken with capsules of crushed apricot kernels (Apricaps). She was taking these products to avoid surgery for ductal breast cancer. The cause of her death might have been attributed to cancer, which is usually blamed (perhaps often erroneously) for the deaths of patients taking laetrile, except that the law required an autopsy in her case because no physician, “metabolic” or otherwise, was seeing her at the time she died. According to Alameda County Chief Deputy Coroner Roland Prahl and the autopsy report, the cyanide poisoning was first suspected when Dr. P. Herrmann made the first autopsy abdominal incision, because the aroma of cyanide rose from her
stomach. Her whole blood cyanide was 3.8 µg/ml, her gastric content contained 175 µg cyanide, and her vitreous fluid contained 0.8 µg-CN/ml. The Alameda County Coroner certified "cyanide intoxication" as immediate cause of death. Her death was apparently due to the β-glucosidase in the crushed apricot kernels (health food store Apricaps) found in her alimentary tract releasing cyanide from both her routine laetrile dose and the crushed kernels. She was not only a victim of the cult of cyanide but also of the Bohanon decision in Rutherford, now under appeal to the Supreme Court, since the Coroner's Investigator's report indicated she obtained laetrile with a "Bohanon affidavit." One wonders whether her next of kin could win civil and punitive damages against the laetrile industry and its vendors, for representing laetrile and apricot kernels as "nontoxic therapy," (and as useful against cancer) for breach of warranty, and strict liability. It has been noted with respect to laetrile, that "patients, physicians, and promoters are potential parties for actions in fraud and deceit, negligence and malpractice, products liability and wrongful death and for homicide prosecutions as well." One also wonders whether the authors and publishers of nutrition cult and laetrile industry books and monthlies alleging laetrile is nontoxic and helpful against cancer are vulnerable to similar suits, in view of recent litigation instituted against the publisher of Adelle Davis' misleading book "Let's Have Healthy Children," because of the injuries and death resulting from Davis' advice to use large doses of potassium (which was then purchased at a health food store) as a remedy for colic. That suit, brought by the law firm of Portley and Sullivan in Pompano Beach, Florida, will be watched with interest. It is usually true that a person who knowingly participates in harm to another or negligently allows that harm to come about generally is liable if the act of negligence has causation to the ultimate injury. Medical World News states that Davis' estate settled out of court for $150,000 the suit of a Maine woman whose daughter's growth was permanently stunted by megadoses of vitamin A recommended in a Davis book.

Early in 1980, the California Attorney General's office raided the Richardson laetrile clinic, run by Richardson's daughter, in connection with the death of Jo Anne Pye. The Richardson clinic is in Albany, California, just a few miles from the Berkeley campus of the University of California.

On page 113 of the book, "Laetrile Case Histories," Richardson warns against eating apricot kernels and laetrile at the same time, but does not provide a reason for the warning. One wonders if the Richardson clinic people who Coroner Prahl stated provided Jo Anne Pye with laetrile gave her that warning, or gave her the reason for the warning, and if she would be alive today had they done so.

Of all the nutrition cults, the cult of cyanide is most dangerous. Its dis-
ciples are slowly and insidiously destroyed by almost imperceptible progressive deterioration from chronic cyanide (−CN), thiocyanate (−SCN), and cyanate (−OCN) poisoning, and intermittent bouts of acute cyanide poisoning, and some are killed outright by more severe acute poisoning, chanting the dogma of the cult as if it were scientific gospel all the way to the grave. The leaders constitute a billion-dollar-a-year industry selling not only laetrile and its promotional materials, but other nutritionally and metabolically destructive products represented as “nutritional and metabolic therapy,” through doctors usually lacking scientific specialty credentials in nutrition, metabolism, or oncology, who label themselves “orthomolecular,” “preventive,” “ecological,” “unorthodox,” “holistic,” “nutritional,” or “metabolic” physicians. In addition to laetrile, they promote other nostrums the FDA prohibits from interstate transport for human use, such as “emulsified vitamin A” and Wobe-Mugos digestive enzymes, the former producing vitamin A poisoning, and the latter capable of producing death from anaphylaxis on repeated injection.

The ultimate irony that laetrile, promoted as a cancer preventive, may actually cause cancer (see section above on “Laetrile may cause cancer”), is compounded by the fact that a frequent ingredient of the other fake vitamin created by Krebs (“B₁₅”) turns out to be a mutagen and a highly dangerous nerve, eye, and gonad poison. Our only protection from these poisons has been the FDA enforcement of the “safety and efficacy” requirements of federal law, and the FDA has been under constant attack by the nutrition cultism industry to narrow its application of these requirements so that anything the industry calls a “food supplement” (including laetrile, “B₁₅”, and dangerously high doses of “emulsified vitamin A”) can be freely sold to a gullible public. Interestingly, attacks on food additives and preservatives in the nutrition cult literature ignore laetrile and pangamate, both of which may be much more potent carcinogens than any food additive or preservative. This makes clear that the nutrition cult literature is more interested in undermining confidence in food scientists and government protection agencies, to build confidence in what the cult sells (see discussion of “Prevention” magazine on pages 183-187 of The Health Robbers), than it is in providing responsible information on real dangers from nutrition cult practices.

References


29. Greenberg, D. M.: The case against


51. Cyanide poisoning from the ingestion of apricot kernels. Calif. Morbidity, Sept. 1, 1972. (Published by the Bureau of Communicable Disease Control, State Department of Public Health, Calif.)


53. Osuntokun, B. O.: Nutritional problems
79a. Cairns, T., J. E. Froberg, S. Gonzales,


120. U.S.A. v. John Anton Richardson, Ralph S. Bowman, Frank Salaman, Robert William Bradford, U.S. Ct. of Appeals for the Ninth Circuit, Nos. 77-2202, -2204, -2262, -2268. Criminal convictions upheld October 20, 1978. All convicted of conspiracy to smuggle (Bradford also convicted of smuggling) and given suspended sentences, 3 years' probation, and fines. (Criminal convictions 76-0448, U.S. District Ct. for the Southern District of California, filed May 16, 1977.) Richardson's license to practice medicine in California was suspended in 1976 for "gross negligence" among other reasons. An agent of the California Food and Drug Bureau "estimated that Mr. Bradford takes in $150,000 to $200,000 a month in laetrile sales." Richardson reported in 1974 a net income of $172,981 on a gross income of $783,000 according to Lyons, and, according to the San Francisco Examiner, has a vast country estate.

121. U.S.A. v. Andrew R. L. McNaughton. No. 76-0448. Criminal conviction for conspiracy to facilitate the transportation of smuggled merchandise, filed December 12, 1977. (Given suspended sentence and 2 years' probation.)

122. Her Majesty the Queen vs. Andrew R. L. McNaughton. Court of Sessions of the Peace, Province of Quebec, District of Montreal, no. 499-72. Criminal conviction for stock fraud, judgment rendered April 22, 1974.


125. Lewis, W. H., and M. P. F. Elvin-Lewis: Medical Botany: Plants Affecting


135. Chad Green. Custody of a Minor, Plymouth Superior Court No. 78-6816, Hearing held (and transcribed) January 8-19, 1979, Plymouth, Massachusetts. Judge: Guy Volterra. For the Commonwealth of Massachusetts:


147. Tisman, G., V. Herbert and H. Edlis: Determination of therapeutic index of drugs by in vitro sensitivity tests using human host


153. Medical Affairs Department, American Cancer Society. Informal Summary as of 3/73 on Wobe Enzymes and Vitamin A emulsion (proposed for the treatment of cancer by Max Wolf, M.D., (President, Medical Enzyme Research Company, Grunwald, Germany), Karl Ransberger (President of Mucos Pharmaceuticals, Grunwald, Germany), and the laetrile-promoting Hoefer-Janker Strahlen Klinik of Bonn, Germany).

154. Halperin, J. A.: Sworn affidavit of Deputy Director, Bureau of Drugs, United States Food and Drug Administration, dated 5 January 1979. “... Wobe Mugos or Wobenzyme is a 'new drug' ...(with no) new drug application permitting the distribution in interstate commerce... for administration into the human body...(and no) acceptable IND (Investigational New Drug) application which permits the investigational use of Wobe Mugos or Wobenzyme in humans.” The FDA has seized shipments of Wobe Mugos (U.S.A. v... Wobe Mugos... No. CV 78-3736, Complaint for Forfeiture, U.S. District Court, Central District of California).

155. Halperin, J. A.: Sworn affidavit of Deputy Director, Bureau of Drugs, United States Food and Drug Administration, dated 5 January 1979. “... Wobe Mugos or Wobenzyme is a 'new drug' ...(with no) new drug application permitting the distribution in interstate commerce... for administration into the human body...(and no) acceptable IND (Investigational New Drug) application which permits the investigational use of Wobe Mugos or Wobenzyme in humans.” The FDA has seized shipments of Wobe Mugos (U.S.A. v... Wobe Mugos... No. CV 78-3736, Complaint for Forfeiture, U.S. District Court, Central District of California).

156. Public Health Law, State of New York, Article 24-A, effective September 1, 1975: Protection of Human Subjects, Section 2440-2446. Section 2441 reads in part that the article covers“... any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs or which increases the ordinary risk of daily life...” Section 244-3 reads “Each person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a human research review committee, and such human research as he conducts or proposes to conduct shall be subject to review by such committee in the manner set forth in this section.” The provisions of this law preclude physicians in private practice from engaging in research except pursuant to the provisions of the article (according to Department of Health Counsel).


Laetrile: Cult of Cyanide


161. Verdict of Coroner in the Matter of the Death of Jo Anne Etta Pye, 1 February, 1979; Pathologist's report, 1-26-79; Investigator's report, 12-3-78. Alameda County Coroner's Department, County of Alameda, Oakland, CA 94607.


170. In Cancer Treatment Reports for January 1980, Drs. H. P. Koeffler, L. Lowe, and D. W. Golde reported that the dose of laetrile which kills human cancer cells also kills human normal cells; i.e., the dose of laetrile that kills the tumor kills the patient.

171. Judge Brown's decision, as predicted by expert witness Herbert, presaged Joe Hofbauer's death with untreated Hodgkin's disease, while receiving questionable cancer remedies from promoter Lawrence Burton in Freeport, the Bahamas ("Boy in laetrile case dies." NY Times, July 18, 1980). See pages 60-63.

172. Two deaths from coffee enemas were reported in the October 3, 1980 Journal of the A.M.A.

173. Nikki Decker (see page 63) was given laetrile, relapsed, and died (case reported by Dr. P. Mehta in the May 1980 issue of Clinical Pediatrics). Chad Green, Joey Hofbauer, and Nikki Decker would almost certainly be alive today were it not for the laetrile industry.

174. On September 19, 1980, the National News Council (One Lincoln Plaza, New York, NY 10023) issued a report (Complaint No. 180, Drs. Barrett and Herbert against US magazine) unanimously concluding that the complaint was warranted that an article in US magazine in 1980 misled the public by giving the appearance of reliability for Dr. Kurt Donsbach and his Donsbach University School of Nutrition in Huntington Beach, California. The report notes: "Dr. Donsbach holds a doctor of chiropractic degree...His Ph.D. in nutrition came from Union University in Los Angeles...the current president of Union said he has seen the Ph.D. on Dr. Donsbach's wall, but that he has no record of Dr. Donsbach as a student...."

M. T. Bogumill, fraud co-ordinator for the Food and Drug Section of the California Department of Health Services, confirmed that Dr. Donsbach pleaded guilty in 1971 to one count of practicing medicine without a license. He was charged with 'prescribing vitamins, minerals and herbs as treatment for serious diseases'...a municipal judge in West Orange County found Dr. Donsbach guilty of violating a condition of his probation in the 1973 charge."

Undaunted by a criminal conviction and
two criminal sentences of two years probation each in relation to nutrition frauds, Donsbach is now selling degrees in nutrition after home-study courses which teach largely nutrition cultism rather than nutrition science, and leave the degree-holder largely a scientific illiterate with respect to sound nutrition practices, untrained in separating facts from fictions, reciting the gospel of nutrition cultism, and taught to use a computer programmed with cult "facts" to "scientifically" convince any user that he needs to buy a wide variety of usually unnecessary and therefore worthless "health food" items.
The Health Hustlers

We are in the midst of a vitamin craze. Health hustlers are cleaning up by stoking our fears and stroking our hopes. With their deceptive credentials, they dominate air waves and publications. The media hosts love them. Their false promises of super-health draw audiences of millions.

The situation now appears even worse than it was 15 years ago, when the U.S. Food and Drug Administration Commissioner, George P. Larrick, stated:

“The most widespread and expensive type of quackery in the United States today is the promotion of vitamin products, special dietary foods, and food supplements. Millions of consumers are being misled concerning the need for such products. Complicating this problem is a vast and growing ‘folklore’ or ‘mythology’ of nutrition which is being built up by pseudo-scientific literature in books, pamphlets and periodicals. As a result, millions of people are attempting self-medication for imaginary and real illnesses with a multitude of more or less irrational food items. Food quackery today can only be compared to the patent medicine craze which reached its height in the last century.”

“Health food” rackets cost Americans over a billion dollars a year. The main victims of this waste are the elderly, the pregnant, the sick and the poor.

The “Basic Four” of Good Nutrition

Have you been brainwashed by the hucksters? Do you supplement your diet with extra nutrients? Why? Do you believe that, “If some is good, more may be better”? Do you believe, “It can’t hurt”? Do you believe you are getting “nutritional insurance”? If you believe any of these things, you have been misled.

The fundamentals of good nutrition are simple: To get the amounts and kinds of nutrients to maintain a positive state of health, all you need to eat is a moderate amount of food from each of the four basic categories (the “four basics”). Foods are categorized on the basis of “leader” nutrients they contain, and you should eat a wide variety in each category. Your daily average should be:

1. Fruits and/or vegetables and/or fruit juices: four servings, at least one of which is fresh or fresh-frozen and uncooked. Wide variety is desirable, since vitamin content varies. For example, watermelon is high in vitamin A and low in vitamin C.
2. Grains and/or grain products (including cereals, breads, rice, macaroni, etc.): four servings.

3. Meats and/or meat products (including fish and/or poultry and/or eggs): two servings. “Leader” nutrients in this group are proteins, iron, and niacin, so it also includes nuts and beans (dried).

4. Milk and/or milk products: two to four servings, with less needed as one grows up.

An easy way to remember the four basics categories is to think of a cheeseburger with lettuce and tomato—it has them all (although the “fast food” variety may be too fatty to recommend it for a steady diet).

In addition to the “four basics” is a fifth category, “extras,” which includes alcohol, fats, oils, sugars. These add variety and calories, and should be taken in moderation. Fats and oils also include essential fatty acids.

The health huckster doesn’t tell you that the normal person needs no vitamin supplements if he gets the “four basics” each day. Why? Because his profits come from withholding that truth. Unlike your family doctor, he does not make his living by keeping you healthy, but rather by tempting you with rash, extravagant and false claims. Such claims raise his personal appearance fees, sell his books and magazine articles, and sell the products of companies in which (unknown to you) he may have a financial interest.

When on the defensive, the quack is quick to demand, “How do you know it doesn’t help?” The reply to this is “How do you know it doesn’t harm?” Many substances which are harmless in small or moderate doses can be harmful either in large doses or by gradual build-up over many years. Just because a substance (such as a vitamin) is found naturally in food does not mean it is harmless in large doses. In fact, an entire book has been written on this subject (Toxicants Occurring Naturally in Foods, 2nd Edition, published by a subcommittee of the National Research Council, National Academy of Sciences). The book includes a chapter on the toxicity of vitamins.

What do scientists mean by “excess” vitamins? They are referring to dosages in excess of the “Recommended Dietary Allowances (RDA)” set by the Food and Nutrition Board of the National Research Council, National Academy of Sciences. The Recommended Dietary Allowances are the “levels of intake of essential nutrients considered, in the judgment of the Food and Nutrition Board on the basis of available scientific knowledge, to be adequate to meet the known nutritional needs of practically all healthy persons.”

RDA’s should not be confused with “requirements.” They are actually more than most people require.

Quacks charge that the RDA’s are set by a group which has a “conflict of interest to work to benefit the food industry.” If you ever hear this, don’t believe it. The RDA Committee of the Food and Nutrition Board consists of
recognized nutrition experts from the Universities of California, Iowa, Wisconsin, New York State and Harvard, as well as from the National Institutes of Health and the U.S. Department of Agriculture. There is not one representative of industry on the RDA Committee. Its work is supported by the National Institutes of Health, but members themselves serve without pay. Meeting at regular intervals, the RDA Committee sets its values after thorough study of the best evidence that scientists all over the world have developed.

There are only two situations in which the use of vitamins in excess of the RDA’s is legitimate. The first is the treatment of medically diagnosed deficiency states—conditions which are rare except among alcoholics, persons with intestinal malabsorption defects, and the poor, especially those who are pregnant or elderly. The other use is in the treatment of certain conditions in which vitamins are being used experimentally for their chemical (non-vitamin) actions.

Too much vitamin A can cause lack of appetite, retarded growth in children, drying and cracking of the skin, enlarged liver and spleen, increased intracranial pressure, loss of hair, migratory joint pains, menstrual difficulty, bone pain, irritability and headache.

Prolonged excessive intake of vitamin D can cause loss of appetite, nausea, weakness, weight loss, polyuria, constipation, vague aches, stiffness, kidney stones, calcifying of tissues, high blood pressure, acidosis and kidney failure which can lead to death.

Large doses of nicotinic acid or nicotinamide, recommended by purveyors of “orthomolecular psychiatry” can cause severe flushing, itching, liver damage, skin disorders, gout, ulcers and blood sugar disorders.

Excess vitamin E can cause headaches, nausea, tiredness, giddiness, inflammation of the mouth, chapped lips, GI disturbances, muscle weakness, low blood sugar, increased bleeding tendency and degenerative changes. By antagonizing the action of vitamin A, large doses of vitamin E can also cause blurred vision. Vitamin E can also reduce sexual organ function—just the opposite of the false claim that the vitamin heightens sexual potency. (This claim is based on experiments with rats… Quacks don’t tell you that what may be true with rats may be just the opposite with man!)

Another way to look for health trouble is with large doses of ascorbic acid—vitamin C. Here the quacks take great pleasure in attempting to link themselves with one of the truly great men of our age, Dr. Linus Pauling, two-time Nobel Prize winner. Pauling’s belief that vitamin C has value against the common cold may have slight validity, but its value is quite limited. Like an antihistamine tablet, in some cases it may reduce the symptomatology of a full-blown cold or completely eliminate the symptomatology of a mild cold (thereby creating the impression that no cold occurred). There is no reliable evidence that large doses of vitamin C prevent colds, and it is therefore not logical to take such doses in the absence of a cold.
Our laboratory has published evidence that under certain circumstances, large doses of vitamin C can reduce the availability of vitamin B₁₂ for absorption. In addition, excess vitamin C may damage growing bone, produce diarrhea, produce "rebound scurvy" in newborn infants whose mothers took such dosage, produce adverse effects in pregnancy, cause kidney stones and produce false urine tests for sugar in diabetics. There may be other adverse effects. What should you do? Don't take more than 60 milligrams (mg) of ascorbic acid a day (the adult RDA) unless you have checked with your doctor, are pregnant (RDA 80 mg/day) or are breast-feeding (RDA 100 mg/day).

Health Hustlers are Usually Charlatans and Quacks

The Random House Unabridged Dictionary of the English Language says that a charlatan is "one who pretends to more knowledge or skill than he possesses; quack." It then defines a quack as "1. a fraudulent or ignorant pretender to medical skill. 2. a person who pretends, professionally or publicly, to skill, knowledge, or qualification which he does not possess; a charlatan. 3. being a quack: a quack psychologist who complicates everyone's problems. 4. presented falsely as having curative powers: quack medicine. 5. to advertise or sell with fraudulent claims."

The quack's pretense to greater knowledge or skill than he really has comes in various forms, some quite subtle. For example, the pretense often comes in the form of impressive-sounding credentials. It is typical for the talk show host to remark, when a quack and a genuine scientist are brought together as guests, "You both have such excellent credentials, and yet you make diametrically opposed statements. What is the layman to think?" What the layman should think is that one of the "experts" is very likely a quack!

Often the talk show quack will support his case by quoting the findings of a "great scientist" (another quack) who has "published over a hundred studies in scientific journals on vitamin E (or whatever)." Be cautious. He may be referring to publications which will publish anything submitted by almost anybody. Many journals do not have review systems to screen out garbage. The scientist knows which journals are scientific and which ones are not. The layman may not know this. But the quack does not care about the quality of his sources of information. He merely accepts any findings which appear to support him and rejects any evidence which contradicts his ideas.

Some quacks have a more modest-seeming approach, "I have published a few papers on this—maybe it takes more papers to convince some people." Don't let this fool you. It is not the number or papers which determines scientific truth, but the quality of the contents of each paper. One thousand poorly designed studies are one thousand pieces of junk. One well-designed study is worth its weight in gold. (The quack hates well-designed "controlled" studies.) Also keep in mind that when a quack refers
to his own "research," what he really means is his unscientific combination of thoughts, plagiarized from two or more sources.

**Recognizing the Quack—Sixteen Tips**

How can you spot the health hustlers, the food quacks, the con men, the charlatans? The following should make you suspicious:

**Tip #1: He advises that you go out and buy something which you would not otherwise have bought.**

He tells you all the wonderful things that nutrients do in your body and what can happen if you don’t get enough. But he conveniently neglects to tell you that a balanced variety of foods should give you all the nutrients you need. He wants you to think that more is better.

Ask yourself whether the friendly fellow with the benign smile who is recommending large doses of vitamin C or E, or some other vitamin or combination of vitamins, could have a financial interest in what you do. Next time you hear someone on a talk show pushing a vitamin, call or write the station and ask whether he or the station has a financial interest, direct or indirect, in one or more companies selling vitamins. You might also ask whether Old Toothy Smile has ever been convicted of practicing medicine without a license. And whether any company in which he has or has had a financial interest has ever had its vitamin products seized by the FDA for mislabeling. The silence which greets your inquiry will astound you.

**Tip #2: He is a Fake Specialist, with Imposing “Front” Titles.** Credentials sell people. Because he knows this, and sometimes because he has grandiose character traits with messianic feelings, the quack often provides himself with impressive-sounding titles. Such include “Director” or “President” of the “X Nutrition Institute” or the “Y Nutrition Society,” or “Nutrition Consultant” or “Nutrition Expert” or “World’s Foremost (or Greatest or Leading) Nutritionist.” Be suspicious of such titles. The “Institute” or “Society” will usually prove to be a “front” (created by the quack or his agents) with no standing among genuine nutrition scientists. The titles and institutes are rarely affiliated with legitimate scientific or academic institutions. When the quack is a “Nutrition Consultant,” it will usually turn out to be to an organization which peddles misleading health information and/or vitamins and/or health foods. Often, the organization is controlled by him.

Information on who incorporated an institute or society is available from the State Attorney General where the institute is located. As for the title, “World’s Foremost (or Greatest or Leading) Nutritionist,” there is no such title given by any reputable scientific organization. It is a “cover” anyone can use, no matter how ignorant he may be about nutrition. There is no law against it, just as there is no law against anyone calling himself “World’s Foremost Lover.”
Some reputable organizations which work for the advancement of science will accept any private citizen as a member. Quacks often join such groups in order to add "legitimate" credentials to their list. In order to protect the public, "open" membership organizations should forbid advertising of membership. The American Association for the Advancement of Science is one which does this. Anyone who publicizes AAAS membership is likely to receive a letter like this from its business manager:

"Several years ago, our Board of Directors passed a resolution forbidding members to advertise the fact of their membership.

The reason for this resolution was that this Association will accept anyone's application for membership and, therefore, membership in this Association does not indicate any scientific achievement of the individual. On the other hand, the reader of the printed matter, not knowing the Association's non-existing membership requirements, most likely will misinterpret the announced membership of an individual in this Association as an indication of his scientific status.

Please remove at once all printed matter which lists you as a member of our Association from circulation and please prevent reference to your membership in this Association in any public statements. Thank you in advance for your cooperation."

The largest private (non-government) group of genuine health research scientists in the world is probably the Federation of American Societies for Experimental Biology (FASEB). The American Institute of Nutrition (AIN) is the nutrition branch of FASEB, and the American Society for Clinical Nutrition (ASCN) is the clinical nutrition arm of AIN. These three organizations screen out quacks, so be suspicious if a "nutrition expert" does not list one of them among his credentials—especially if he includes some other group with "Nutrition" in its title. Some quacks try to seem more respectable by attacking other quacks.

Your doctor may be able to help you separate good nutrition information from nutrition nonsense. Unfortunately, a doctorate degree is not a guarantee of reliability. A few people with M.D., D.D.S., or Ph.D. after their names—who have received their training in reputable institutions—have strayed from scientific thought. Some of them have written books. The medical and dental degrees of Emanuel Cheraskin and the dental degree of W.M. Ringsdorf, Jr., did not prevent them from writing *New Hope for Incurable Diseases*, a book which stimulates false hopes that vitamins can cure various diseases which, at present, are incurable. An advertisement for this
book deceptively states that, "In an era of increasing faddism and misinformation about foods, the reader will benefit from the authoritative treatment of the subject contained herein." Unfortunately, the law does not protect you from this type of deception. When this ad was sent to the New York State Attorney General and the FDA, both replied that it was out of their jurisdiction. In the Fall, 1972 issue of the *Journal of Nutrition Education*, Dr. C.E. Butterworth, Jr., Director of the Nutrition Program at the University of Alabama (where Cheraskin and Ringsdorf were on the dental faculty), wrote a devastating review of their book, closing with:

“There are a number of other statements throughout the book which are patently erroneous or misleading... The main objection to this book is the tone and attitude of the presentation. There are subtleties and innuendoes readily apparent to an educated reader but which, alas, are likely to be missed by the lay public. One expects more from university professors who write interpretations of science for the general public. This book has apparently been written for the faddist fringe and 'health' food store market and for readers who seemingly want to believe the miracles wrought by diet without regard for scientific evidence.

Surely hope is an essential element of life, both to the sufferer from an incurable disease and the members of his family. But it is cruel to raise false hope under any pretense. In my opinion, this book raises nothing but false hopes, many of them not even new, in the mind of an uneducated reader.”

**Tip #3:** He says that most disease is due to a bad or faulty diet. This is not so. Inspect any medical school textbook of medicine or ask your doctor. They will tell you that most diseases have nothing to do with diet. Malaise (feeling poorly), tiredness, lack of pep, aches (including headaches) or pains, insomnia and similar complaints are usually the body's reaction to emotional stress, overwork, etc. The persistence of such complaints is a signal to see a doctor to be evaluated for possible underlying physical illness. It is not a signal to add vitamins.

**Tip #4:** He says that most people are poorly nourished (the old "Sub-Clinical Deficiency" gambit). This is an appeal to fear which is not only untrue, but ignores the fact that the main forms of "poor" nourishment in the United States are undernourishment in the poverty-stricken and over-nourishment in the economically well-to-do. The poverty-stricken can ill afford to waste money on unnecessary vitamins. Their food money should be spent on the "basic four" which contain not only all the vitamins in proper amounts, but also the other necessary nutrients.
It has been alleged that our advertising age has produced an addiction to snack foods, making a well-rounded diet exceptional rather than usual. This is an exaggeration, since the “basic four” need not be obtained in each meal, but rather over the course of an entire day. It is true that some snack foods are mainly “empty calories” (sugar without other nutrients). But it should be noted that acquiring the “basic four” is not all that difficult.

The quack tells you that everyone is in danger of “sub-clinical deficiency.” Does that sound scary? It is meant to be. It is a typical sales tactic, like that of the door-to-door furnace huckster who tells you your perfectly good furnace is in danger of blowing up and you can only be saved by replacing it with his product. Scientists sometimes use the term subclinical deficiency to refer to the situation of a patient on the road to deficiency from an inadequate diet. But no normal person eating a well-balanced diet each day is in any danger of “subclinical vitamin deficiency.”

There is a form of poor nourishment which is particularly common in this country—fluoride deficiency. Fluoride is necessary to build strong teeth which resist decay. The best way for people to get an adequate amount of this essential nutrient is to adjust community water supplies so that the fluoride concentration is about one part fluoride for every million parts of water. Strangely, the quack is usually opposed to water fluoridation. It almost seems as if when he can’t personally profit from the sale, he isn’t interested in your health.

Tip #5: He tells you that soil depletion and the use of chemical fertilizers cause malnutrition. If a nutrient is missing from the soil, a plant just does not grow. Chemical fertilizers counteract the effects of soil depletion. The quack is dead wrong when he claims otherwise! He is also wrong when he claims that plants grown with natural (animal) fertilizers are nutritionally superior to those grown with synthetic fertilizers. The only “extra” you may get from an animal fertilizer is a good case of salmonella diarrhea or gastrointestinal parasites. Moreover, “natural” foods are more likely to have molds growing on them which produce aflatoxins which are among the most potent carcinogens (cancer-producers). Some food additives reduce the growth of these molds.

Don’t make the mistake of thinking that the law forces people to tell the truth about nutrition. FDA regulations forbid only labeling claims that a deficient diet may be due to the soil in which a food is grown. But our laws do not protect you from the quack who states the same thing on TV or radio or in a publication.

Tip #6: He alleges that modern processing methods and storage remove all nutritive value from our food. This is a gross distortion of fact. It is true that food processing can change the nutrient content of foods. But the changes are not so drastic as the quack, who wants you to buy his supplements,
He wants you to believe. While some processing methods destroy nutrients, others add them. As long as you select your foods properly, you will get all the nourishment you need.

The quack distorts and oversimplifies. When he tells you that milling removes B vitamins and iron, he does not bother to tell you that enrichment puts them back. When he tells you that cooking destroys nutrients, he does not tell you that only a few nutrients are sensitive to heat. Nor does he tell you that these few nutrients are easily obtained by having fresh fruit, vegetable or fruit juice each day.

**Tip #7:** He tells you that under stress, and in certain diseases, your need for nutrients is increased. An increasing number of major pharmaceutical manufacturers have been using this tactic lately. One company asserts that “if you drink, smoke, diet, or happen to be sick, you may be robbing your body of vitamins.” Another warns that “stress can deplete your body of water-soluble vitamins... and daily replacement is necessary.” Another plugs its product to fill the “special needs of athletes.”

While it is true that the need for vitamins may rise slightly under stress and in certain diseases, the ads are misleading. The average American, stressed or not, is simply not in imminent danger of scurvy or beriberi. The increased needs referred to in the ads are neither significant nor unmet by proper eating. A person who is really in danger of deficiency as a result of illness would be a very ill person who needs medical care, probably in a hospital. But these promotions are aimed at well-nourished members of the general public who certainly do not need vitamin supplements to survive the common cold, a round of golf, or a jog around the neighborhood!

**Tip #8:** He says that you are in danger of being poisoned by food additives and preservatives. This is a scare tactic designed to undermine your confidence in food scientists and in government protection agencies. The quack wants you to think that he is out to protect you. He hopes that if you trust him, you will buy what he recommends. The fact is that the tiny amounts of preservatives used to protect our food pose no threat to human health.

This chapter cannot cover this subject in detail, but I would like to comment on how ridiculous quacks can get about food additives, especially those which are found naturally in food anyway. Calcium propionate, which is used to preserve bread, occurs naturally in Swiss cheese. The quack who would steer you toward (higher-priced) bread made without preservatives is careful not to tell you that one ounce of Swiss cheese, which you may eat in a sandwich, contains enough calcium propionate to retard spoilage of two loaves of bread. Similarly, the organic food quack who warns against monosodium glutamate (MSG) does not tell you that wheat germ is a major natural source of this substance.

Also curious is the fact that many plant substances sold in health food stores are potentially toxic and can even cause death. The April 6, 1979,
Medical Letter lists more than 30 such products, most of them used for making herbal teas.

Tip #9: He tells you that if you eat badly, you'll be OK if you take a vitamin or vitamin and mineral supplement. This is the “Nutrition Insurance Gambit.” It is dangerous nonsense. Not only is it untrue, but it encourages careless eating habits. The cure for eating badly is a well-balanced diet. Money spent for a vitamin or mineral supplement would be better spent for a daily portion of fresh fruit or vegetable. With one exception, the “four basics” diet contains all the nutrients, known and unknown, that normal people need. (The exception involves the mineral, iron. The average American diet contains barely enough iron to meet the needs of infants, women of child-bearing age and, especially, pregnant women. This problem can be solved simply by cooking in a “Dutch oven” or any iron pot or eating iron-rich foods such as soy beans, liver and veal muscle.)

Tip #10: He recommends that everybody take vitamins or health foods or both. The nutrition quack belittles normal foods. He does not tell you that he earns his living from such recommendations—via public appearance fees, endorsements, sale of publications or financial interests in vitamin companies, health food stores and/or “organic” farms. On the subject of “health food” stores—the term itself is deceptive. Did you ever stop to think that your corner grocery, fruit market, meat market and supermarket are also health food stores? They are—and they charge less for food which is identical or superior to that provided by “health food” stores! (See page 92).

The quack often makes nutritional claims for bioflavonoids, rutin, inositol, para-aminobenzoic acid (PABA) and other such food substances. These “non-essential” ingredients are not needed in the diet, and the FDA forbids nutritional claims for them in labeling.

By the way, have you ever wondered why people who eat lots of “health foods” must also load themselves up with vitamin supplements?

Tip #11: He claims that “natural” vitamins are better than “synthetic” ones. This claim is a flat lie and anyone who makes it should be immediately classified by you as a quack. Each vitamin is a chain of atoms strung together as a molecule. Molecules made in the “factories” of nature are identical to those made in the factories of chemical companies.

Tip #12: He promises quick, dramatic, miraculous cures. The promises are usually implied or subtle—so he can deny making them when the Feds close in. Such promises are the health hustler’s most immoral practice. He does not see, know, or want to know the people who have been broken financially or in spirit—by the elation over his claims of quick cure followed by the depression when the claims prove false. Nor does the health hustler keep count of how many people he lures away from proper medical care.

Quacks will tell you that “megavitamins” (huge doses of vitamins) can
cure many different ailments, particularly emotional ones. But they won’t tell you that the “evidence” supporting such claims is unreliable because it is based on inadequate investigations, anecdotes and testimonials. Nor do quacks tell you that megadoses may be harmful.

Ginseng is currently being promoted as a healthful tonic and aphrodisiac. It is also being used to get “high” (naturally, of course!). But before you try it, take heed. It contains a variety of potentially toxic chemicals, some of which act like steroid drugs. Among its toxic effects are diarrhea, skin eruptions, insomnia, nervousness and severe mental confusion. Ginseng also contains small amounts of estrogens and has been reported to cause swollen and painful breasts.

*Tip #13: He uses testimonials and “case histories” to support his claims.*

We all tend to believe what others tell us about their personal experiences. When you hear someone claim that product X has cured his cancer, arthritis or whatever, be skeptical. He may not have actually had the condition he names. If he did have the condition he names, his recovery most likely would have occurred without the help of product X. (Most conditions recover with just the passage of time.) Establishing medical truths requires careful and repeated investigation—with well-designed experiments, not reports of what people imagine might have taken place. That is why testimonial evidence is forbidden in scientific articles.

Symptoms which are psychosomatic in origin are often relieved by any product which is taken with the suggestion that it will relieve the problem. Most headaches and minor aches and pains will respond to any enthusiastically recommended nostrum. For these problems, even physicians may prescribe a placebo. A placebo is a substance which has no pharmacological effect on a normal person, but is given merely to satisfy a patient who supposes it to be a medicine. Sugar tablets and vitamins (such as B₁₂) are commonly used in this way.

Placebos act by suggestion. Unfortunately, some physicians, like most laymen, really “believe in vitamins” beyond those supplied by a good diet. Those who share such false beliefs do so because they confuse placebo action with cause and effect.

Talk show hosts give quacks a tremendous boost when they ask them, “What do all the vitamins you take do for you personally?” Then, millions of viewers are treated to the quack’s talk of improved health, vigor and vitality—with the implicit point: “It did this for me. It will do the same for you.” A most revealing testimonial experience was described during a major network show recently which hosted several of the world’s most prominent promoters of nutritional faddism. While the host was boasting about how his new eating program had cured his “hypoglycemia,” he mentioned in passing that he no longer was drinking “20 to 30 cups of coffee a day.”
Neither the host nor any of his “experts” had the good sense to tell their audience how dangerous it can be to drink so much coffee. Nor did any of them suggest that some of the host’s original symptoms might have been caused by caffeine intoxication.*

*The average cup of brewed coffee contains a pharmacologically stimulant dose of caffeine (about 100 mg). The average cup of instant coffee contains about 60 mg.

**Tip #14: He’ll offer you a vitamin that isn’t.** With vitamins so popular, why not invent some new ones? In 1949, Ernst T. Krebs, M.D., and his son, Ernst T. Krebs, Jr., patented a substance which was later called pangamate and trade-named “vitamin B-15.” The Krebs’ are also the modern developers of the quack cancer remedy, laetrile, which has been marketed in recent years as “vitamin B-17.”

To be properly called a vitamin, a substance must be an organic nutrient which is necessary in the diet; and deficiency of the substance must be shown to cause a specific disease. *Neither pangamate nor laetrile is a vitamin.* Pangamate is not even a single substance but is a mixture of synthetic ingredients. Laetrile contains 6 per cent cyanide by weight and has poisoned people.

Pangamate is also known as pangamic acid. It is a label, not a substance. The seller puts in the bottle any chemical he chooses. It is being promoted through the media for use against a wide variety of conditions including heart disease, aging, fatigue, diabetes, cancer, glaucoma, alcoholism, schizophrenia, hepatitis, allergies and breathing problems. There is no scientific evidence to support these claims and it is illegal to market “B-15” for the treatment of any condition. Recent experiments have shown that ingredients in some of the most widely sold “pangamates” can cause mutations in bacteria—which means they may also cause cancer in humans.

**Tip #15: He espouses the “Conspiracy Theory” and its twin, the “Controversy Claim.”** The quack claims he is being persecuted by orthodox medicine and that his work is being suppressed. He claims that orthodox medicine or the AMA is against him because his cures can cut into the incomes doctors make by keeping people sick. Don’t fall for such nonsense. There is so much more medical business available than we doctors can handle that we import from other countries about as many doctors each year as we graduate from our own medical schools. Moreover, many doctors in health plans receive the same salary whether or not the patients in the plans are sick—so keeping their patients healthy reduces their workload but not their incomes.

The quack claims there is a “controversy” about facts between himself and “the bureaucrats,” organized medicine and/or “the establishment.” He clamors for medical investigation of “his” claims (ignoring the negative re-
Health Hustlers

suits of all past investigations). In reality, there is no fact controversy. The collision is between his misleading statements and the facts. The gambit, "Do you believe in vitamins?" is one way in which he tries to increase confusion. Everyone "believes in vitamins." The real question should be, "Do you need additional vitamins beyond those in a well-balanced diet?" The answer is no.

Any physician who found a vitamin or other preparation which could cure sterility, heart disease, arthritis, cancer and the like, could make an enormous fortune from such a discovery. Not only would patients flock to him, but his colleagues would shower him with prizes and awards—not the least of which would be the tax-free $190,000 + Nobel Prize!

Tip #16: He is legally belligerent. The majority of "nutrition experts" who appear on TV talk shows and whose publications dominate the "health" sections in bookstores and health food stores are quacks and charlatans. Why are they not labeled as such? Ralph Lee Smith, a former investigative reporter who became Associate Professor of Communications at Howard University, answered this question in the December 16, 1965 issue of The National Reporter. Writing in The Vitamin Healers, a hard-hitting article which ripped the lid off Carlton Fredericks, Smith said it is the "question of libel":

"A reputation for being legally belligerent can sometimes go far to insulate one from critical publicity. And if an attack does appear in print, a threat of libel action will sometimes bring a full retraction. Carlton Fredericks frequently threatens to take libel action against those who disagree with him. So assiduous has he been in this respect that he even writes threatening letters to physicians who have questioned his ideas in private correspondence."

If a "nutritionist" travels with a lawyer and threatens libel actions against those who disagree with him, he is probably a quack.

As Smith noted, the threat of a libel action can be particularly effective when made against scientific and scholarly publications, especially those which are sponsored by publicly supported societies and universities.

Dena C. Cederquist is Chairman of the Department of Foods and Nutrition at Michigan State University. In March 1964, she testified at the hearings on health frauds and quackery held by a U.S. Senate subcommittee: "My salary is paid by the State of Michigan to teach, and yet on advice of our lawyer at the University, I did not write a criticism of the book Calories Don't Count [by Dr. Herman Taller who was subsequently convicted of mail fraud, conspiracy and violating FDA regulations] for he said I would be liable and
we simply could not afford this kind of thing." She further stated about a paper relating to food faddism, presented by Kenneth L. Milstead of the FDA to the American Dietetic Association in October 1962, that, "He submitted this paper first to the Journal of the American Dietetic Association and secondly to the Journal of the American Medical Association, and both organizations refused to publish it, a paper full of facts. They refused to publish for fear of being hauled into court in one of those long, drawn-out law suits . . . , and so this very valuable bit of information which should have gone to all practicing dietitians in the United States—and could well have been read by all physicians, was not made available for publication."

The public feels that doctors should speak out against nutrition quacks because they have "nothing to fear" from a libel suit from a quack. Nothing to fear? Successful defense against a libel suit can take three years and cost the doctor $10,000 or more. We need "Good Samaritan" laws to cover the cost of defending libel actions brought by quacks! We also need vigorous enforcement of the laws against malicious prosecution. Any physician or genuine nutritionist who is sued by a quack should consider a counter-suit for malicious harassment.

This writer was threatened in connection with the 1974 David Susskind TV show, "The Vitamin Craze." Just before the show was taped, I was handed a nutrition book written by a velvet-suited, silky-voiced co-panelist whom I had never heard of before—one Gary Null. After perusing it, I stated, "This book is garbage." Null immediately threatened me with a lawsuit if I repeated the statement. He told me he travels with two lawyers just to take care of people like me. Calling one of them over, he introduced us and asked his lawyer to watch me closely and hit me with a lawsuit if I said anything "out of line." Null told me he was "Director of the Nutrition Institute of America" and had 36 Nobel Prize winners on his board of directors. I replied that his Institute sounded like a quack "front" and that I did not believe it had 36 Nobel prize winners on its board. (Subsequent investigation proved that I was correct on both counts.) With this warm-up, we went on the air. It was a lively program—one of the few in which the public heard immediate rebuttal of nutritional misinformation.

The Weakness of the Law

Anybody can state, in any medium of his choice, any false, misleading or deceptive health information he chooses. The First Amendment ("freedom of speech") protects him against the consequences of the harm he does, unless the false information is on the label of a product, or the fraud occurs in the course of a provable doctor-patient relationship. Thus, the U.S. Food and Drug Administration, which can act against misleading labels, has no jurisdiction over misleading books.

Can the Federal Communications Commission (FCC) or the Federal Trade Commission (FTC) attack nutrition misinformation via laws which
require broadcasters to operate in the public interest as well as laws which require “truth in advertising”? The FCC usually acts only after receiving complaints, and a public that does not know it is being misinformed cannot complain. The FTC appears to act only against very gross forms of advertising deception or deceptive trade practice. It does not appear to act against subtle forms of misleading information, and many complaints it receives are shelved for “lack of agency manpower.” Purveying deceptive misinformation for profit appears on its face to be a deceptive trade practice. The FTC should be able to move against those who profit from public appearances in which they purvey false, deceptive or misleading nutrition information.

Why do the State Attorneys General not act? Isn’t the presentation of misleading nutrition information perpetrating a fraud on the consuming public? If the First Amendment does not protect smut speech and writings which are alleged to injure mental health, why does it protect misleading nutrition speech and writings which can be proved to be harmful to both mental and physical health? When quack books were brought to the attention of the New York State Attorney General, however, he merely referred them to the FDA (which, of course, did not have jurisdiction over them).

The FDA has pointed out that excess vitamins can hurt you. How many Americans know this? How many preachers of nutrition gospel have ever mentioned this on a television talk show? This failure to mention should be prosecuted as negligence chargeable not only to the huckster, but also to his talk show host and sponsoring network. It also seems possible that the States and/or their courts can revise or interpret their “reckless endangerment” statutes to include reckless endangerment of public health by promotion of dangerous nutritional ideas. I also wonder whether the more dangerous of the quack’s misrepresentations could be enjoined as a public nuisance. Perhaps a public-spirited prosecutor will try these approaches someday.

Under our civil laws, it may be possible for a private citizen to recover substantial damages if he relied on misinformation purveyed by the quack to the detriment of his health. He would need to establish that the quack had a duty not to mislead him. If a doctor recommends a remedy, he has a duty both to use care in selecting it and to warn of complications. If a patient is harmed because his doctor fails to do either one of these, he can sue for malpractice. Is it too much to expect that the unlicensed quack can be held responsible for the harm he does? The widow Scott collected $30,000 at the conclusion of her legal actions in 1979 against physician-congressman Larry McDonald (D-GA), who gave laetrile to her husband.

A recent California case has created a precedent which can be cited by anyone who has been harmed by following the advice of a nutrition quack when given in a broadcast. In Weirum vs. RKO General, Inc., the Supreme Court of California upheld a jury verdict of $300,000 against a radio station.
The station had offered a cash prize to the first person who could locate a traveling disc jockey. Two teenagers spotted the disc jockey and tried to follow him to a contest stopping point. During the pursuit, one of the cars was forced off the road, killing its driver. The jury found that the broadcast had created a foreseeable risk to motorists because its contest conditions could stimulate accidents. Many radio and television stations which broadcast nutrition quackery have been put on notice by scientists that they are creating an unreasonable risk of harm. Such stations might have serious difficulty defending themselves against suits by injured listeners.

When the charming quack does have an interest in a vitamin company, you can be sure that the labeling of his products makes none of the health benefit claims which he makes on the air or in his publications. This is because our laws forbid nutritional misinformation or outright lies only in connection with the sale of products. One way to find out whether someone on the air or in a book is telling the truth is to send him a label from a bottle of a vitamin preparation he sells. Attach the label to a sheet of paper stating the claims he makes for the product (in positive terms, such as “This preparation will cure the following illnesses ___ ___ .”). Ask him to sign the statement and return it to you with the label still attached. If he does not do so, you may assume that he is afraid that his signature on labeling can get him prosecuted for false statements.

Quacks project an aura of sincerity and public interest. They spout (unproveable) “case histories” and tales of personal experience. They cite sloppy research as “the great work of great men.” Yet their deceptions dominate the media.

The food quack benefits only himself, collecting large fees for his public appearances, publications or “consultant” status to health food and vitamin companies which he often controls. The public is not only milked financially (for more than a billion dollars a year), but may also suffer damage from vitamin overdosage and from seduction away from proper medical care.

There is nutritional deficiency in this country, but it is found primarily among the poor, particularly among those who are elderly, are pregnant or are small children. These groups need to have their diets improved. Their problems will not be solved by the panaceas of the huckster, but by better nutritional practices. Again, the best way to buy vitamins and minerals is in the rational combination packages provided by nature: the “basic four” of (1) fresh fruits and vegetables; (2) meats, fish and fowl; (3) whole grain or enriched bread and cereal; and (4) milk products. A cheeseburger with lettuce and tomato contains the basic four.

The basic rule of good nutrition is moderation in all things. Contrary to the health hustler’s claim that “It may help,” his advice not only does not help, but may harm—both your health and your pocketbook. He will continue to “rip
off” the American public, however, until the communications industries de-
velop sufficient concern for the public interest to expose his quackery. And if
the media cannot develop adequate social conscience on their own, they
should be forced to do so by stronger laws and more vigorous law enforce­
ment.

Recently, successful civil lawsuits have been brought by aggrieved per­
sons against questionable nutrition promotions. In 1975, Mrs. Katherine
Young of Maine won an out-of-court settlement of $150,000 in her suit
against the estate of Adelle Davis, author of “Let’s Have Healthy Chil­
dren,” and the book’s publisher. The large doses of vitamin A she gave her
daughter Eliza as a result of the advice in the book resulted in injury to the
infant’s nervous system and dwarfing for life of her physical development.
A case is now pending in Florida against the Adelle Davis book because of
the death of an infant whose parents followed the book’s advice of high
doses of potassium to treat infant colic, according to plaintiffs’ attorney
Peter Portley of Pompano Beach, Florida.

Four suits were brought in New York against Dr. Robert Atkins of “Diet
Revolution” fame in relation to a diet the American Medical Association
warned “has potentially harmful results.” Three were settled out of court in
favor of the plaintiffs and Atkins successfully defended against the fourth,
according to plaintiffs’ attorney, Herman Glaser of New York City.

Recommended Reading

The Great Vitamin Hoax, by Daniel Tatkon.
The Nuts Among the Berries, by Ron Deutsch (A history of food quackery).
The Bellybook, by James Trager.
Eating for Good Health, by Fredrick J. Stare, M.D.
The Family Guide to Better Food and Better Health, by Ron Deutsch.
Let’s Talk About Food, by Philip L. White.
Megavitamin and Orthomolecular Therapy in Psychiatry, Task Force report
of the American Psychiatric Association. ($3.00 from Publications Ser­
vices Division, APA, 1700 N. 18th Street, N.W., Washington, D.C.
20009.)

Recommended Dietary Allowances, National Academy of Sciences. ($6.00
from Publishing Office, National Academy of Sciences, 2101 Constitu­
List of Nutrition Books, Recommended, Recommended for Special Purposes,
Not Recommended. Reliable guide to nutrition books. Compiled by
Chicago Nutrition Association. ($2.00 from Chicago Nutrition Associ­
ation, 8158 South Kedzie Avenue, Chicago, Illinois 60652.)
Nutrition Misinformation and Food Faddism. A collection of 17 papers pub-
lished by the Nutrition Foundation. ($2.50 from Nutrition Foundation, Office of Education, 888 17th Street, N.W., Washington, D.C. 20006.)

Food. Home and Gardens Bulletin #228, prepared by Science and Education Administration, U.S. Department of Agriculture, 1980. (An excellent hassle-free guide to a better diet in living color.)


Author's note: The concept that "you are what you eat" is much more complex than most promoters of that slogan realize. For example, milk fat has a relatively high content of cholesterol and saturated fatty acids (myristic and palmitic) and low levels of polyunsaturated fatty acid (linoleic). Contrary to expectations, serum cholesterol falls when humans eat yogurt and whole milk, because two chemicals in the nonfat portion of milk inhibit cholesterol synthesis (Carol R. Diet Modification: Does It Reduce the Risk of Heart Disease? Amer. Council on Science and Health, N.Y., 1980). Normally, our livers make much more cholesterol each day than we absorb from our food (see pages 213-216).

Tactics of deception related to many products labeled "natural" are discussed in the article, "It's natural! It's organic! Or is it?" in the July 1980 Consumer Reports.
The destructive "nutritional and metabolic antineoplastic diet" of laetrile proponents

In the quackery*-promoting book, Laetrile Case Histories, the authors delineate the "nutritional and metabolic antineoplastic diet" they recommend as laetrile proponents. As a physician-nutritionist-attorney involved in preparing plaintiff's case in Scott vs. McDonald,** I analyzed that diet and found as follows (as did also Professor Thomas Jukes of the University of California at Berkeley, who so testified).** The diet calls for:

1) **No meat, fish or fowl:** these are the major sources of absorbable iron in the American diet, and their lack results in a much higher frequency of iron deficiency and iron deficiency anemia, thereby weakening rather than helping patients with cancer.

2) **No dairy products:** these are the main sources of calcium in the American diet. Lack of adequate calcium damages bone maintenance, thereby weakening rather than helping patients with cancer.

3) **No animal protein:** animal protein is the entire source of vitamin B₁₂ in the American diet, except for vitamin B₁₂-fortified foods and microorganisms such as in seaweed. Lack of this vitamin interferes with basic biochemical processes in normal tissue, thereby weakening rather than helping patients with cancer.

4) **Increased ingestion of fruits and vegetables:** such a diet is high in bulk and low in calories, just opposite to the needs of cancer patients. In addition, it is low in needed animal protein, thereby weakening rather than helping patients with cancer. Furthermore, many nuts (almonds, etc.), stone fruit kernels, apple seeds, fruits (peaches, plums, etc.) and vegetables (green peppers, mushrooms, lettuce, carrots, celery, bean sprouts, etc.), contain varying quantities of the enzyme β-glucosidase (E. Conn, personal communications) which releases cyanide from laetrile, thereby weakening

---

*Random House Dictionary of the English Language (Unabridged ed.). New York: Random House, 1967, p. 1173. Quack: n: 1. a fraudulent or ignorant pretender to medical skill. 2. A person who pretends professionally or publicly, to skill, knowledge, or qualifications which he does not possess; a charlatan.

**Scott vs. McDonald et al., United States District Court, Northern District of Georgia, Atlanta Division, Civil Action File no. C75-1613A.
rather than helping patients with cancer; making almost certain that cancer patients swallowing the worthless16 cancer remedy, laetrile, will get some chronic cyanide poisoning. Contrary to popular belief that cyanide either kills or does nothing, low doses of cyanide produce headache, dizziness, fever, malaise, nausea, vomiting, diarrhea, abdominal tenderness and cramps, rash, hepatomegaly, splenomegaly, and lymphadenopathy and slowly progressive fatigue, neuromuscular weakness of arms and legs,17 gradually progressive loss of vision and hearing, and other deteriorative nerve damage.18

Although the authors of "Laetrile Case Histories"2 do not inform their readers that laetrile can be lethal when eaten with vegetarian foods, they appear aware that the β-glucosidase in apricot kernels can release a poisonous amount of cyanide from laetrile. Their apparent awareness is expressed on page 113 of the book, where they state, using italics for emphasis, "The kernels must be taken at a different time during the day than the Laetrile tablets." They neither inform their readers why they make this recommendation, nor do they inform them that not only apricot kernels but also many other vegetarian foods eaten together with a gram of laetrile will generally poison and occasionally kill the patient.* A gram of laetrile contains 60 mg of cyanide, which can be a lethal dose.16 Luckily, as part of the laetrile rip-off, tablets usually contain only 0 to 88% of the laetrile dose stated on the label.16 Like narcotics pushers, laetrile pushers generally sell an adulterated product to make the traffic even more lucrative.

5) Megadoses of vitamin C (ascorbic acid): it was admitted by defense witness Bruce Halstead in Scott vs. McDonald** that megadoses of vitamin C may release some cyanide from laetrile, and that was in fact demonstrated in the laboratory (V. Herbert and R. C. Backer, JAMA, 1979).

Thus, to give megadoses of vitamin C with laetrile is to increase the probability that the patient will suffer from chronic cyanide poisoning complicated by the acute bouts of hypotension, nausea, vomiting, and diarrhea associated with laetrile administration.16 Hypotension from cyanide poisoning is well established.16,19 Other possible undesirable effects of megadoses of vitamin C have been delineated elsewhere.20

6) Megadoses of vitamin E: the possible undesirable side effects of megadoses of vitamin E have been delineated elsewhere.21

7) Oral pancreatic enzymes: these have no value except in pancreatic disease as a replacement for missing pancreatic secretion into the intestine.22,23 Since they are proteins, they are not absorbed from the intestine and are

---

*This article may have been prescient. Shortly after it was written, 42-year-old Jo Anne Pye, who lived not far from the Richardson Clinic of the author of "Laetrile Case Histories," died of cyanide poisoning from laetrile (see Ref. 160 & 161 in chapter on Laetrile).
destroyed therein. Giving them constitutes not only a waste of money but also a possible source of undesirable side effects for cancer patients. Giving them by enema is bizarre and can aggravate any surface-damaging lesion in the colon. Injecting them is not only worthless, but can produce anaphylactic shock.

8) Pangamic acid ("vitamin B\textsubscript{15}"): this is a worthless and possibly harmful drug of variable chemical composition whose proponents have trade-named it a vitamin.\textsuperscript{24} To call something a vitamin does not make it one. A vitamin must meet the dictionary definition\textsuperscript{*} of the word, which requires among basic essential features that lack of the substance produces a specific deficiency disease syndrome (i.e., lack of vitamin C produces scurvy), and that supplying the substance corrects that deficiency syndrome.

9) Laetrile (amygdalin; "vitamin B\textsubscript{17}"): This substance, listed under its correct name, amygdalin, in the Merck Index\textsuperscript{25} is a cyanogenetic glycoside with no known value in human nutrition.\textsuperscript{16,26} It has been proposed as a cancer remedy ever since 1845 but has never been found to be of value against cancer,\textsuperscript{25} and has often produced acute and chronic cyanide poisoning.\textsuperscript{16,26} In the time of the pharoahs, it was used in the form of extract of peach kernels for performing executions.\textsuperscript{16} Its proponents have trade-named it "vitamin B\textsubscript{17}" but it is not a vitamin.\textsuperscript{16,26} It is two parts sugar, one part benzaldehyde, one part cyanide, and no parts vitamin.\textsuperscript{25} Patients taking laetrile often suffer chronic and acute cyanide poisoning (see 4 above).\textsuperscript{16}

Laetrile proponents confuse the public by claiming Laetrile, with an upper case L, is different from amygdalin, and this is true, but irrelevant. Laetrile\textsuperscript{25} is the product whose never-reproduced synthesis was patented by E. Krebs, Jr.; it has never been marketed, and has been successfully synthesized via another route by an FDA-Johns Hopkins team in 1977.\textsuperscript{27} It differs in content from amygdalin in that it is one part sugar, one part benzaldehyde, and one part cyanide. Laetrile, with a lower case l, is a synonym for amygdalin\textsuperscript{16,25} and is the substance sold by laetrile proponents. Five lines of evidence suggest laetriles may cause cancer.\textsuperscript{16}

The nutritional and metabolic program of laetrile proponents is perhaps as unhealthy a diet from the nutrition and metabolism standpoint as it is possible for the mind of man to conceive. The promoters of laetrile have stripped the words "nutritional," "metabolic," and "holistic" of their dictionary meanings and use them in code phrases that describe health quackery. To quote the Wall Street Journal cartoon caption reproduced on page 2 of the December 1976 issue of "The Choice," a magazine that promotes the

lucrative health quackery industry: "Orthodox medicine has no known cure for your condition. I could recommend a good quack."

Persons who use the "laetrile metabolic program" violate the first rule of medicine, "above all, do no harm." In addition, in appropriate circumstances, they may run the risk of being convicted of homicide.

Addendum

Two reviews of the dangers of laetrile recently appeared. A letter summarizing the main points of the current paper was recently published, as was evidence that an ingredient of some formulations of pangamic acid is mutagenic. Proof of acute and chronic cyanide poisoning from laetrile and the "laetrile diet" is obtainable not only clinically but also in the laboratory, by measuring blood (red cell) cyanide and 24-hr urine thiocyanate.

References

22. Physicians Desk Reference, Oradell,
Diet of Laetrile Proponents


Supported by Veterans Administration Medical Investigatorship and United States Public Health Service Grant AM 15163.

The October 1980 issue of Prevention magazine carried an article on "how I cured my Hodgkin’s disease with natural foods," and a separate full-page ad by defrocked Texas dentist William Kelley, whose "natural food" and coffee enema treatment of screen actor Steven McQueen (who had mesothelioma) was associated with rapid deterioration and wasting of the actor. Had the article been included in the Kelley ad, Kelley could have been prosecuted for making deceptive and misleading claims. This is an example of how Prevention uses the First Amendment of the Constitution to promote its advertisers while protecting them from the law against fraudulent representations, by publishing articles “independent” of the advertising which make the claims which would be illegal labeling if included in the advertisements. Two deaths from coffee enemas were reported in the October 3, 1980 Journal of the American Medical Association. They were cardiac deaths, similar to that of McQueen, whose cardiac death, however, followed surgery.
Dear Sir:

I am surprised that you allowed the diatribe by Dr. Victor Herbert regarding so-called “metabolic” cancer therapy\textsuperscript{1} to be published. Dr. Herbert decries the proscription of animal protein and the high residue nature of typical “metabolic” diets. Certainly the use of low-protein, low-calorie diets for patients with late stage cachexia is to be deplored. But the situation could well be different for patients whose disease is still microscopic or not yet fulminant. In various animal models, moderate protein and/or calorie restriction has decreased the incidence of spontaneous tumors and of autoimmune disease while enhancing T cell function.\textsuperscript{2} In a number of animal studies high dietary fat has shown immunosuppressive and tumor promoting properties.\textsuperscript{3-5} Whether such data will ever prove to be relevant to the human cancer situation remains to be seen, but they do indicate that it is far too early to permit dogmatic statements as to the ultimate impact of macronutrient content on cancer progression. In any case, it is well known that vegetarian diets can be quite adequate in protein if complementary proteins are eaten, and a vegetarian diet need not be hypocaloric.

With regard to the micronutrients, Dr. Herbert raises the specter of iron, calcium, and B\textsubscript{12} deficiency in patients on a vegetarian diet; this claim conveniently ignores the fact that most if not all “metabolic” patients receive multi-vitamin-mineral supplements, which traditionally contain ample amounts of these three nutrients. Furthermore, the low-fat, unrefined diets of “metabolic” regimens are almost certainly higher in most essential trace minerals, on a per calorie basis, than the high-fat, overrefined diets favored by most Americans. Whether a ritualistic “metabolic” regimen is nutritionally ideal is open to grave doubt, but it is likely in any event to prove superior to the common American clinical practice of giving little or no dietary advice to cancer patients.

Dr. Herbert condemns mega-C therapy on the basis of his purely hypothetical claim that in combination with oral amygdalin use it might increase the risk of cyanide poisoning. However, despite the existence of thousands of metabolically treated patients, he fails to cite even one case in which his fear has been realized. No doubt he believes that his chimeric speculation is far more important than the many years of experience of Dr. Ewan Cam-
cron with mega-C therapy, which he carefully fails to cite. Cameron, in collaboration with Dr. Linus Pauling, has found that mega-C therapy (10 g/day p.o.) extends the lives of terminal cancer patients by an average of about 300 days. This study has been criticized for its use of historical and contemporary controls from the same hospital rather than of randomized prospective design (for the humanitarian reason that Dr. Cameron was unwilling to withhold therapy that he believed to be efficacious), but within these limits that study was conducted intelligently, and its conclusions could very well be valid.

Large doses of vitamin A have potentiated the efficacy of antimitotic and immunotherapy in animal models, have prevented stress-mediated immunosuppression, and have been shown to enhance various immunological parameters in recent clinical studies at the University of Vienna.

It is obviously and admittedly true that "B15" and "B17", whether or not they possess any prophylactic or therapeutic benefit, are not vitamins in the formal sense of that term used by biochemists and nutritionists. With respect to pangamate, I have encountered difficulty in evaluating the voluminous research literature, since I do not read Russian. As to "laetrile", it can be regarded as established that parenteral amygdalin, in most if not all instances, has failed to prolong the life of rodents with malignant tumors. This does not logically preclude the possibility that amygdalin might nevertheless have some palliative or even tumor retardant efficacy in humans. The National Cancer Institute has at length taken the step of admitting that perhaps humans may not be biochemically equivalent to rodents, and is accordingly planning a blinded trial to evaluate the alleged palliative effects of amygdalin.

Sublethal cyanide doses have shown some antitumor efficacy in experimental tumors and in veterinary practice, and recent evidence from Japan suggests that relatively small amounts of benzaldehyde may have an unexpected tumor retardant effect. Each of these substances will be released if administered amygdalin gains access to cleavage by the emulsin complex of gut bacteria (which obviously does occur in human therapy since increased levels of serum cyanide and thiocyanate can be measured). As to Dr. Herbert's warnings about cyanide poisoning, it is widely acknowledged that the only significant side effects encountered with any frequency in patients taking amygdalin in prescribed doses are transient hypotension, and occasional mild gastrointestinal upset with oral use. Intense clinical scrutiny may well reveal a few rare contraindications, but this is certainly true for any drug.

Dr. Herbert is fond of quoting the data of Osuntokun demonstrating high serum cyanide levels in the cassava-eating victims of tropical ataxic neuropathy; he conveniently omits the fact that these patients (the protein
content of whose diet was extremely poor in both quantity and quality) had unmeasureably low serum levels of both sulfur-containing amino acids.

Mark F. McCarty, B.Sc.

Research Director for Medical Biochemistry
The McNaughton Foundation
P.O. Box B-17
San Ysidro, California 92073

References


Reply to letter by McCarty

Dear Sir:

The specious logic of the letter from Mr. McCarty would be surprising for its scientific naivete were it not for the fact that Mr. McCarty identifies himself as an employee of the McNaughton Foundation, a propaganda arm of the multi-billion dollar laetrile and pangamate industries, a substantial portion of which industry appears to be owned by Mr. McNaughton, a twice-convicted criminal currently limited by the terms of his probation to the area around San Ysidro.¹

Our paper was not a "diatribe" but a concise delineation of scientific facts with pertinent references on the nutritionally and metabolically destructive effects of the euphemistically labeled "metabolic" diet promoted by the laetrile industry.²

Mr. McCarty appears unaware of the basic scientific canons that no proposed therapy is safe until proved safe, or effective until proved effective, and would have us give patients the dangerous and bizarre "metabolic" diets based on his speculations that "the situation could well be different for patients whose disease is still microscopic or not yet fulminant" even though he recognizes that the nonrelevant animal data he cites may never "prove to be relevant to the human cancer situation."

Mr. McCarty refers to a "tradition" of ample amounts of iron, calcium, and vitamin B₁₂ supplementation in the "metabolic" regimens of the laetrile industry. There is no "tradition" in the laetrile industry; its "metabolic" recommendations change from seller to seller and from year to year. Mr. McCarty apparently does not adequately read his own laetrile industry literature. The 1978 revised edition of "Laetrile: Nutritional Control for Cancer with Vitamin B₁₇," by laetrile industry promoter Glenn Kittler lists the recommended "accessory therapy" on pages 294, 295, 309, and 310. Nowhere in those pages is any "multi-vitamin-mineral supplement" listed, nor is iron or B₁₂ listed. It is stated on page 295 that "calcium supplements are prescribed to reduce pain and in an attempt to correct calcium deficiencies." It does not mention that those calcium deficiencies may be produced by the recommended vegetarian diet. It also recommends the panoply of bizarre laetrile industry recommended "metabolic" agents, including 75,000 units of vitamin A daily (45,000 units daily was toxic for Chad Green—see page 1145 of Reference 1). With respect to all the material after page 155 in the 1978 Kittler book, it is stated on page 155 that "Professional comments and inquiries are invited by the McNaughton Foundation, P.O. Box B-17, San Ysidro, California 92073."

The claim by Mr. McCarty of a "common American clinical practice of giving no dietary advice to cancer patients" is typical false laetrile industry
Letters

rhetoric. Sound nutritional advice and support are a routine part of common American clinical practice, and both the National Cancer Institute and the American Cancer Society have held national symposia on nutrition and cancer in the past several years.

Mr. McCarty refers to my statement that megadoses of vitamin C may increase the risk of cyanide poisoning by increasing the release from amygdalin of free cyanide as "purely hypothetical." It is factual, and the data have been published.3

The "many years of experience of Dr. Ewan Cameron with mega-C therapy" is typical anecdotal and testimonial citation, useful in advertising but scientifically worthless.1 A year ago, I visited the regional hospital in Scotland where Dr. Cameron works to speak with him. He happened to be on vacation and I spoke with his executive secretary and a senior nurse on a ward where he puts his patients. It was indicated to me that all his patients are given mega-C, that they usually discontinue it because it makes them nauseated or gives them diarrhea, and that no double-blind studies were then being done to their knowledge. A double-blind controlled study of mega-C therapy in cancer patients carried out at the Mayo Clinic does not support the claim by Cameron and Pauling that mega-C is of value.4

Mr. McCarty would have us ignore the known toxicity of megadoses of vitamin A and particularly the greater toxicity of the emulsified vitamin A promoted by the laetrile industry.5 He would have us accept as significant the studies of questionable benefit in some animal models, and the allegation by a Vienna group linked with the German arm of the questionable cancer remedy industry that the highly toxic preparation "A-mulsin",1,5 illegal for sale in the United States (see p. 1145 and citation 154 of Reference 1), stimulated immune response in lung cancer patients. If Mr. McCarty read the Vienna paper more carefully, he would have noted that, of the nine patients, two died during the first treatment period, one more died "due to possible toxicity of the drug...", and "desquamation of the dermis was noticed in every patient," indicating vitamin A toxicity.6 The paper contains no double-blind control group who did not get megadoses of vitamin A, an omission making the study worthless because of the many factors that could have produced the improved immune response and tumor effect that the authors attributed to the toxic doses of A-mulsin.

Mr. McCarty notes that B15 and B17 are "not vitamins in the formal sense of that term used by biochemists and nutritionists." They are not vitamins in any sense; they are toxicants.1,7 Mr. McCarty indicates that, "With respect to pangamate, I have encountered difficulty in evaluating the voluminous research literature, since I do not read Russian." This is surprising, in view of the fact that the McNaughton Foundation underwrote the translation into English of that literature, according to the Stacpoole review of
that literature. However, Mr. McCarty can read all about it in English in the Stacpoole review, and our subsequent review pointing out the anecdotal nature of the Russian studies cited by Stacpoole (I do read Russian, although haltingly).

In his discussion of the antitumor efficacy of cyanide and of benzaldehyde, Mr. McCarty apparently has failed to note that the level at which these two agents are toxic to tumor cells is so close to the level at which they kill normal cells that they are generally worthless in the chemotherapy of cancer (see Reference 1, pp. 1148 and 1149).

Mr. McCarty's allegation that "the only significant side effects encountered with any frequency in patients taking amygdalin in prescribed doses are transient hypotension, and occasional mild gastrointestinal upset with oral use" is ridiculous in view of the contrary fact of cyanide poisoning from laetrile and apricot kernels, the laboratory diagnosis of poisoning, the clinical signs of poisoning, and the factors affecting toxicity described on pages 1126 through 1132 of Reference 1. His statement about "prescribed doses" is ludicrous in the face of the fact that not a single batch of laetrile seized by the Food and Drug Administration has contained the quantity stated on the label; as pointed out elsewhere, the venality of the laetrile industry is such that the actual content is usually from 0 to 80% of the quantity stated on the label, and that is the reason for less than expected degrees of cyanide poisoning at given "prescribed doses." ¹

I plead guilty to his charge that I am "fond of quoting the data of Osuntokun." Osuntokun is Professor of Medicine at the University of Ibadan Medical School in Nigeria, was for 5 years the Dean, and is just now concluding a year as Commonwealth Professor of Medicine at the University of London at the Royal Postgraduate Medical School. He is an international authority on the degenerative neuropathy with blindness related to laetriles in the diet of Nigerians. His most recent paper notes that while the sulfur-containing amino acids were undetectable in 60% of chronically poisoned patients and greatly reduced in the others, and the plasma levels of the other essential amino acids were also reduced, the pattern differed in many respects from that found in protein-calorie malnutrition and protein deficiency states, and hepatic rhodanese activity was not significantly lower than in controls. It should be noted that the vegetarian diet promoted by Mr. McCarty would probably also sharply reduce sulfur-containing amino acids in the blood, and it is surprising he and his colleagues have never bothered to publish measurements of these amino acids or to publish plasma cyanide levels, plasma thiocyanate levels, and 24-hr urine thiocyanate levels in patients given laetrile. The cynic might conclude the laetrile industry doesn't want people to know that their product poisons its users.

In separate sections of his letter, Mr. McCarty argues that animal data should be used if it can be interpreted in a way favorable to the laetrile
industry, but must be disregarded when it is unfavorable. He cannot have it both ways.

Mr. McCarty argues both that a low-protein diet may prevent tumors and may potentiate the toxic effects of cyanide, i.e., using laetrile with those diets, he speculates, might kill both the tumor and the patient. Since cyanide is approximately equally toxic to normal cells and to tumor cells, that is not surprising.

There is real hope for cancer victims from the fact that approximately 40% of the people who today develop invasive malignancies are being cured by medical science, supported by genuine (rather than bogus) nutritional science. The acutely remunerative "alternative therapy" offered by "metabolic" regimens offers such cancer patients false hope and certain death, and there is evidence developing that "metabolic" patients die twice as fast as patients getting no therapy at all, because of the combined effects of lack of proper medical and nutritional care, and chronic cyanide poisoning (see citation 36 of Reference 1).

There are five lines of evidence suggesting that, far from curing cancer, laetriles may cause it (see section entitled "Laetrile may cause cancer" in Reference 1). A sixth line of such evidence has just been published. Additionally, "B₁₅" (pangaminate) the other bogus vitamin sold by the laetrile industry, almost invariably contains either the dangerous poison dichloroacetate, or dimethylglycine; the former is a mutagen by Ames test and the latter reacts with nitrites to form a potent carcinogen.⁷,¹¹-¹³

The possibility that synthetic retinoids and megadoses of vitamin C may do more good than harm in relation to certain human cancers is currently being evaluated by responsible scientists,¹⁴ but vitamin A itself is too toxic for such use and vitamin C has so far shown more toxicity than value.¹⁴

The "nutritional and metabolic therapy" promoted by the laetrile industry is nutritionally and metabolically destructive¹,²,⁷ and no amount of specious logic by spokespersons for that industry alters that fact one iota (see section entitled "The allure of quackery: specious logic versus the logic of science, the overlap of cultism and quackery" in Reference 1).

Victor Herbert, M.D., J.D.

References

Pangamic Acid ("Vitamin B$_{15}$")

A cover story in the March 13, 1978 issue of *New York Magazine* lauded B$_{15}$ "as a possible cure for everything short of a transit strike." The article, according to a note on the masthead page of *New York Magazine* on April 3 "made it impossible to find the vitamin on any dealer's shelf in the metropolitan area for a full week."

"Vitamin B$_{15}$" is the latest rage in health food stores in the U.S. Numerous articles have appeared in lay publications and on radio and television extolling this substance. Yet according to the Food and Drug Administration, "vitamin B$_{15}$" is "not an identifiable substance... not a vitamin nor a provitamin... no accepted scientific evidence establishing any nutritional properties of the substance or any deficiency... in man or animal... no medical, nutritional, or other usefulness for these substances has been established."

Pangamate ("B$_{15}$") is a label, not a product. The label means "magic pill," but the pills inside may give you cancer. When you buy a bottle labelled "pangamic acid," "pangamate," "calcium pangamate," "sodium pangamate," "Russian formula," "vitamin B$_{15}$," "B$_{15}$" or "15" in your local health food store, that label tells you nothing about the contents in the bottle. The fact is that the pills inside contain anything the seller chooses to put in them. Often he chooses to put poison in them, particularly a poison like DIPA (diisopropylamine dichloroacetate, 1976 Merck Index #3181), which produces blood vessel dilation and a drop in blood pressure resulting in a "kick" that makes you say, "That is one powerful vitamin."

According to the November 29, 1979 press release by Savvy Management, New York City advertising firm for the Orlandi B$_{15}$ operation in the United States, Orlandi and five other sellers use DMG (dimethylglycine) as the active ingredient in the B$_{15}$, 22 sellers use DIPA, and the rest use an assortment of other chemicals. Taking their cue from the Krebs family who created the "B$_{16}$" (pangamate) and "B$_{17}$" (laetrile) industries, many of the leading promoters of B$_{15}$ and B$_{17}$ are father-son teams (the Orlandis), father-daughter teams (the Richardsons, the Manners), husband-wife teams (the Griffins, the Salamans) or brother-sister teams (the Bradfords).

The work of the author is supported in part by the Veterans Administration Medical Research Program and in part by U.S. Public Health Service Research Grant # AM 20526.
Background: In 1943, Ernst Krebs, Sr. and Jr., applied for a patent for material similar to that previously discovered by Krebs, Sr., and isolated from apricot kernels, which they named "pangamic acid." Krebs, Sr. and Jr., then trade-named such material "vitamin B\textsubscript{15}", just as Krebs, Jr. trade-named amygdalin, another chemical also isolated (in 1830) from apricot kernels,\textsuperscript{4,5} first as "laetrile" and subsequently as "vitamin B\textsubscript{17}".

The B\textsubscript{15} patent claimed pangamate is "a preparation for the immunization of toxic products present in the human or animal system" which has "the property of detoxifying toxic products formed in the human system". "This invention relates to a preparation for relief and immunity to persons afflicted with asthma and allied diseases... affections of the skin, respiratory tract, painful nerve and joint affections, and even cell proliferation... eczema... arthritis, neuritis..." Not a sliver of data is present in the patent application\textsuperscript{3} to support any of these snake-oil panacea claims it suggests.

Two decades ago, pangamic acid was promoted for horses,\textsuperscript{1,6} but it has been heavily promoted for humans since publication of a review by the stepson of Ernst Krebs, Jr., in \textit{World Review of Nutrition and Dietetics}.\textsuperscript{7} Without citing supporting evidence from any country's national nutrition policy body, the review alleged that "pangamic acid has been widely studied and accepted in many countries as a necessary food factor with important physiological actions." It dated the history of pangamic acid from 1951 and did not mention the earlier work by Krebs, Sr., or the pangamic acid patent sought in 1943 by Krebs, Sr. and Jr.,\textsuperscript{3} in which they claimed pangamate had the property of detoxifying toxic products formed in the human system. The review also failed to note the backgrounds of the American creators and promoters of pangamate or their difficulties with health authorities and the law in connection with it, and in connection with their concurrent promotion of laetrile.\textsuperscript{4,8} The review acknowledged that "this work was funded in part by a grant from "the McNaughton Foundation." The author was formerly a Research Associate at the McNaughton Foundation* in Mill Valley, California,\textsuperscript{9} and had previously published related material in that capacity.\textsuperscript{9} The McNaughton Foundation publishes lay booklets which promote pangamate ("B\textsubscript{15}") and laetrile ("B\textsubscript{17}") as if they were vitamins. Among their booklets sold to the public at health food conventions are the "Physician's Handbook of Vitamin B\textsubscript{17} Therapy," published October 18, 1973 ($2.00), and "Vitamin B\textsubscript{17}, Vitamin B\textsubscript{15} and Vitamin B\textsubscript{13}," published June 12, 1975 ($1.50). The latter booklet states on page 17: "A review, 'Pangamic Acid (Vitamin B\textsubscript{15})' will shortly be pub-

\textsuperscript{*}As indicated elsewhere,\textsuperscript{4,8} Andrew McNaughton appears to be a laetrile factory owner with two criminal convictions, and Krebs appears to be a medical school flunk-out with 2 criminal convictions. They appear to interact closely in promoting "B\textsubscript{15}" and "B\textsubscript{17}".
Pangamic Acid

lished by Dr. Peter Stacpoole in the American Journal of Clinical Nutrition and lists over 125 references to studies on pangamic acid, most of them clinical." In fact, the American Journal of Clinical Nutrition rejected the review as inadequately scientific for the following reasons:

The title of the review declared pangamate a vitamin (with no qualifying quotation marks). The review did not cite the position of either the Canadian or United States food and drug authorities that not only was there no evidence that pangamate was a vitamin, but also no acceptable scientific proof that it had any therapeutic benefit or was safe for human use.2,6,7 In the review, none of the biochemical data gave any description of biochemical or chemical reactions that take place physiologically. Data on absorption, blood levels, urine levels, excretion, degradation, etc., of pangamic acid were not provided. The usual toxicologic studies were not described. No dose response data were provided. The clinical data were not obtained under controlled conditions. There was no critical evaluation of the literature, which might help the reader assess the various claims of different investigators. It was not convincing that the claims had any foundation in fact. Most of the claims were conclusory statements extracted from uncontrolled anecdotal observations published in Russia. What was provided were general statements with no controlled data. No negative or contradicting data were cited. Neither the amount of uncontrolled or anecdotal studies nor the number of papers published determines whether or not a substance is a vitamin or whether it has physiologic functions; however, the author took all of these deficient studies and attempted to derive meaningful positive information from quantity instead of quality, appearing not to heed the humorous but valid scientific dictum, "Garbage in, garbage out." These poorly designed studies with conclusions not derived from the data—studies lacking adequate controls—could not produce meaningful positive information.

Chemistry: Krebs et al.,10 and a number of Russian workers cited by Stacpoole,7 used the term pangamic acid to describe a product, claimed to be isolated from various plant sources and also obtained by laboratory synthesis, having the empiric formula C_{10}H_{19}O_{8}N, d-gluconodimethyl aminoacetic acid (an ester of d-gluconic acid and dimethylglycine (glycine is aminoacetic acid)), molecular weight 281 daltons, having an unstable ester bond, which does not crystallize.11 The synthetic Russian preparation of calcium pangamate crystallizes with a water molecule and has a molecular weight 618.7 and four methyl groups (from its two pangamate monomers).11 It is described as a mixture consisting of no less than 70% of the calcium salt of gluconic acid ester and dimethylglycine, no more than 25% calcium gluconate, and no more than 6% calcium chloride11 (which can be a poison15). It is slightly hygroscopic and must be stored dry and sealed to retain stability.11 It is a white powder, soluble 1:1 in water, relatively stable.
in acid, and resists heat to 100°C when dry.\footnote{11} It has a characteristic weak amine odor and a slightly bitterish taste.\footnote{11} The Merck Index, 8th edition, 1968,\footnote{5} notes pangamic acid as a mixture of sodium gluconate, glycine, and diisopropylamine dichloroacetate.\footnote{*} The 9th edition of the Merck Index\footnote{12} gives the structure as D-gluconic acid 6-bis (1-methylethyl) amino acetate.\footnote{**} Products marketed as “B\textsubscript{15}” or “pangamic acid,” or “calcium pangamate” could contain any or all of the above materials, plus other materials, since there is no standard of identity for the product. The term “pangamic acid” appears to be used indiscriminately regardless of which of various adducts are on the ester linkage. Those “B\textsubscript{15}” products containing the chloride ion may be synthetic, and for them the designation “derived from natural sources” is meaningless. The Russian preparation is also synthetic, as are the American equivalents of it.

The Food and Drug Administration has repeatedly seized B\textsubscript{15} tablets which include mixtures of calcium gluconate and dimethyl glycine marketed under various names such as calcium pangamate, Aangamik and Caldiamate; default decrees have ordered their destruction. The chemical composition varies from product to product\footnote{*} and its various promoters and vendors designate its chemistry differently from year to year and from article to article, hence the FDA statement that it is “not an identifiable substance.”\footnote{2.5.6.7}

Krebs appears to have been selling a product containing calcium gluconate, because testimony in his probation revocation case\footnote{4} included that “... there were three probationary searches ... on each occasion there were empty barrels of calcium gluconate... these were all 200 pound drums... sales records... 1975... $10,310 passed from Mr. Bradford to Mr. Krebs for the B\textsubscript{15}.”

\footnote{Diisopropylamine dichloroacetate (tradename DIPA) is a solid which dissociates in water into diisopropylamine and dichloroacetate (DCA), both of which are liquids. The tradename DIPA is chemically DIPA-DCA.}

\footnote{**But the same 9th edition, under the entry for diisopropylamine dichloroacetate (DIPA) lists that drug as the active ingredient of B\textsubscript{15}. The fraud perpetrated on the Merck Index is evident in these two incompatible entries in the same edition. The editor of the Merck Index indicated to this reviewer that “pangamic acid” and “vitamin B\textsubscript{15}” will be deleted from the 10th edition, since they were deceived into listing it.}

\footnote{*Claimant’s Answer to Government’s Written Interrogatories (Interrogatory No. 2) in U.S. v. Aangamik 15 Calcium Pangamate, etc. (Consolidated Cases Nos. 77C 662, etc., U.S. Dist. Ct., N. Dist. Ill., E. Div.) states the seized calcium pangamate was a blended mixture of N, N-dimethylglycine hydrochloride, calcium gluconate, dicalcium phosphate, stearic acid and avicel.

Claimant’s Answer to Interrogatory no. 9 stated there are about 20 mg of dimethylglycine in 100 g of meat eaten by man, but did not state whether any of it was free (as in claimant’s product) rather than bound, or whether any of it was dimethylglycine hydrochloride (as in claimant’s product). In his order of December 5, 1978 denying defense motion for rehearing in U.S.A. v... “B\textsubscript{15} (sodium pangamate) 50 mg...”, Civil Action no. 76-1860, U.S. Dist. Ct., Dist. of N.J., Judge Curtis Meanor stated: “the chemical composition of the articles under seizure is 64% calcium gluconate, 16% glycine, and 20% of the salt formed from di-isopropylamine and dichloroacetic acid.”}
Because of lack of any proof that pangamic acid is either a definite chemical entity, safe for human use, or of any therapeutic benefit, its distribution in Canada was prohibited by that country's Food and Drug Directorate. A "pangamic acid (vitamin B₁₅)" sold by one corporation for chemical and investigational use proved to be a mixture of diisopropylammonium dichloroacetate, sodium gluconate, and glycine. Correspondence in 1978 with their successor organization has not revealed what is packed under the "pangamic acid (vitamin B₁₅)" label of the material purchased in 1978 from them. In the course of our correspondence with them, they attempted unsuccessfully to get additional specifications or analysis from their European supplier, and then discontinued sales.

**Pharmacology:** The gluconic acid, glycine, and acetate in some of the formulations are essentially inert. One pharmacologically active agent is diisopropylamine, which has been studied by Kraushaar and others. This amine acts on smooth muscle to lower blood pressure and decrease body temperature. Acute toxic doses cause death in rodents by cyanosis and respiratory failure. The material is nutritionally worthless and is one more of the "toxicants occurring naturally in foods," others of which are described in the book of that name published by the National Academy of Sciences, Washington, D.C., 1973. It is pertinent that the term "pangamic acid" (Gr. *pan* = universal; *gamic* = seed) was coined to describe the fact that the substance is frequently found in seeds, which is also the case for cyanide. Stacpoole et al., reporting on certain acute metabolic effects of dichloroacetate, state "the efficacy and safety of chronic dichloroacetate administration are unknown." Their findings made a case for its use in the short-term treatment of acute life-threatening lactic acidosis, hitherto often fatal. One can, of course, legitimately use poisons to save lives in acute emergencies (such as the use of nitroprusside in acute hypertensive emergencies). However, the question has been raised as to whether dichloroacetate offers anything over bicarbonate in the treatment of lactic acidosis. In addition, the substance has been shown to inhibit the pyruvate transporter in rat liver mitochondria *in vitro*, which would be an undesirable effect if reproducible in humans.

Adverse effects noted by Stacpoole et al. included mild sedation and increased serum uric acid levels in diabetic patients. Crabb and Harris suggest that dichloroacetate (DCA) may produce oxalic acid stone formation and renal dysfunction, because DCA converts to glyoxylate which is a precursor of oxalate.

Halogenated organic compounds have recently begun to cause concern regarding their carcinogenic potential because of the ease with which they can form free radicals. The potential of dichloroacetate for carcinogenesis therefore requires evaluation. We recently found it mutagenic by Ames test.
It should be noted that toxic cataracts frequently appear months or years after chemical or drug exposure, and the connection to prior drug or chemical exposure may not be made in the absence of adequate alertness. A year ago this reviewer requested information from Stacpoole on possible mutagenicity and cataract production by DCA. Subsequent to our preliminary report on DCA mutagenicity, Stacpoole et al. announced the suspension of chronic oral administration to patients on the basis of serious toxicity to animals and at least one human. There was dose-related hind limb paralysis, germinal epithelial degeneration of the testis and vacuolation of the myelinated tracts of the cerebrum in rats and dogs. Dogs also showed severe ocular lesions including irreversible lenticular opacities. A man developed polyneuropathy. DCA may be more toxic orally than parenterally, as is the case for laetrile.

The d-gluconodimethyl aminoacetate formulation has been reported to have neuromuscular blocking activity in rabbits and chickens and to produce hypotension in dogs. Russian calcium pangamate of this formulation is contaminated with up to 6% calcium chloride, and all calcium pangamate of similar formulation should be considered contaminated with calcium chloride until proved otherwise. It is possible that contamination with dichloroacetate may also occur, and this possibility should be evaluated in each preparation.

Some formulations of pangamic acid contain methyl groups, but these are not labile. Furthermore, there are no published data stating that the large promoted doses of such formulations are normally found in the diet, concentrate in human tissues, or play a salutary physiologic role not due to folate or choline present in the diet (and not carried out with less energy loss by choline and methionine). None of the formulations of pangamate appears from available data to be lipotropic, or to be a methylating or trans-methylating agent. One-carbon compounds can be oxidation products of some of the formulations, and those products can then enter the one-carbon pool, as do similar oxidation products of many substances. The Krebs patent “N-substituted glycine esters of gluconic acid” states “a particular object is to provide synthetic compounds...which are more effective methyl donors than known methyl donors such as methionine and choline,” but no data are presented to support the claim that any of the “pangamates” in the patent is labile. Indeed, the diisopropylamino product cannot be a methyl donor because its methyl groups are on C, and only methyl groups on an N or an S can serve as methylating agents, and then only when there is no need for an added energy source. This is not the case for dimethylglycine, a product of choline catabolism, which is synthetically attached in an ester linkage to gluconic acid in some pangamate formulations. Its methyl groups, like those of sarcosine, are not labile, and so must be removed by oxidation and only then can enter the one-carbon unit pool. It was established in 1946 that dimethylglycine was not lipotropic.
It enters one-carbon metabolism at the oxidation level of formaldehyde, and worsens methyl depletion of rats on diets creating methyl deficiency who are given nicotinamide supplements, resulting in renal cortical necrosis in mature females and damaged growth and development of fetal rats.\textsuperscript{24a} Alkali-metal (Na, K, NH\textsubscript{4}) salts of dimethylglycine are claimed to chelate alkaline earth metals (Mg, Ca), thereby rendering absorbable certain sulfated polysaccharides claimed to be lipemia-clearing.\textsuperscript{24b} The safety and efficacy of such claimed effect requires evaluation before use (see Addendum).

Dimethylglycine (N-methylsarcosine), a tertiary amine, reacts with nitrites (which are formed \textit{de novo} in the intestine)\textsuperscript{25} to form both the potent carcinogen, dimethylnitrosamine, and the weaker carcinogen, nitrososarcosine.\textsuperscript{26} Nitrites which effect this reaction occur in human saliva\textsuperscript{27}: nitrososarcosine induces cancer of the oral pharyngeal cavity and esophagus in the rat.\textsuperscript{27}

Thus, dimethylglycine ingested in concentrated free form in a tablet appears much more likely carcinogenic than the same amount bound in 100 g of meat\textsuperscript{4}, since only the former is presented to the oral cavity and esophagus in high concentration, and the dimethylglycine in human muscle as a catabolic product of choline is not presented at all to the oral cavity and esophagus. In addition, what purveyors of pangamate and B\textsubscript{15} appear to be selling is not dimethylglycine, but dimethylglycine hydrochloride, of different composition and reactivity.

Hundreds of compounds found in seeds and plants have chemical and pharmacological effects. This does not make them nutrients or physiologic agents. Many are poisons.\textsuperscript{15}

**Clinical Use:** The allegations of long-term medicinal value for pangamic acid in cancer, alcoholism, hepatitis, heart disease, allergies, diabetes, schizophrenia, glaucoma, retarding aging, purifying air, and increasing respiratory ability by providing “instant oxygen” are anecdotal and testimonial stories rather than studies, and lack comparison for effectiveness in controlled studies to other treatments or to “the doing of nothing” (placebos).\textsuperscript{6,23,29} A number of these stories, either totally uncontrolled or lacking the crucial choline control, originate in Russia. The authors often claim spectacular results from “pangamic acid” or “vitamin B\textsubscript{15}” without identifying which of the many chemicals and chemical combinations which go by that name they are using, without distinguishing drug effect from placebo effect, and without reporting any evaluation of patients for short-term or long-term toxic effects.

The Food and Drug Administration regards the products as illegal—whether used as a food or as a drug—and has made a number of seizures of them.\textsuperscript{2,30} On June 12, 1978, in the New Jersey seizure case, a Newark District Court judge upheld the Food and Drug Administration contention that
“B_{15}” is essentially an untested “food additive” which is not generally recognized by scientific experts as safe for human consumption and cannot be sold legally on the market.\textsuperscript{30} Pangamate was prohibited within Canada for more than a decade.\textsuperscript{6} Because of these facts, any physician who prescribes it should first secure an I.N.D. (Investigational New Drug) number for it, describing which of the many different chemical mixtures called “pangamate” is the one to be used; should submit his proposal to a Human Studies Committee; and should get informed consent from his patients after informing them that it is not a vitamin, has no known nutrient value, no known value in the long-term treatment of any diseases, that its safety has not been established, and it may be mutagenic.

The claim that “B_{15}” supplies calories is deceptive and misleading. Carbohydrates and proteins supply 4 cal/g and fats supply 9 calories per g, so the most a 50 mg tablet of “B_{15}” could supply, regardless of its ingredients, is less than half a calorie.

As noted elsewhere,\textsuperscript{4,29} there are four basic scientific canons for evaluating medical information:

1. Does it go beyond “personal observation” to stand the test of scrutiny and criticism by other scientists, i.e., is it a study or a story? Is it science or anecdote?

2. Was it compared for effectiveness in double-blind controlled studies to other treatments and to suggestibility or to the “doing of nothing,” i.e., to a placebo? What is the natural history of the disorder in the absence of therapy? Was the observed result cause and effect, placebo effect or coincidence due to the natural history of the disorder?

3. Has it been proved safe? Safe compared to what? Is the risk justified? What is the risk:benefit ratio? (Note that if there is no benefit, the risk:benefit ratio is infinity, which is not tolerable.)

4. The burden of proof is on those who propose doing or giving something, especially if it involves a remedy or procedure not well established in medical practice.

Valid weapons against disease are forged in the crucible of these canons. After three decades, “B_{15}” has yet to successfully meet any of these basic scientific challenges.

Conclusion: Pangamic acid, pangamate and “B_{15}” are synonyms for an alleged entity which in fact is a number of different products of variable composition which do not constitute a definite chemical entity. The label originally described what may have been partly Na or Ca d-gluconodimethyl aminoacetate. However, the label more often describes a product which is one part sodium (or calcium) gluconate, one part glycine (or dimethyl glycine); often also one part diisopropylamine dichloroacetate. Often still other synthetic mixtures are sold as “B_{15}” and “calcium pangamate.” Pangamic acid is \textit{trade-named} “vitamin B_{15}”, but it has no known nutritional
worth, no vitamin properties, and no such vitamin exists. In fact, pangamic acid can be said not to exist, since there is no standard of chemical identity for products sold under that label. There is no proof that it has any therapeutic benefit or is safe for human use; and it may be mutagenic.* All of the “B₁₅” and “pangamate” products being sold, including those in health food stores, appear to be at least partly synthetic. The use of pangamate may thus violate the primary ethical rule of medicine—above all, do no harm.³¹,³²

In the Middle Ages, anecdotal claims of efficacy and safety of nostrums were automatically accepted, and it was for science to disprove them. This required science to prove a negative, often difficult or impossible to do. The Age of Reason began with the recognition that protecting the public health and safety required adopting the rule that it is for the proponent to prove his claim, rather than for science to disprove it; and that nostrums should be considered inefficacious and unsafe until proved efficacious and safe. With laetrile and pangamic acid, we are in danger of returning to the age when anecdote substituted for science. Both products appear to meet the criteria which define a quack remedy,⁴,²⁹,³³–³⁷ and both appear to be more toxic on oral than parenteral administration.⁴,²⁰

Because of its usual content of dichloroacetate or dimethylglycine hydrochloride, persons buying pangamate in the erroneous belief they are purchasing nutrition may be purchasing mutagenesis or other unknown harms.

The United States Food and Drug Administration “Statement on Pangamic Acid” dated August 18, 1978, concludes:

“FDA considers ‘vitamin B₁₅’ to be a food additive for which no evidence of safety has been offered. It therefore is illegal for the substance to be sold as a dietary supplement. No new drug application for ‘Pangamic Acid’ has been submitted or approved by FDA and the substance legally cannot be marketed as a drug.”

*The scientific papers from our laboratory regarding the mutagenicity by Ames test of DCA and DMG, the two most-used basic ingredients of pills labelled “pangamate,” appear respectively in the Spring 1980 issues of the American Journal of Clinical Nutrition and Proceedings of the Society of Experimental Biology and Medicine. In 9 cases out of 10, agents mutagenic by Ames test are carcinogenic (cancer-causing). DMG is a waste product of choline breakdown, and is probably excreted in stool and urine. The DMG commercially available is usually synthesized from its ethyl ester.

ADDENDUM

Regarding the patent of dimethylglycine to enhance absorption of heparin,⁴² the Manager of Professional Services of the corporation to which the patent is assigned informed this reviewer by letter dated 2 May 1979 that, “We never carried out any long term animal studies with this particular
agent, and therefore I am unable to answer your question about toxicity. Also, dimethylglycine was never tested in humans. We never marketed any products of this type since the extent of absorption (of heparin) never reached levels greater than five percent of the administered dose.”

Despite the U.S. government position that pangamate is illegal, worthless, and possibly unsafe, in 1979 it was still being vigorously promoted and sold in every “health food” store in the United States visited by this reviewer, including those of the multimillion-dollar General Nutrition Center chain. Mr. Paul Sage, of the Bureau of Enforcement of the FDA, informed this reviewer that the FDA lacked enough personnel to seize pangamate from these thousands of stores, and was doing its best to fight the huge and lucrative pangamate industry by bringing court cases against producers. However, while the cases grind through the courts, the producers of pangamate such as Aangamik continue to promote and sell, and others spring up and do likewise. Where there is money to be made, there are those who will make it.

With respect to the misleading health claims, the government has no power to stop them, unless they are stated on the labeling of the product, and the multibillion dollar nutrition cultism industry and its pangamate arm are too legally sophisticated to do that. The claims are made in nutrition cultism literature sold in “health food” stores and elsewhere, which is protected “free speech.” Many “health food” stores were selling in 1979 the General Health and Nutrition Centers, Inc. vitamins and minerals placemat which misleadingly claims pangamic acid as a vitamin which facilitates “cell oxidation and respiration, metabolism (protein, fat, sugar), glandular and nervous system stimulation,” whose “deficiency symptoms” are “heart disease, nervous and glandular disorders,” and whose “therapeutic applications are “alcoholism, asthma, atherosclerosis, cholesterol (high), emphysema, heart disease, headaches, insomnia, poor circulation, premature aging, rheumatism, shortness of breath.”

Parenthetically, victims have just brought the first civil suit against the author and publisher of a nutrition cultism book sold in “health food” stores and elsewhere which made a misleading nutrition claim which they say led them astray and thereby caused the death of their child. The misleading claim was that large doses of potassium can help against colic.

On June 18, 1979 the United States Supreme Court ruled 9-0 against laetrile in Rutherford v. USA. Many of the same interests promote both laetrile and B₁₅. In February, 1980, the 10th Circuit Court reversed Bohanon’s philistine pro-laetrile decision.

On January 31, 1980, the largest health food chain in the U.S., GNC (General Nutrition Center), signed a consent decree in federal court in
Pittsburgh to stop packaging the poison DIPA (diisopropylamine dichloroacetate—see item #3181 in the 1976 Merck Index) under their “pangamate” “B15” label. They have now switched to DMG, apparently. In the consent decree, GNC stated they did not know the basic ingredient in the “pangamate” they were selling was the poison DIPA. This despite their claim of the best quality control in the world, and despite the fact that their 1976 copy of the Merck Index lists DIPA as the active ingredient in B15! Clearly, not only does the public not know what noxious chemicals are thrown into bottles labeled “pangamate” and “B15”, but the seller may not know or care unless or until the law catches up with him years later (if ever). In 1980, Herbert and Herbert had some of the “original” B15, sent in 1953 by Beard (of Krebs, Krebs, and Beard) to Prof. William Darby at Vanderbilt University, tested for nuclear magnetic resonance spectrum. It was pure lactose (milk sugar), with no DIPA, DCA, or DMG.

References


Not a single preparation of “B15” or “pangamate” has ever been verifiably chemically identified as being the molecular weight 281 ester of DMG and gluconic acid claimed by Krebs and some Russian authors, and there is considerable doubt such a stable substance exists with the straight-chain sugar gluconic acid. Nuclear magnetic resonance studies carried out at my request in 1980, on a sample of “B15” supplied by Beard (see Ref. 10) in 1953 to Vanderbilt University, showed the spectrum of pure lactose, with no DMG on DCA contamination! I am indebted to Dr. William Darby for the sample.
CAN B15 (PANGAMATE) CAUSE CANCER?

The latest (1976) edition of the Merck Index, the encyclopedia of chemicals and drugs available in every pharmacy in the United States, says that vitamin B15 (pangamic acid) is D-gluconic acid 6-diisopropylamino acetate (Merck Index #9676), and that its active ingredient is diisopropylamine dichloroacetate (Merck Index #3181). In the Pittsburgh federal court case of “U.S.A. v. General Nutrition Corporation,” on January 31, 1980, the defendants and their attorney, Robert Ullman,* signed a Consent Decree of Permanent Injunction admitting that certain lots of calcium pangamate shipped by GNC “contained diisopropylamine dichloroacetate which is an unsafe food additive” which “has heretofore been accompanied by label or labeling claims representing said product for the diagnosis, cure, mitigation or prevention of disease in man, for which claim it is not generally recognized as safe and effective, and, as such, is a new drug...that the defendants...be perpetually restrained and enjoined...from...introducing or delivering into interstate commerce any such article when represented or labeled as a drug...any such article of food...” The defendants, who were estimated to be taking in about $10,000 daily for years selling calcium pangamate, paid the $44 in court costs.

In the June 1980 issue of the American Journal of Clinical Nutrition, our group reported on “Mutagenicity of dichloroacetate, an ingredient of some formulations of pangamic acid (trade-named ‘vitamin B15’),” raising the possibility that it might induce cancer in people taking it.

Aangamik (DMG)

According to Medical World News (January 21, 1980, pages 6 and 8), the wealthy Orlandi family began to support Andrew R.L. McNaughton financially in 1963 in his promotion of laetrile and B15. In the same year, New York-New Jersey Mafia caporegime Joseph “Joe Bayonne” Zicarelli gave the McNaughton Foundation $300,000. Allegedly, Dr. Krebs had given laetrile to the elder Mrs. Orlandi in the early 1960s for breast tumors, and to Zicarelli’s sister in 1963 for breast cancer. Guido Orlandi and his son Dom founded the Laetrile Corporation to peddle B17, and two other com-

*Ullman is also an attorney for Aangamik and for the health food financial interests who sued Harvard nutritionists Fredrick Stare and Elizabeth Whelan for writing about health food rip-offs.
Aangamik, the best-selling "calcium pangamate" in the United States, has the synthetic chemical dimethylglycine (DMG) hydrochloride as a basic ingredient. DMG is a waste product and intermediary metabolite of choline breakdown but is represented by the sellers as a "non-fuel nutrient." In fact, it contains one-fifth of a calorie per 50 mg tablet.

The May 1980 issue of the *Proceedings of the Society for Experimental Biology and Medicine* contains a scientific paper from our group entitled "Mutagenicity of dimethylglycine when mixed with nitrite: Possible significance in human use of pangamates," in which we presented research raising the possibility that DMG may promote cancer.

On October 29, 1980, Federal Judge Stanley J. Roszkowski of U.S. District Court, N. District of Illinois (Eastern Division, Chicago), in Consolidated cases Nos. 77C662, etc. (U.S.A. vs. ...Aangamik 15 Calcium Pangamate, Defendant, FoodScience Laboratories, Inc., Claimant-Defendant), found that, "N,N-dimethylglycine is a food additive...It is the court's opinion that N,N-dimethylglycine is not generally recognized among qualified experts as having been shown to be safe under the conditions of its intended use...N,N-dimethylglycine, as a food additive, is deemed unsafe within the meaning of 21 U.S.C. §348(a)...There is no scientifically recognized vitamin B₁₅...The court finds that the average consumer could conceive the Aangamik 15 tablets as a vitamin product. Consequently, they are misbranded within the meaning of 21 U.S.C. §343(a)...It is ordered that judgment be and the same is hereby entered in favor of plaintiff and that such article be condemned pursuant to 21 U.S.C. §334. All costs of this action shall be assessed against claimant/defendant, FoodScience Laboratories, Inc."

DMG is found in quantities too small to measure in food. The defendants alleged that DMG is a food even though they did not disagree with the contention by expert witness Herbert that their product was probably synthetic, since it would be too costly to extract the trace amounts from food to create the large amounts in a tablet. The Judge noted as a Conclusion of Law that a "food" may also be a "food additive" as defined by the Federal Food, Drug and Cosmetic Act, and referred to U.S. v....Orotic Acid, 414 F. supp. 793 (E.D.Mo. 1976), affirmed No. 76-1554, 8th Cir. 1977) where the court found orotic acid was both a food and an unsafe food additive. Although the orotic acid in question had been manufactured, orotic acid is found naturally in cows' milk. He referred to U.S. v. 41 cases more or less, 420 F. 2d 1126, 1131 (5th Cir. 1970) which held, "The sole criterion for identifying a food additive is whether the substance which may become a component of or affect the characteristics of any food be not generally recognized among qualified experts as having been shown to be safe..." In that case, the court went on to state that a substance does not gain immunity from this criterion merely because it also qualifies as a food.
The Rationale of Massive-dose Vitamin Therapy
(Megavitamin Therapy: Hot Fictions vs. Cold Facts)

Massive-dose vitamin therapy means treatment with daily quantities of a vitamin or vitamins substantially above the daily Recommended Dietary Allowances (RDA) of the Food and Nutrition Board.¹ The RDA should not be confused with United States Recommended Dietary Allowances (U.S. RDA), which are a set of values derived from the RDA by the Food and Drug Administration as standards for nutritional labeling. The RDA are the levels of intake of essential nutrients considered, in the judgment of the Food and Nutrition Board on the basis of available scientific knowledge, to be adequate to meet the known nutritional needs of practically all healthy persons. The non-scientific term “megavitamin therapy” is frequently used in literature directed at food faddists and the lay public in general. In its overtones of magic and power, the term tends to be deceptive and misleading.

When Is Massive-dose Vitamin Therapy Rational?

The sole unequivocal indication for vitamin therapy is vitamin deficiency. There are six ways in which vitamin deficiency may occur: inadequate 1) ingestion, 2) absorption, or 3) utilization, and increased 4) destruction, 5) excretion, or 6) requirement.² ³ In which of these six situations is massive-dose vitamin therapy rational?

Inadequate ingestion. In basic terms, inadequate ingestion means that the amount of nutrient that gets to the stomach is inadequate in quantity, and therapy is simply to supply an adequate amount of nutrient. Where the inadequacy is of a vitamin, the therapy is simply to supply the missing vitamin. In such a situation, there is no role for massive-dose vitamin therapy, since the problem is solved by ordinary therapeutic amounts of the vitamin, initially,⁴ followed by maintenance on a diet containing the RDA for the vitamin.

While it is true that inadequate vitamin ingestion is corrected by supplying

---

The work of the author is supported by USPHS (NIAMDD) grant AM15163, Career Scientist Award 1-683 from the Health Research Council of the City of New York, and a Medical Investigatorship (3570-01 and 02) from the Veterans Administration.
the missing vitamin, the nutritionist must consider the interplay of foodstuffs one with another. For example, vitamin C in doses greater than the RDA may destroy substantial amounts of vitamin B₁₂ in food. Small amounts of iron in the food may stabilize vitamin B₁₂ against destruction by ascorbic acid, but large amounts of iron may themselves destroy vitamin B₁₂. Conjugase inhibitors in certain beans may destroy intestinal folate conjugase and thereby inhibit the breakdown of food folate polyglutamate to absorbable monoglutamate form: this inhibitory effect may be aggravated by heating. Nevertheless, none of these phenomena constitutes an indication for massive-dose vitamin therapy. Parenthetically, it should be noted that inadequate ingestion may occur despite adequate quantity of vitamin in the raw diet, if the diet is subjected to heavy processing, including prolonged cooking, which may destroy substantial amounts of various vitamins.

**Inadequate vitamin absorption.** Structural or functional damage along the alimentary tract, including damage to those organs (liver and pancreas) that bud off the embryonic alimentary tract, may reduce vitamin absorption from food. Lack of adequate biliary secretion may reduce the absorption of the fat-soluble vitamins; inadequate pancreatic secretion may reduce absorption of vitamin B₁₂. A generalized malabsorption syndrome encompassing many nutrients may occur as a result of tropical sprue or any number of other medical disorders involving the alimentary tract. In each of these situations, appropriate treatment is tailored to remedy the underlying disorder where possible. Vitamin therapy is aimed at correcting the deficiency due to inadequate vitamin absorption and may consist of the usual therapeutic doses of the lacking vitamins, often given parenterally, but sometimes effective when given orally. Here again, there is no role for massive-dose vitamin therapy. In fact, treatment only with vitamins in large doses, without seeking to learn the cause of the inadequate absorption, may allow unchecked progression of a serious underlying disorder and would be unwise.

**Inadequate vitamin utilization.** Inadequate vitamin utilization may be congenital or acquired. The acquired defects in vitamin utilization generally result from malnutrition or disease. For example, vitamin B₁₂ deficiency produces inadequate utilization of folic acid. Alcohol interferes with utilization of various nutrients, and liver disease, regardless of cause, may reduce vitamin utilization by various mechanisms including damage to apoenzyme production. It is in the disorders associated with inadequate utilization of vitamins that massive-dose vitamin therapy has rational value. This is particularly true in the “vitamin-dependent genetic diseases,” also known as the “vitamin-dependent inborn errors of metabolism.” In these situations, there is inadequate utilization of a vitamin due to a congenital defect of an enzyme involved in vitamin metabolism. These situations include enzyme defects
Megavitamin Therapy Rationale

in metabolism of thiamin, nicotinamide, pyridoxine (vitamin B₆), biotin, cobalamin (vitamin B₁₂), folic acid, and calciferol (vitamin D).

The vitamin-dependent diseases are all alike in being inherited, in involving a specific biochemical abnormality, and in responding to doses of vitamin ranging from 10 to 1,000 times the physiologic requirement. As Rosenberg has pointed out, it is important to recognize that, although high-dose vitamin therapy may correct the biochemical abnormality, improvement of the clinical disease may not necessarily occur. For example, in homocystinuria, the high serum and urine levels of homocystine are reduced to normal by large doses of vitamin B₆, but the abnormalities remaining include ectopia lentis, osteoporosis, and skeletal and central nervous system abnormalities. A hopeful note is the possibility that if the biochemical abnormality is treated within the first few weeks of life, the irreversible effects of the disease may be prevented, as occurs with phenylketonuria.

A fundamental defect in the vitamin-dependent genetic diseases is in production of a protein, more specifically of an enzyme. The defect may be in production of either an enzyme involved in converting a vitamin from a form in which it is absorbed to the form in which it is metabolically active, or in production of the protein apoenzyme which combines with the vitamin coenzyme to yield the active enzyme (more fully referred to as holoenzyme).

**Increased destruction, excretion, or requirement.** There have so far been no reported instances of sufficiently increased vitamin destruction within the bloodstream or tissues, or increased excretion, or increased metabolic requirement of sufficient degree to warrant massive-dose vitamin therapy. As stated above, the increased “vitamin requirement” in the vitamin-dependent inborn errors of metabolism is subsumed under the rubric of inadequate vitamin utilization (i.e., more vitamin is needed because the machinery for vitamin utilization is working badly rather than working overtime). The increased vitamin requirement that accompanies increased metabolic rate has never been reported to be so great as to require massive-dose vitamin therapy.

Vitamin deficiencies due to increased excretion or increased requirement are treated by supplying moderately increased amounts of the vitamin; massive-dose therapy has never been reported to be necessary. For example, the pregnant woman needs about 20% to 50% more of each vitamin in her RDA, and infants need for growth more vitamin per unit body weight than do adults.

**The Dangers of Massive-dose Vitamin Therapy**

Vitamins, like many natural substances, may be toxic when taken in large quantities. Just because a substance, such as a vitamin, occurs naturally in food does not mean it is harmless in large doses. In fact, an entire book has
been written on the subject of *Toxicants Occurring Naturally in Foods*, and Chapter 11 of that book is devoted to "Toxicity of the Vitamins."

The toxicity of large doses of vitamins A and D is widely recognized. Single, massive doses of vitamin A in infants may produce transient hydrocephalus and vomiting. Prolonged excessive intake of vitamin A can cause anorexia, growth retardation in children, drying and cracking of the skin, hepatospleomegaly, increased intracranial pressure, alopecia, migratory arthralgia, bone pain, hypomenorrhea, irritability and severe headache.

Prolonged excessive intake of vitamin D can cause anorexia, nausea, weakness, weight loss, polyuria, constipation, vague aches, stiffness, generalized vascular, soft tissue and premature epiphyseal calcification, nephrocalcinosis, hypertension, anemia, hypercalcemia, acidosis, irreversible renal failure, and death.

The large doses of nicotinic acid or nicotinamide used by the purveyors of "orthomolecular psychiatry" frequently cause flushing and itching. Hyperbilirubinemia may also occur, as well as liver damage, dermatoses, elevations in serum glucose concentration, hyperuricemia with gouty arthritis, and peptic ulceration. In fact, the whole "megavitamin and orthomolecular therapy in psychiatry" movement is so far supported only by anecdote and not by scientific facts, leaving open the possibility it is primarily quackery. While large doses of niacin may lower lipid levels, they do not improve the survival of men who had heart attacks, and may increase arrhythmias, gastrointestinal problems, and produce elevated serum enzymes, uric acid, and glucose.

Although not much work has yet been done on the toxicity of massive doses of vitamin E, among the possible undesirable effects of such doses are headaches, nausea, fatigue, giddiness, blurred vision (vitamin E in large doses antagonizes the action of vitamin A), reduced human gonadal function (i.e., just the opposite of the false claims that vitamin E heightens sexual potency, which claims are based on work with rats and not with humans), inflammation of the mouth, chapping of the lips, gastrointestinal disturbances, muscle weakness, low blood sugar, increased bleeding tendency, and degenerative changes.

Large doses of ascorbic acid may produce "rebound scurvy" in the newborn infants of mothers taking such doses. Also, adults who become conditioned to large doses may get scurvy with swelling and bleeding of the gums, loosening of the teeth, muscular pain, and skin roughening on cessation of the massive vitamin C doses. Massive doses of vitamin C may also produce adverse effects on growing bone, a false positive Clinitest for sugar and a false negative Testape, renal problems, diarrhea, and may induce menstrual bleeding in pregnant women. Additionally, massive doses of vitamin C destroy substantial amounts of vitamin B₁² in food, and the possi-
bility exists that such doses may produce vitamin B₁₂ deficiency if continued for a long enough period of time. In addition, large doses of vitamin C produce false-negative tests for blood in the stool and thereby may prevent diagnosing chronic gastrointestinal bleeding from various lesions. Vitamin C in large doses may also produce hemolytic reactions in approximately 13% of American black males, as well as Orientals, male Sephardic Jews, and other males of Mediterranean origin with G6PD deficiency.

Recent studies suggest that large doses of vitamin B₆ may produce liver damage.

Not only may large doses of vitamin C destroy vitamin B₁₂, but vitamin B₁ (and its degradation products) may also destroy vitamin B₁₂, and other vitamin antagonisms also occur, such as the antagonism of vitamins A and D, A and E, and the possible competitive blockade by vitamin K of absorption of vitamin A.

The comments that vitamin doses in excess of the RDA may produce "optimal" health are pure speculation, unsupported by any facts in human metabolism, and contradicted by the toxicity of vitamin and mineral doses substantially in excess of the RDA.

The same is true of the "individual variability" argument, which ignores the fact that the RDA is deliberately set at a level to encompass the range of normal "individual variability" in nutrient requirement. Furthermore, the promoters of exotic exaggerations of "individual variability" forget that this argument cuts both ways (i.e., there is a wide individual variability in toxicity), so that less of an excess above the RDA of a given vitamin or mineral may produce toxicity in patient A than would be required to produce toxicity in patient B.

Testimonials from private citizens, no matter how famous, and testimonials from physicians and "nutritionists," alleging high doses of vitamins and minerals make them and their patients feel better, are worthless. They represent placebo effect (suggestibility) masquerading as cause-and-effect, as pointed out by Darby and by Bruch. The entire Special Supplement of Nutrition Reviews for July 1974 is devoted to the puncturing of various forms of nutrition misinformation, food faddism, and downright quackery surrounding the fraudulent claims for magical powers of vitamin E, vitamin C, vitamin A, megavitamin therapy, and other abuses of public gullibility.

The quack's first line of defense is, "It can't hurt." In answer to that allegation, Heenan states that statistics compiled by FDA's National Clearinghouse for Poison Control Centers reveal 4,000 cases of vitamin poisoning reported each year, with some 3,200 involving children.

To dispense with one final bugaboo, namely vitamin C for the common cold, the most recent study divided 2,349 volunteers into eight different groups; one of the two groups given only a placebo had the least illness both
in frequency and severity. A recent study, taken together with the findings from our laboratory that large doses of vitamin C may destroy 50% to 95% or more of the vitamin B₁₂ in a meal, presents positive evidence for a bad effect of such doses without any adequately counterbalancing good effect.⁵

Two reports in 1975 further affirm that vitamin C will neither prevent nor cure the common cold, and provide further review of possible adverse effects of large doses of vitamin C.²⁷,²⁸

Further undesirable side-effects of megadoses of Vitamin E have been delineated by Briggs,²⁹ and the lack of scientific justification for megavitamin therapy in schizophrenia has been discussed by Wyatt, Klein, and Lipton.³⁰

Megadoses of folic acid may promote convulsions in epileptics.³¹,³²

References


Facts and Fictions About Megavitamin Therapy

An American physician wrote, "Quackery kills a larger number of U.S. citizens each year than all the diseases it pretends to cure." One might expect that this commentary of the times was written yesterday, but it wasn't. It appeared in an 1861 issue of National Quarterly Review. Today, we are still inundated with health misinformation, quackery, gimmicks, Laetriles, and the latest rage—vitamin megadoses. This chapter emphasizes the hazards of anecdotal health information, self-prescribed vitamin megadoses, and other dubious health claims. It sorts the nutritional wheat from the chaff for people who are confused by the popular press.

What do doctors have to know in order to give their patients intelligent advice when they come in with what they've read in the lay press or what they heard on a TV talk show? What doctors have to know is, what vitamins are, what they can do, and what they can't do. I'll pass this information on to you.

First, the definition of a vitamin. It's an organic molecule not made in the human body which is required in small amounts to sustain normal metabolism. Notice that there are three exceptions to this definition. On adequate exposure to sunlight you can make vitamin D in your skin. (Of course, D is really a hormone, but that's a different subject.) The vitamin niacin can also be synthesized in humans to a significant degree from the amino acid, tryptophane; and intestinal bacteria make significant amounts of vitamin K. Crucial to the definition of a vitamin is that lack of it produces a specific deficiency syndrome, and supplying it cures that deficiency.

Vitamins can function in two ways—as vitamins and chemicals. The fat soluble vitamins function as regulators of specific metabolic activity; the water soluble vitamins function as coenzymes. The fact that they function as coenzymes is fundamental to understanding why the term megavitamin therapy is a misnomer by definition. The vitamin coenzymes come in from food, seek out the cells that need them, are taken into the cell, and combine with a protein already present. The protein is called an apoenzyme. The vitamin coenzyme coming in from outside attaches to the apoenzyme within the cell to form a holoenzyme (or enzyme, for short). It is this which serves the catalytic function that all coenzymes serve. So only when combined with its apoenzyme within the cell does the vitamin become capable of vitamin function. The quantity of apoenzyme any cell can make per unit
time is limited, as is the capacity of any cell to make any other protein per unit time. That limited capacity is saturated at levels of vitamin roughly in the range of the recommended dietary allowance (RDA). Since the protein apoenzyme is saturated by a level of vitamin in the range of the RDA, it is obvious that any excess coming in cannot possibly serve a vitamin function. The concept of megavitamin therapy is predicated on a total failure to understand the basic biochemical concept just stated.

I mentioned above that vitamins can also serve chemical functions. This is what they do when present in excess above the amount that can saturate the apoenzyme. This excess will serve whatever function vitamins can perform as chemicals. The classic example is the reducing action of vitamins C and E. Both can do harm as strong reducing agents when present in excess quantity. Since vitamin C is water soluble, it will go to areas where the milieu is water; and E, being fat soluble, will go to areas where the milieu is fat. If there are excesses, they will present excessive reducing action in those areas.

Nutrition—Facts and Fallacies

The key to understanding good nutrition for the layman is very simple. The layman reads a lot of nutritional garbage in some monthly magazines and newspapers which confuses him into thinking that he has to know, for example, exactly what vitamin A does, and exactly what magnesium does, which is all nonsense. The layman doesn’t have to know the intricacies of the value of a specific nutrient any more than he has to know how a carburetor functions to be a good driver. Running the human machine, from a nutritional point of view, is also very simple.

Many years ago, the U.S. Department of Agriculture decided the way to simplify nutrition for laymen was to break nutrition down into food groups. They divided the foods in terms of their nutrient content into seven groups. If you ate from those seven groups each day you were guaranteed good nutrition, assuming you didn’t have a disease such as intestinal malabsorption. The seven food groups turned out to be a little hard for people to remember, so the USDA reduced it to four basic food groups which form the basis of current nutritional teaching. All you have to tell your patients, and all they have to know to get good nutrition for themselves each day, is to take foods from the grain group, the milk group, the meat group, and the fruit and vegetable group. At the end of the day the patient should be able to look back and say, “In the course of this day I’ve had four portions from the grain group (and that includes cereals, breads, pastas, etc.), four portions from the fruit and vegetable group (including one fresh uncooked fruit or vegetable or fruit juice), two to four portions from the milk group (depending on whether it’s for a child, adult or pregnant woman), and two portions from the meat group (which includes fish and fowl as well as
meat). That would automatically include adequate quantities of each of the
vitamins and minerals that we know of (though it may be marginal in iron
for women in the childbearing years). Final rule: eat less calories to lose
weight; eat more to gain.

That's the totality of what the layman needs to know about good nutri­
tion. Instead he's bombarded with all kinds of ridiculous advice about "nat­
ural" foods and other things. There's a good article you may have seen by
Max Gunther, "The Worst Diet Advice... is the kind dispensed on many
TV shows" which appeared in the January 11, 1975 TV Guide. The Health
Robbers is another very important book because it is an attempt to tell
people how to recognize and avoid health quackery of every description. It
contains a chapter by Jean Mayer on obesity quackery, a chapter by Wil­
liam Masters on sex clinic quackery, and a chapter by neurologist Arthur
Taub of Yale on "quackupuncture." Each chapter is heavily documented
factually yet written in so clear and lucid a way that patients can be given
this reference when they have a question about any dubious health claim.
There are several chapters dealing with various forms of nutrition misinfor­
mation and quackery, including a chapter concerning The Confused (Nutri­
tion) Crusaders, which deals with a number of people and their claims,
including Adelle Davis, Carlton Fredericks, the Shute brothers with their
vitamin E claims, Cheraskin's New Hope for Incurable Diseases, and Linus
Pauling and vitamin C. You may recall that Adelle Davis took the position
that if you followed her nutrition advice you would never get cancer. She
doesn't give that advice anymore, since she died of cancer. The Health Rob­
bers is so important that it was the first book not their own ever reviewed by
Consumer Reports.* I urge you to have a copy on your bookshelf. If it's not
widely available nearby, you can get it from the publisher.*

I must make a disclaimer at this point. Although I wrote a chapter (The
Health Hustlers: How to Spot a Food Quack), neither I nor any of the other
chapter authors get royalties. As indicated at the beginning of the book, the
royalties go to the Lehigh Valley Committee Against Health Fraud, Inc., a
major organization fighting quackery of all types in the health field. There's
also a chapter by Tom Jukes3 on the "organic" rip-off, pointing out the
misinformation in natural food teachings, and noting the New York State
public hearings on organic foods. The Director of the New York State Food
Laboratory reported more products labeled "organic" and purchased at
health food stores contained pesticide residues than foods not labeled or­
ganic (30% vs. 20%)!

There is no need for added vitamins when eating a well-balanced diet.

---

ington Sq., Phila., Pa. 19106. ($10.50)
There are some who believe in "nutritional insurance," that is, taking a capsule a day containing the RDA of the major vitamins. I have no quarrel with that. I think it's totally unnecessary, but if it makes someone feel better he or she is only out a couple of cents a day, not the larger amounts one spends if one follows the advice of *Prevention Magazine* and the National Health Federation.

It's been alleged that megadoses of vitamins are harmless. This is *not* true. Generally speaking, the literature shows that at doses about 10 times the RDA, we start to see toxic effects. So, as a general rule, a megadose is 10 times the RDA or more. There's an increasing body of evidence on the various forms of harm which result from megadoses of various nutrients. The *Annals of Internal Medicine* reported in 1976 that megadoses of vitamin C raise the urine uric acid level and may precipitate gout in people so predisposed. Another harm is that although most of us catabolize ascorbic acid (vitamin C) fairly rapidly past the oxalic acid stage and excrete it in our urine, some (possibly about one out of fifteen) have a congenital defect whereby they can't get ascorbate past the oxalic acid stage readily, and those people will have an increased susceptibility to oxalate kidney stones. When I talked on this subject at Columbia University it turned out that one of the medical students had just had an attack of renal colic due to a kidney stone after seven weeks of following his mother's advice to take a gram of C each morning prior to breakfast.

What are other undesirable side-effects of megadoses of C? Rebound scurvy is a particularly dangerous one when it occurs in a newborn. This was reported from Nova Scotia some years ago. The RDA for C is 60 mg a day (except for pregnant women in whom it's 80 and lactating women in whom it's 100). 450 mg of C a day would be a megadose. If a pregnant woman is taking a megadose of C, her body's machinery for destroying the C is speeded up in order to get rid of all that excess reducing capacity. That speeded up machinery will now destroy C, hypothetically, let's say, 10 times as fast as normal. The fetus acquires the same speeded up machinery to get rid of the transplacentally-passed ascorbate. Hence, the newborn is born with C-destructive machinery 10 times normal, but is getting normal C from mother's milk, which it destroys with 10 times normal speed. Therefore, the newborn runs out of C and gets scurvy with dangerous life-threatening bleeding. This is clearly an undesirable side-effect. It has also been reported in adults who stop megadoses of C "cold turkey" rather than tapering off over a period of about 10 per cent a day or 20 per cent every other day. In adults it's been reported to produce bleeding into the gums and skin, loosening of the teeth, roughening of the skin (i.e., the stigmata of scurvy).

**Vitamin C Megadoses—Thumbs Down**

About 13 per cent of American Blacks and even a larger percentage of
Sephardic Jews, Orientals, and certain other ethnic groups have congenital glucose 6-phosphate dehydrogenase (G6-PD) deficiency, which is activated into hemolytic anemia by a strong reducing agent. In the March 1977 issue of *Blood* there is a paper describing the severe hemolysis produced by megadoses of C. In that article, the authors reflect on a patient who died from a megadose of C with its accompanying severe hemolysis. A similar phenomenon was reported from Montefiore Hospital in the Bronx in a patient with sickle cell disease. This is biochemically logical because it is reduced sickle hemoglobin which takes the sickle shape and clogs capillaries. If you give a megadose of C to a patient with SS hemoglobin you’re going to convert his oxidized SS hemoglobin to reduced SS hemoglobin. It’s going to take the sickle shape, and that patient can go into a severe sickle crisis.

Where else is mega-C dangerous? When diabetics check their urine, two of their favorite tests are the Testape® test and the Clinitest®. Megadoses of C cause the Testape test to be falsely negative and the Clinitest to be falsely positive. Now, if the patient doesn’t know that and if he doesn’t inform his physician, the physician won’t know that the patient is getting false-positive or false-negative test results, and that patient runs the risk of either diabetic ketoacidosis or insulin shock. Also, it has recently been reported that the strong reducing action of megadoses of C cause tests for blood in the stool to be falsely negative. If you suspect a patient has a carcinoma of the colon and you do three stool guaiacs and they’re all negative, it may be because the patient is one of the almost two million people in the United States taking megadoses of C. Your clinical suspicion of a carcinoma of the colon may be correct, but the negative stool tests may throw you off the track.

Where else is mega-C harmful? In our own research unit, we’ve been studying the effect of megadoses of C on vitamin B₁₂ in food, in the bile, and in body stores. We found that mega-C, when added to a typical VA hospital diet, could destroy 50 to 95 per cent of the B₁₂ in that diet. A group from the pharmaceutical firm which sells most of the C in the U.S. has taken issue with that. You can read the colloquy between them and us in the March 1977 issue of the *American Journal of Clinical Nutrition*. You can prevent the destruction of B₁₂ by megadoses of C if you introduce the appropriate amount of iron, whose redox potential will antagonize the reducing action of C on the B₁₂. The same happens when you eat a meal. If the quantity of redox agents such as iron is appropriate, then a megadose of C will not harm the B₁₂ in that meal. If it’s not appropriate, it may. More data are in the February 1978 *American Journal of Clinical Nutrition*, and the November 23, 1979 Journal AMA (page 2285). Megadoses of vitamin C may not only destroy vitamin B₁₂, but may convert it to forms that interfere with vitamin B₁₂ metabolism.⁷⁻⁸

**C and the Common Cold**

It’s been alleged that vitamin C prevents colds. As it happens, there’s
absolutely no evidence for that. If you look in the 1974 Congressional Record you’ll see a Chicago radio station colloquy between Linus Pauling and Victor Herbert in which Linus Pauling admits that there’s no evidence that vitamin C prevents colds. However, he did then, and he continues to hew to the line that C reduces the symptoms of colds by about a third. If you look at the evidence on the reduction of cold symptoms you’ll find it’s largely subjective.

This is an area where much trouble arises in informing the public about nutrition. The public is unable to tell the difference between anecdote and science. When Carlton Fredericks, for example (whose doctorate is not in nutrition) makes an allegation that sugar is bad for you, or that megadoses of C are good for you, this to the layman is just as good evidence and just as important as scientific data in a medical journal. This is a fundamental flaw in the logic of the layman, and the fundamental difference between the layman and the trained scientist or trained physician who learns that anecdote is not reality. Reality is what you can objectively ascertain and not what somebody said. If you look at the objective data regarding vitamin C and the common cold, you’ll find that in late 1976 the same group that two years earlier reported in the New England Journal of Medicine that megadoses of C reduced colds in Navajo children report that they were wrong the first time! When they did the study the proper way, with proper controls, they found out that megadoses of C did not reduce the symptoms of colds. Anderson’s group in Canada divided more than 2,000 patients into eight groups: six got megadoses of C and two got placebos. Guess which group had the least colds? One of the two placebo groups. So there is really little evidence that C has any value versus colds. There is some slight evidence that it may have a mild antihistaminic effect. If we take that claim at its most favorable possibility, is it worthwhile to take a megadose of C 365 days a year, with possible undesirable side effects, in order to achieve a mild antihistaminic effect during the eight days out of the entire year that the average person has a cold?

Anecdotal and testimonial evidence is as worthless in medicine as it is in law, where it is excluded from courts as hearsay (an article of mine in the November 18, 1977 issue of Science, cites the pertinent medical quackery cases).

No Value for Schizophrenia

What about megavitamin therapy for schizophrenia? This is heavily pushed and completely anecdotal. This is no scientific study demonstrating that megavitamin therapy has any value in schizophrenia. If you want facts look at the official report of the American Psychiatric Association Task Force on Vitamin Therapy in Psychiatry. They convened a group of experts who went over the various reports of the proponents of megavitamin therapy and ascertained that they were all anecdotal. There was not a single scientifically controlled study showing any value. That report was published
in 1973, you can get a copy of it from the American Psychiatric Association in Washington, D.C. Linus Pauling was upset by that report and the American Journal of Psychiatry published his views on orthomolecular psychiatry in the November 1974 issue. I urge you to read not only this eloquent argument by a brilliant man, but also the three papers immediately following the Pauling paper, which completely devastate that argument.

What about the undesirable side effects of the large doses of nicotinic acid and nicotinamide used by the promoters of orthomolecular psychiatry? These undesirable side effects begin with frequent mild ones like flushing and itching, and go on to liver damage with hyperbilirubinemia and jaundice, and many other abnormalities, including severe dermatoses, elevated serum glucose and serum uric acid levels, and elevated concentrations in the serum of enzymes which arise from the liver (and are associated with liver damage), as well as peptic ulceration. As you may know, a large national study of the use of megadoses of niacin was completed which notes the chemical effect of lowering serum lipid levels on the survival of men who've had heart attacks. This study showed absolutely no value with respect to mortality from megadoses of niacin to lower serum lipid levels. What it did show was that the megadoses of niacin produced an increased frequency of cardiac arrhythmias, gastrointestinal problems, and abnormal blood chemistry findings.

We know that if you lower the serum level of lipid or vitamin or anything else, it does not necessarily mean that the tissue level is lowered. Therefore, it does not necessarily have any clinical value. Clinical value is determined by what happens in the cells, not by what happens in the serum. If, for example, an agent lowers the serum lipid level by driving the lipid into the coronary arteries, that's not a good thing. Lowering the serum level by itself, unless you know what it means in terms of the tissue level and the intracellular level in the shock organs, may have no meaning or a bad meaning instead of a good one.

The Truth About Vitamin E

Let's turn now to vitamin E, so heavily touted as the sex tonic of the age. Is it true? As you can guess, it is not. Not much has been done yet to determine whether massive doses of E are toxic, but there is a fair amount of literature beginning to develop on it. We're not even sure E is a vitamin. We know that its role in humans is in helping in the metabolism of polyunsaturated fatty acids (PUFA), and we know that premature infants may have a tendency to increased red cell hemolysis which can be corrected by adding vitamin E. Does that mean they have E deficiency? Hematologists know that when an anemia responds to a given nutrient or a given agent, it doesn't necessarily mean the patient was suffering from a deficiency of that agent. Just because
pneumococcal pneumonia responds to penicillin doesn't mean it's due to penicillin deficiency. The fact that the hemolysis of premature infants responds to vitamin E turns out, in a study reported by Oski and his associates in the *New England Journal of Medicine* to be due to the fact that premature infants invariably are given large amounts of iron supplement. This strong redox action of the iron in association with the PUFA in their diets brings about the weakening of the red cell membrane and increased susceptibility to hemolysis, especially *in vitro* in the presence of peroxide. Instead of adding a reducing agent such as E, we simply reduce the amount of iron supplement in their diet. The problem goes away just as it does by giving them megadoses of E (or by itself by waiting three months).

The allegations of vitamin E as a sex vitamin go back to the original study in the early '20s which first isolated vitamin E. This was a study in rats in which all fat was extracted from the diet and most of the fat was put back, except one fraction. That fraction happened to be the one containing the subsequently isolated vitamin E. It was found that these rats became generally weak, suffering from generalized malaise and debility (including debility in sexual function); when the fraction that had been deleted was added back, they became normal again, including normal sexual function. That's the basis for the anecdotal allegations that vitamin E increases sexual potency in humans.

It's almost impossible in the U.S. to get a vitamin E deficiency unless you're suffering from intestinal malabsorption, in which case patients shouldn't be dosing themselves with megadoses of E to the exclusion of medical care. Even if we put a patient on a no-E diet, as Horwitt did for years, or even if a patient has generalized intestinal malabsorption (so that he's unable to absorb fats and therefore has reduced absorption of the fat-soluble vitamins like E), we don't see any clinical disease after years of such a situation. All we see is an increased susceptibility of the red cells to hemolysis when exposed to H₂O₂ (hydrogen peroxide); and if you do a proctosigmoidoscopic exam you'll see some ceroid pigment in the colon.

What are the undesirable side effects of megadoses of E? Those reported so far include headaches, nausea, fatigue, dizziness, and blurred vision. Blurred vision is particularly interesting because E in large doses antagonizes vitamin A, and that may be the mechanism whereby the blurred vision occurs. The only report in the literature relating to human gonad function is that megadoses of E may *decrease* function, contrary to the allegations of the promoters of E that it *enhances* it. Megadoses of E also have undesirable effects in the skin and mucous membranes, including inflammation of the mouth, chapping of the lips, GI disturbances, muscle weakness, low blood sugar, increased bleeding tendencies, and degenerative changes.

It is interesting to note that one of the early advocates of vitamin E as a
preventive of heart attacks recently had a heart attack himself and had a triple coronary bypass operation.

What We Know About B12

There are vitamins whose toxicity in megadoses has not yet been clearly established—for example, vitamin B₁₂. There's been only one case so far of so-called allergy to vitamin B₁₂, and we're not sure whether it's real or related to a preservative in the B₁₂ preparation. B₁₂ is, of course, a favorite "remedy." Because of its nice color, it looks potent and people think it's potent. The fact is, every objective study demonstrates that B₁₂ is not an appetite stimulant and that any such effect is that of a placebo.

Contrary to the allegations that B₁₂ helps various neurologic disorders, it has absolutely no value in any neurologic disorder other than the one due to B₁₂ deficiency, where a low serum B₁₂ level provides the diagnosis. There is one possible exception—tobacco amblyopia. Since some ophthalmologists insist that there's no such thing as tobacco amblyopia, it's hard to work out exactly what's going on there. B₁₂ in the hydroxo form does bind cyanide, and it's been alleged that it's the cyanide in tobacco smoke that produces tobacco amblyopia (if in fact it does exist). There may be a rational tie here, because B₁₂ in the hydroxocobalamin form will bind cyanide and will itself then be converted to cyanocobalamin. There are certain foods which are very high in cyanogens (cyanide generating substances), such as cassava in Africa, where huge populations all suffer from chronic cyanide poisoning because of the daily ingestion of cassava. It's been alleged that this type of poisoning can be reduced with injections of hydroxocobalamin.

The Laetrile Fraud

It is interesting that a cyanogen right now is very popular in the U.S. That cyanogen is, of course, Laetrile, which is currently the most popular form of quackery in this country. This quack cure for cancer is promoted under the guise that it is a vitamin (B₁₇) which it is not. Vitamin B₁₇ is a trade name created for it by its promoters; there is currently no law preventing promoters from trade-naming cyanide as vitamin B₁₇, or arsenic as vitamin B₁₈, for that matter. The scientific designation of a substance as a vitamin, on the other hand, requires that it conform to the dictionary definition of the word. It has been alleged (with no evidence), that it cures cancer by destroying cancer cells because of the cyanide it releases. Study of the cyanide released by Laetrile shows that the cyanide, as you would expect, diffuses throughout the body and does not home in on cancer cells or any other cells. If the dose used releases enough cyanide to be toxic to cells it will kill the host, as we know from a 1977 report from Buffalo, New York of the 10-month old girl who took her father's Laetrile pills and died of cyanide poisoning.
Laetrile has been studied at many places and found to be fraudulent. The Merck Index says Laetrile (under its chemical name, amygdalin) is a poison which has been falsely promoted as a cancer cure since 1840. These facts have been in the Merck Index, available in every hospital and pharmacy in the country, since it was first published in 1889. Laetrile is a trade name for amygdalin. It is 2 parts glucose, 1 part benzaldehyde, 1 part cyanide, and no parts vitamin. There is also a synthetic Laetrile®, which is 1 part glucose, 1 part benzaldehyde, 1 part cyanide, no parts vitamin, and mutagenic by Ames test. Low grade cyanide poisoning occurs in nearly every patient taking Laetrile. See the Merck Index listing for “hydrogen cyanide” for the symptoms of low grade cyanide poisoning (nausea, vomiting, diarrhea, hypotension, progressively increasing weakness, etc.). Only one of these symptoms may appear at any one time.

We do know that if a cancer patient takes Laetrile instead of undergoing curative therapy, that patient will die. This has been reported in a number of diseases, particularly Hodgkin’s, where it is known stages I through III can now be cured. If a patient with stage I through III Hodgkin’s is talked out of chemotherapy and radiation therapy (which is considered curative), and gets Laetrile instead, that patient will die of Hodgkin’s—and that death, in my view, is murder. There is precedent for calling it murder, and there is precedent for convicting such people of murder. It’s on page 2 of the book The Health Robbers (see above), and it’s the case of a little girl who had been scheduled for surgery to remove a tumor from her left eye. Her doctors thought cure was possible because the tumor had not spread. Shortly before the operation, in the hospital waiting room, her parents met a couple who told them how a chiropractor had cured their son’s brain tumor without surgery. Mrs. Epping phoned the chiropractor and informed him of her daughter’s diagnosis. Without ever seeing the child, the chiropractor replied, yes, he could help by chemically balancing her body. Elated by this promise, the parents removed their daughter from the hospital and refused the surgery which would have enucleated the eye (but saved the child). The chiropractor then treated her with vitamins and food supplements. (You should know that the promoters of Laetrile call it “a food supplement,” and they’re now trying to get a bill through Congress forbidding the FDA from asserting any authority over food supplements.) Despite the new treatment with food supplements, the little girl’s tumor grew quickly, became tennis ball size, and pushed her eye out of its socket, so that there was no longer any hope that surgery could save her. She died within a few months. The Assistant DA for Los Angeles County was incensed and indicted the chiropractor for murder. He was convicted of second degree murder and sentenced to prison. I predict that we will see similar things happening to some of the promoters of Laetrile. Those who promote Laetrile point out that
cyanocobalamin also contains cyanide; they neglect the fact that an average dose of Laetrile contains one million times as much cyanide as an average dose of cyanocobalamin.

**Pangamic Acid ("Vitamin B₁₅")**

According to both the American Food and Drug Administration and the Canadian Food and Drug Directorate, this substance isolated from apricot pits has no known value for humans, and may be harmful. The FDA is pursuing a number of court actions against Pangamate purveyors.

Let us remember the harmful effects of megadoses of some other nutrients. B₆ in megadoses used to be considered harmless, but now that megadoses are being used more frequently, there is evidence that large doses may produce liver disease. It's been established in rats and there is a study under way in humans.

Megadoses of folate also used to be considered harmless, but it's been established that large doses antagonize the protective effect of dilantin against convulsions in patients with epilepsy. Patients with epilepsy who take dilantin, and who have been free of convulsions for years because of the dilantin, can be thrown into convulsions with a megadose of folate. This was reported by Butterworth's group in the *American Journal of Clinical Nutrition*.

**Vitamin C and Cancer**

It was reported in that eminent "medical journal" *The National Enquirer* that Linus Pauling and Cameron, working at a great international medical research center in Scotland (which turned out to be a small regional hospital in the Scottish Highlands), found that megadoses of vitamin C increase survival of terminal cancer patients four-fold. This was published in the *Proceedings of the National Academy of Science*, a prestigious journal. You have to realize, however, that the basic criterion for getting something published in this journal is to be a member of the Academy. In fact, what was being described, in my view (and in the view of a number of cancer experts) is the placebo effect. The fact that these patients lived an average of eight months instead of an average of two months, is simply due to the fact that the patients were in the hands of enthusiastic doctors who felt that they could help. This is true at every cancer center in the United States! Put a patient in Sloan-Kettering or in Roswell Park or in MD Anderson, and that patient is going to live longer. The hope of the patient, and the fact that the doctor is interested in the patient makes a tremendous difference; this relates to the placebo effect. ⁶ In fact, there is a study on megadoses of C in cancer which goes the other way. This is a report published in *Nature* in 1976 by a group at the University of Vancouver in British Columbia who found that megadoses of C may have mutagenic effects and actually induce neoplasia.

**The Placebo Effect**

As far as the placebo effect is concerned, this is very strong and very real.
Lay persons do not usually understand that placebos work not only when the illness is just emotional, but also in remitting real symptoms of real disease. If the patient believes he will be helped, he often will. This is crucial to remember. In the famous World War II study of Beecher, the professor of anesthesiology at Harvard who devoted much of his life to studying placebo therapy as well as medical ethics, he observed with his associates that 68% of soldiers with severe battlefield injuries needed no morphine for pain relief, whereas 83% of civilians with the same type of injury did need morphine. This is the placebo effect. Beecher has stated that the placebo effect is a powerful therapeutic tool “on the average about one-half to two-thirds as powerful as morphine in the usual dose in relieving severe pain.” Thus, if both the doctor and the patient believe something will relieve a symptom, it often will. Those who study psychosomatic medicine know from statistics in that field that 80% of symptoms with which patients present when they first see a doctor will go away without treatment. Four out of five times, whatever you do or don't do, including what you add to or subtract from the patient’s diet, is going to be associated with complete relief of the symptom even though in four out of five instances that symptom is going to go away by itself with no treatment.

The possibility that placebo effect may be mediated by endorphin release deserves study, since any mind-body interaction in relation to pain may well involve these endogenous painkillers. Recent studies in the U.S. and China suggest that both the placebo effect and another form of suggestion, acupuncture, are in fact mediated by endorphin release.

There's nothing wrong with giving a patient vitamin B₁₂ or something else as a placebo, provided you know what you're doing, and provided you continue to observe the patient to ascertain whether there's some underlying disease causing the subjective complaint—and then deal with that underlying disease. Using placebo therapy without knowing what you’re doing is quackery. Using placebo therapy when you know what you’re doing and when you’re observing the patient for real disease, is appropriate.

References

The Vitamin Craze

There would be no controversy about the use of vitamins in health and disease if all health professionals and those whose comments on health matters are addressed to the public adhered to facts rather than to promoting sensational anecdotes alleging efficacy—and if they heeded the axiom that, in matters of health, no substance is safe until proven safe, or effective until proven effective.¹⁻⁴

Thousands of people have been victimized by deceptive and misleading “nutrition information” from charming, self-styled nutritionists whose nutrition credentials and anecdotal claims fall apart under close scrutiny.²⁻⁵ Among the code phrases of nutrition cultism often used to promote “nutritional” remedies of unproven safety and efficacy are “orthomolecular nutrition,” “ecologic nutrition,” “nutritional therapy,” “metabolic therapy,” “holistic therapy,” “unconventional therapy,” “alternative therapy,” “unorthodox therapy,” and “nontoxic therapy.”²⁻³,⁶

Laetrile and Pangamic Acid

The most egregious and specious use of the code phrases of nutrition cultism is in connection with the lucrative sales of the noxious chemical substances pangamic acid and laetrile. These chemicals have been called “vitamins” B₁₅ and B₁₇ by the multi-billion-dollar nutrition cultism industry, although neither of these toxicants is a nutrient, much less a vitamin.²⁻³ The May-June 1979 issue of the laetrile industry magazine “Choice” indicates that sales of laetrile alone were in the vicinity of one billion dollars annually, not counting servicing their customers. The New York Times for July 5, 1979 indicates that New Jersey laetrile customers pay $1,000 for three weeks of laetrile plus an additional $1,500 service charge to have it injected. Laetrile is 6% cyanide by weight, and laetriles have produced chronic cyanide poisoning in thousands of people, and even killed some users.² The toxicity of pangamate is discussed elsewhere.³

How To Evaluate Nutrition Claims

The Harvard Medical School Health Letter¹ notes four basic scientific canons for evaluating medical information. These can be paraphrased and elaborated as follows²:

1. Does the information go beyond “personal observation” to stand the test of scrutiny and criticism by other scientists, i.e., is it a study or
a story? Is it science or anecdote? Are the claimed results reproducible by physicians not involved in promoting the product, or does it "work" only in the hands of its promoters?

2. Was it compared for effectiveness in controlled studies to other treatments and to suggestibility or to the "doing of nothing," i.e., to a placebo? What is the natural history of the disorder in the absence of therapy? Was the observed result cause and effect, or coincidence due to the natural history of the disorder?

3. Has it been proven safe? Safe compared to what? Is the risk justified? What is the risk:benefit ratio? (Note that if there is no benefit, the risk:benefit ratio is infinity, which is not tolerable.)

4. The burden of proof is on those who propose doing or giving something, especially if it involves a remedy or procedure not well established in medical practice.

Valid weapons against disease are forged in the crucible of these canons, and products which fail to meet these canons either disappear or become quack remedies.

To protect patients from worthless and possibly harmful remedies for which the unscrupulous make miraculous claims, physicians should a) never lose patience or give up hope, b) never tell a patient his condition has no legitimate basis or that nothing can be done, and c) always involve the patient in his own therapy.

What Is Megavitamin Therapy?

Megavitamin therapy is treatment with quantities of one or more vitamins in amounts of ten or more times the Recommended Dietary Allowances of the Committee on Dietary Allowances, Food and Nutrition Board, National Research Council of the United States. \(7 \cdot 8\) The recommended dietary allowance (RDA) for each vitamin is determined by scientific study of the entire range of normal human vitamin need, then adopting a level substantially above the top of that range to allow a "safety factor." New editions are published about every five years, the RDA usually decreasing progressively as the excessive "safety factor" is gradually whittled down by increasing nutrition knowledge. The single most useful book on this subject is called "Recommended Dietary Allowances," and is available from the Printing and Publishing Office of the National Academy of Sciences, 2101 Constitution Avenue, Washington, D.C. 20418, for a nominal cost of $6.00 for the 1980 edition. \(7 \cdot 8\)

What Is (and Is Not) a Vitamin?

The term megavitamin therapy as used by nutrition cultists is a misnomer, since it misinforms about the mode of action and is really megachemical
therapy, not nutrient therapy. Vitamins function in regulating specific metabolic activity, usually by acting as a coenzyme (with vitamin D also functioning as a hormone). When vitamin coenzymes enter the body, they are taken up by the cells that need them and combined with a protein (apoenzyme) already present to form a holoenzyme (enzyme, for short). Thus vitamins generally have no useful metabolic function by themselves. Only when combined with its apoenzyme within the cell does a vitamin become capable of vitamin function. The quantity of apoenzyme any cell can make per unit of time is limited, as is the capacity of the cell to make any protein per unit of time. That limited capacity is saturated at levels of vitamin roughly in the range of the recommended dietary allowance, so that any excess vitamin coming in cannot serve a vitamin function. Since all vitamins are chemicals as well as nutrients, such an excess can then only function as a chemical and not as a nutrient.

The word *vitamin* is defined as organic chemical compound which is neither carbohydrate, fat, nor protein; which is necessary for normal human metabolism; which the body does not make itself in adequate amounts to sustain normality, so lack of which produces a specific vitamin deficiency disease (such as beriberi, pellagra, rickets, or scurvy), and provision of which corrects that deficiency.

There are thirteen substances which are vitamins for humans, four fat-soluble (A, D, E, K) and nine water-soluble (vitamin C and the eight “B complex” vitamins: thiamin, riboflavin, niacin, B₆, pantothenic acid, B₁₂, biotin, and folic acid). It is probable that no new vitamins will be found. The last vitamin (B₁₂) was discovered in 1948, and the past three decades of intensive search have not uncovered any more. In addition, patients have now lived quite well for years on total parenteral nutrition (i.e., intravenous solutions containing the known nutrients) without the development of any deficiency state which would suggest the existence of another vitamin beyond the known thirteen (unless it is one made in adequate quantity by bacteria in the human intestine). It should be noted that the recommended dietary allowances for pantothenic acid, biotin, vitamin K are listed as “unknown” by the Food and Nutrition Board because deficiency due to dietary lack of them has never been reported. This is probably because the body absorbs these vitamins after they are synthesized by bacteria in the human intestine. It should also be noted that two other vitamins can be made to a significant extent in the human body: vitamin D can be made from ergosterol in the skin on exposure to sunlight, and some niacin can be made in the body by conversion from the amino acid tryptophan.

In addition to the thirteen vitamins for humans, there are substances which are growth factors (vitamins) for bacteria and some other forms of life, but not for humans. These substances include PABA (para-aminobenzoic acid), bioflavonoids (“vitamin P”) including hesperidin, cho-
line, inositol, lipoic acid, and ubiquinone. Some are not needed at all by humans. Others are made in the human body as needed. Far from being of value to humans (other than the active ingredient in some sun-screen lotions), PABA, as a growth factor for microorganisms, can reverse the antibacterial action of sulfonamides, and some bioflavonoids contain quercetin, a mutagen.

**Efficacy of Megavitamin Therapy**

There are only three situations in which the use of megavitamin therapy is rationally based and often efficacious:

1. Vitamin-dependent genetic diseases. In these situations, the patient is born with a defect in the machinery for utilizing vitamins, and this defect may sometimes be overcome (and sometimes not) by the mass action effect of megadoses of the vitamin.

2. Diseases associated with defective transport of vitamins across cell membranes. This includes defects in transport across intestinal cell membranes as well as the external and internal membranes and barriers of other cells. Such situations are diagnosable by measuring vitamin levels and vitamin function in blood and tissues.

3. As an antidote to the toxicity of antivitamins (such as antifols like methotrexate used in the treatment of malignancy and certain other disorders, the antifol trimethoprim used as an antibacterial, and the antifol triamterene used as a diuretic).

**Undesirable Effects of Megadoses of Vitamins**

Undesirable effects ranging from minor to serious have been reported for all of the vitamins used in megadose quantities. Recent reviews on the toxicity of megadoses of vitamins have been published by Hayes and Hegsted, DiPalma and Ritchie, the National Nutrition Consortium, Alfin-Slater and Aftergood, and myself. As these reviewers point out, chronic ingestion of megadoses of vitamin A or D could result in death. In one bizarre case, a patient died after an 80 g intravenous dose of vitamin C. "Emulsified vitamin A," a product promoted by the nutrition cultism industry, is more toxic than the vitamin usually available.

**Megavitamin Therapy and Orthomolecular Psychiatry**

A popular cult exists around the use of megadoses of vitamins to treat a host of disorders, mental and physical. Megavitamin therapy and orthomolecular psychiatry are largely supported by anecdotal accounts (testimonials) which are worthless as scientific or legal evidence. They are considered so questionable that in 1975 the U.S. Defense Department stated it would no longer reimburse physicians for giving such therapy to the dependents of military personnel, on the basis of testimony before the
U.S. Senate regarding alleged abuses. A task force of the American Psychiatric Association reported that such therapy was founded largely on anecdote, and was of unproven safety or efficacy. Lipton and Kane provide further information on this subject.

“Orthomolecular psychiatry” can be far more lucrative than conventional psychiatry. While the conventional psychiatrist earns an average of $50 for a 50-minute hour, my investigation of an orthomolecular psychiatrist and megavitamin therapist showed that he collected $200 to $600 for a first half-hour visit for “nutritional evaluation” including laboratory tests like hair analysis (which is useless for assessing vitamin status), and $25 for each subsequent 5-minute visit, plus an additional large income from direct sales of megavitamins and promotional literature. He also collected large sums for worthless “cytotoxicity testing” and “sublingual provocative tests” to “diagnose” non-existent “cerebral allergies” to foods.

Popular Misconceptions about Vitamins

There are many false but popular misconceptions about vitamins, particularly among “health food” users. The majority of the charismatic “nutrition” preachers to the public promote these misconceptions in their lucrative books, magazines, and media appearances. A study carried out for the Food and Drug Administration revealed that 14% of the general public and 42% of confirmed health food users did not know that anyone in this country who eats a balanced diet can get enough vitamins in his regular food; 71% of the general public and 75% of confirmed health food users erroneously believed that if people feel tired and run down, they probably need more vitamins and minerals; 67% of the general public and 73% of confirmed health food users did not know that older people need about the same amount of vitamins as young adults; 29% of the general public and 42% of confirmed health food users did not know that people who eat a variety of available foods every day can get all the vitamins and minerals they need; 21% of the general public and 37% of confirmed health food users erroneously believed that many diseases, including arthritis and cancer, are partly caused by lack of vitamins and minerals; and 10% of the general public and 23% of confirmed health food users erroneously believed that people can protect their health if they take more vitamins than they normally need.

*A study of health practices and opinions, 1972—results obtained upon interviewing a representative sample of the U.S. adult population in 1969. The same study showed that 57% of college graduates, 63% of the general public, 69% of those with less than high school education, and 86% of confirmed health food users gave erroneous responses to a series of questions on the healthfulness of the American food supply, including the erroneous belief that synthetic vitamins are different from natural vitamins. (They are apparently unaware, to paraphrase Gertrude Stein, that “a molecule is a molecule is a molecule.”) That survey for the FDA was reviewed by Dr. T.H. Jukes in Animal Nutrition in Health, Dec. 1973, pp. 8-10.
The results of this study, published in 1972, were obtained by interviewing a representative sample of the adult population of the United States in 1969. The same study showed that 57% of college graduates, 63% of the general public, 69% of those with less than high school education, and 86% of confirmed health food users gave erroneous responses to a series of questions concerning the healthfulness of the American food supply, including the incorrect belief that synthetic vitamins are different from natural vitamins.27

As Greengard notes in Goodman and Gilman’s classic pharmacology text,26 “Probably no single class of drugs has been the target of as much quackery, misunderstanding, misrepresentation, and misuse as the vitamins, despite the fact that far more is known about these compounds, including their mechanism of action, than about any other group in the U.S. Pharmacopeia... The practicing physician is exposed to pressures from two types of extremists in the area of vitaminology. One group of extremists, with representatives both in medical practice and in a few pharmaceutical houses, recommends large intakes of vitamins both for prophylactic purposes and for the treatment of an enormous variety of illnesses for which evidence of therapeutic efficacy of the vitamins is lacking... such practice is economically wasteful and, in some instances, causes financial hardship. ... The conscientious physician should assure himself that his patients are not victims of the excessive use of vitamins.... The second group of extremists in the area of vitaminology consists of those who, in reaction to the excessive use of vitamins, have campaigned with a certain degree of success against the use of vitamins in any instances except cases of unequivocal vitamin deficiency. In actual fact, the use of vitamins as ‘dietary supplements’ should be considered by the physician in a wide variety of situations. Such situations may result from (1) inadequate intake, (2) disturbance in absorption, and (3) increased tissue requirements.”

In connection with Greengard’s comment about a few pharmaceutical houses promoting large intakes of vitamins, the June 11, 1979 issue of Barron’s magazine notes that Hoffmann-LaRoche is the largest factor in the $100-million-a-year domestic vitamin C business, the largest corporate donor ($100,000 annually for the next five years) to the Linus Pauling Institute, which promotes the use by the public of megadoses of vitamin C, and a Roche spokesman is quoted as asserting that the vitamin C market has been growing “because people believe that vitamin C is safe” in megadoses.

Doses of vitamin C greater than 200 mg per day have yet to be demonstrated safe, and have in fact been associated with many undesirable effects.4 In an international symposium sponsored by Hoffmann-LaRoche, the Canadian group which carried out the largest scale trials of vitamin C and the common cold found larger megadoses no better than 250 mg doses
Vitamin Craze

(which themselves were of questionable value): they concluded that "we should adhere to the principle of primum non nocere and advise the public to limit their daily intake to 100 or 200 mg."

Use of Vitamin Supplements

No data have been published to demonstrate that healthy people eating a well-balanced diet need any vitamin supplements. A well-balanced diet means that when one looks back at the end of the day on what one has eaten during the day, it should have included a wide variety of foods from each of the "four food groups" (grains, fruits and vegetables, meats, and milk). There should have been four portions of grain products (which include cereals and breads), four portions of fruits and vegetables (including at least one fresh uncooked fruit and/or vegetable and/or fruit juice), two portions of meat products (this group includes not only meat but fish, poultry, eggs, and dry beans, peas, and nuts), and two to three portions of the milk and milk products group. Exception in pregnancy, where supplementation with 0.2 to 0.4 mg of folic acid daily is recommended, there are no reports of normal persons eating well-balanced diets developing vitamin deficiency diseases. Some nutritionists recommend that if one's diet is bad, one should take daily a multivitamin tablet containing the Recommended Dietary Allowance (RDA) of each vitamin as "nutritional insurance," but this is not needed by people eating a well-balanced diet containing a wide variety of foods from each of the four basic food groups.

The proper role of vitamin supplements is in the treatment of patients who have inadequate intake, disturbed absorption, or increased tissue requirements.

A number of multivitamin "stress" products are advertised by otherwise responsible pharmaceutical firms as "high potency stress formula vitamins" for the treatment of alleged vitamin deficiencies and conditions associated with stress, such as surgery, trauma, debilitating infections, and extensive burns. The concept and formulation for these products appears to be adapted largely from a 1952 report on therapeutic nutrition by two nutrition scientists (Food and Nutrition Board, National Academy of Sciences—National Research Council publication 234). The advertising is deceptive and misleading because it does not inform the reader that the National Academy of Sciences subsequently published a 3-page document recalling the report and asking libraries to remove it from their shelves on the grounds that it was based on inadequate evidence—and that there was no justification for substantial dosage increase in "stress."

Similarly deceptive and misleading is the intensive pharmaceutical firm advertising to health professionals and the general public stating that smokers need extra vitamin C and that women taking oral contraceptives need extra folic acid and vitamin $B_6$. While it is true that such individuals
as a group may have lower serum and cell levels of these vitamins, it is also 
true that those lower levels are still within the normal range. (In the case of 
vitamin C, the levels of smokers are ten times deficiency levels.) There is no 
objective evidence to date that "stress" per se, or smoking, or using oral 
contraceptives, warrants the use of any vitamin in amounts substantially 
above the RDA. The best available evidence is that no greater good is 
served by giving "stressed" patients, smokers, and women taking oral con­ 
traceptives "stress" formulas than is served by providing a well-balanced 
diet, including each day one fresh uncooked fruit or vegetable or fruit juice 
and, when such a diet cannot be eaten, providing each day an inexpensive 
vitamin complex containing the RDA rather than some expensive, unneces­ 
sary, and sometimes unsafe multiple thereof.

One of the recommendations of a recent nutrition symposium on "Pre­ 
vention of Disease Through Optimal Nutrition" was that doctors should all 
"promote the Recommended Dietary Allowances (RDA) as a working stan­ 
dard of optimal nutrition." This follows from the general nutrition truth 
that large amounts of any one nutrient are hazardous, but moderate 
amounts are nutritious. Vitamin gurus have no magic potions or startling 
philosophy that can produce a longer, richer, or happier life than this coun­ 
sel of moderation. Magical thinking cannot overturn the fundamental 
axiom of therapy, primum non nocere—above all do no harm. No therapy is 
safe or efficacious until proven so. The burden of proof is on the proponents 
of megavitamins.

A group at the Mayo Clinic recently reported megadoses of vitamin C to 
be valueless in advanced cancer. And the June 11, 1979 issue of Barron's 
magazine reports a controversy at the Pauling Institute over an unpub­ 
lished study done there suggesting that megadoses of vitamin C may in­ 
crease rather than reduce the frequency and severity of rodent cancer. 
Possible roles of vitamins in preventing and promoting cancer have been 
recently reviewed. Another review on toxicities of excess nutrients has 
also recently been published.

"More is better" is slogan, not science. More is sometimes better, some­ 
times worse, and always costlier.

References
1. Anonymous: How to evaluate medical 
information. The Harvard Medical School 
3. Herbert, V.: Pangamic acid ("Vitamin 
4. Herbert, V.: Facts and fictions about 
megavitamin therapy. Resident and Staff Phy­
5. Committee on Food Protection, Food 
and Nutrition Board, National Research 
Council (Eds.): Toxicants Occurring Naturally 
in Foods (2nd Ed.) Washington, D.C., Na­
6. Herbert, V.: The nutritionally and meta­
obically destructive "nutritional and meta-
26c. Breneman, J.C. et al.: Report of the Food Allergy Committee on the sublingual


II. ETHICAL MEDICINE

Acquiring New Information While Retaining Old Ethics

Scientific medical ethics are founded on the moral principles and standards of reason that are a part of ethics generally, and on the cumulative wisdom and experience of scientific knowledge and practice. Scientists of every persuasion, ethicists, philosophers, lawyers, sociologists, economists, and representatives from all walks of life play a role in the shaping of these ethics. Ethics is that branch of philosophy relating to human conduct, to the rightness and wrongness of certain actions, and to the good and bad of the motives and ends of such actions.

Silverman, in his article on retrolental fibroplasia points out that this epidemic of blindness in infants has a moral, not only for medical experimentation on human beings, but also for self-experimentation by the public such as that with laetrile (amygdalin), and with megavitamin therapy, with increased reports of toxicity. As Silverman points out, it is an irony of medicine that the retrolental fibroplasia stemmed from the efforts of physicians to increase the premature baby's chances of survival in good health. After about 12 years of intensive investigation of this epidemic of blindness, the cause was found, and the disease was virtually eradicated. The entire episode sharply presents the painful questions that surround experimentation with human beings, and particularly with newborn infants. When this epidemic appeared, adrenocorticotropic hormone (ACTH) was tried because of its effect on fibrous tissue formation, since the formation of such tissue behind the lens of the eye appeared to be the proximate cause of the blindness in these infants. It seemed curative in three-quarters of the infants on whom it was tried, and was hailed as a therapy for this epidemic. We now know that this disease relates to the oxygen-rich environment that was then standard treatment for premature infants, and that approximately three-fourths of the infants with early eye changes will return spontaneously to normal, with no treatment. The ACTH therapy was irrelevant to the cures achieved, since the 75 per cent cure rate would have been achieved without it. Before we knew that, more than 50 separate causes of the disease were proposed. About half of them were formally examined, and four were tested in prospective clinical trials. The question was whether the causative factor was an excess or a lack of oxygen in the retina of the eye. Campbell in Australia, and Cross in England, published anecdotal evidence incriminating an excess of oxygen in 142 infants. But in Paris,
anecdotal observations of 479 infants led to the opposite (and wrong) conclusion, indicating the low worth of anecdotal accounts as a basis for drawing scientific conclusions.

Meanwhile, Ashton, in a very small series of one mother cat and three kittens, observed that exposure to high oxygen, which resulted in withering of the germinating blood vessels, led to subsequent wild regrowth of blood vessels in the retina, with hemorrhage. This hemorrhage led in infants to fibrous tissue formation, and the fibrous tissue then billowed out from the retina against the back of the lens. This basic and crucial observation was relatively ignored for some time. The use of excess oxygen in the first place in the treatment of premature infants was related to the general acceptance of the hypothesis put forth in the early 1940’s that the high toll of brain damage in premature infants was caused by a lack of oxygen. Subsequent evaluation revealed that curtailing oxygen therapy to reduce retrolental fibroplasia is associated with an increased death rate from hyaline membrane disease in certain infants, and also increased brain damage, as the hypothesis had proposed. It was some time before the narrow, not yet ideal, balance was struck whereby premature infants who need extra oxygen to survive without brain damage get it, but in concentrations that do not seem to give rise to blindness. In his article, Silverman quoted Brody of Michigan State, who said that “scientists and clinicians are prone to error when they confuse scientific problems with value problems and try to solve the latter with the tools of the former.” Proposed treatments must be fully tested before they are presented to the community for consideration and approval. Silverman concluded with a plea for the controlled clinical trial rather than trial and error empirical studies.

To put in legal terminology what Tukey indicates, the only source of reliable evidence rising to the level of proof about the usefulness of any new therapy is that obtained from well-planned and carefully conducted randomized and, where possible, coded (double-blind) clinical trials. Applying that legal terminology to Mosteller’s argument, uncontrolled studies may point a direction but cannot be evidence, as lawyers use the term evidence to mean something probative, which in the law of evidence means having the effect of proof, tending to prove or actually proving.

Sources of Ethical Difficulties

Problems in the borderline of science, statistics, and public policy have been discussed by Cornfield in the context “Carcinogenic risk assessment.” As he indicates, the uncertainties involved are not always fully amenable to statistical evaluation. Insofar as this is the case, they are not fully amenable to ethical conclusions and they are subject to difficult ethical controversy.

A dominant theme in Western civilization is that we are each autonomous beings with inherent dignity and value, and that we each control our
lives and actions by our own choices to the greatest extent compatible with the rights of others. Acquiring new information while retaining old ethics need not involve a clash between respect for the individual and desire of the scientist for knowledge, whether his desire for knowledge is for its own sake, for his sake, or for the sake of others.

As Robertson has pointed out, ethical difficulties with organ transplants, brain death, sterilization, abortion, human experimentation of all types, cloning, genetic screening, psychosurgery, behavior modification, and euthanasia derive from respect for persons. Threats to this respect may take many forms, including inequality, such as when scarce medical resources are allocated on the basis of social worth, as has been done in the past in the selection of a patient for an artificial kidney or for hemodialysis. There is a threat when incompetents rather than consenting adults are used in experimentation. The threat may be manipulation seemingly inconsistent with human dignity, such as behavior modification.

The traditional device for adjusting our knowledge to our ethics in human experimentation has been the concept of consent, because respect for persons means respect for their free, knowing, intelligent, and therefore informed, consent. Informed consent becomes a problem when persons are not capable of giving such consent because they are too young, or incompetent, or unconscious, or the like. Robertson explores the legal concept of the substituted judgment doctrine, which is a reasoned approach to this ethical problem. In the substituted judgment doctrine, the court puts itself in the shoes of the incompetent, and acts on the same motives and considerations that it believes the incompetent would have acted on to make an informed judgment had he been competent. The court seeks to do for the incompetent what he would do himself, if he were capable of formulating and communicating his own choices. This is not only consistent with respect for his person and his dignity, but also recognizes that his welfare, in appropriate instances, may depend on helping others, such as in a transplant of an organ from an incompetent to a close and loving relative.

Good has indicated the need to reflect on the best ways of gaining the new knowledge that we need so badly, while retaining the highest values of our civilization and culture. These highest values are our ethics, our system of moral principles, our rules of conduct.

As was pointed out in the foreword to Ethics in Medicine, ethics is the oldest intellectual discipline in the Judeo-Christian tradition. The fact that ethics may be formalized into law does not mean that those ethics will be adhered to or that the formalization is appropriately handled. Indeed, much of our ethical code, even when formalized in law, has not been reduced to justice. Our morality is our conformity to the rules of right conduct, regardless of whether those rules have or have not been cemented into law. Medical ethics, from the Hippocratic Corpus to the 1975 Tokyo update of the Declari-
ation of Helsinki, are grounded in reflection on what is medically right or wrong, and are a defining characteristic of medicine as a profession.\textsuperscript{1}

**Risks**

Our problems arise because every physician dreams of treating untreatable diseases, or curing incurable ills. Each new treatment involves a risk. Until a treatment is tested in a human, physicians have no certainty as to how much good or harm that treatment may bring to humans. We take calculated risks.

Many medical researchers are unwilling to try anything on a patient that they have not tried on themselves first. For many studies, however, the subject for evaluation must be sick with the disease under study. For this, if the physician doing the study does not himself have the disease, it is necessary to work with those who do. Altman has collected many instances of self-experimentation by medical researchers.\textsuperscript{14}

It is clear that, in a number of experiments, it is an advantage if the subject is a physician. For example, a physician was evaluating the possibility of folate deficiency occurrence in a normal human without intestinal disease.\textsuperscript{15} Studies at Johns Hopkins and elsewhere had suggested that this vitamin deficiency could only occur in people with intestinal malabsorption because intestinal bacteria made the vitamin and presumably it was then absorbed. He had evidence from animal studies that folate was absorbed largely in the upper third of the small bowel, rather than low in the large bowel where the vitamin was made by bacteria, and thus he was inclined to disbelieve that work. He decided to go on a low folate diet and get bone marrow aspirates every 2 weeks to ascertain whether megaloblastic anemia, a characteristic of folate deficiency, developed. About 2 months after the study was begun, he awoke with lower extremity paralysis (it happened to be on Christmas morning). In thinking about the problem, he remembered an article published just a month earlier, about paralysis due to potassium deficiency. Reflecting on that article, he realized that the thrice-boiling of foods that was used to remove all the food folate was probably also removing the potassium. Had the experimental subject, in this first such experiment, not been a physician, the thought would probably not have occurred at that time. Because it did, and because he had on hand a sample of a saturated solution of potassium iodide that had come in the mail, he could drink some, and have enough potassium to get to the laboratory, where the on-duty research fellow was able, using a spectrophotometer and an electrocardiogram,\textsuperscript{15} to confirm that there was, indeed, a severe potassium deficiency, which was then corrected.

Before the physician tries any new treatment on a patient, he must weigh, as best he can, the potential assets and liabilities of alternative courses of action and consider these not only as a scientist, but also as if he were the
patient, and also from the point of view of the social order. At times he must resist the push by zealots transfixed by a "belief" in a magic cure for a dread disease, as is occurring in the laetrile controversy.

Our ethical, legal, medical, and scientific codes in the United States each demand proof of diagnosis before accepting a claim of cure. We know that not every lump ("tumor" in medical parlance) is cancer and a lump that goes away with "magic cure" therapy will also go away with no therapy. Such tumors are either not cancers in the first place, or they undergo spontaneous remission, which occurs with variable frequency in various cancers. It is pertinent here to recall the magic ACTH cure for retrolental fibroplasia, which turned out to be nothing more than the fact that three-quarters of the patients with that disease in its early form recovered with no therapy. As scientists, we recognize the low worth of anecdotal evidence, just as lawyers recognize the "hearsay rule," which says that evidence that does not derive its value solely from the witness, but rests mainly on the veracity and competency of other persons, is not generally admissible in a courtroom. Unless a knowledgeable person can cross-examine the person who made the diagnosis, or gave the treatment, the allegation by a patient that he had cancer or any other incurable disease, or that a given treatment had an effect greater than that of a placebo, is without worth.

Despite the negative facts, we are often pushed into a clinical trial of so-called curative agents. Thomas noted that the only ethical way one can do a clinical trial of a questionable drug (laetrile, for example) is to impose it on existing therapy, rather than to give it instead of existing therapy. To give it instead of existing therapy could be murder. Let me cite a case in point. For example, in California, there was an 8-year-old girl who had a cancer of the eye which was believed by her doctors to be surgically curable. She had been admitted to hospital, was scheduled for surgery, but in the waiting room her parents met a couple who told them that their son had been cured of a brain tumor by a chiropractor using vitamins and food supplements (laetrile is a food supplement, say its promoters). The parents canceled the surgery, removed their daughter from the hospital, and took her to a chiropractor. He treated her with vitamins and food supplements until the tumor grew to the point where her eye bulged out of its socket and the parents realized that the vitamins and food supplements were not helping. The malignancy had spread to the point where surgery could no longer save her, and she died. Subsequently, the chiropractor was indicted and convicted of second degree murder and sentenced to prison.

Ethics in New Kinds of Research

On another subject, we are now witnessing the codification into law of perceived ethics concerning research on recombinant DNA. The federal government is in the process of writing legislation to control research on
DNA molecules, which control the characteristics of all known cells. The proposed federal DNA bill\textsuperscript{15} would preempt all state and local laws regarding the production or use of recombinant DNA molecules unless their requirements are at least as strict as the federal one. This is a particularly delicate undertaking because Congress has no experience with regulating scientific research, and because the kind of research under scrutiny has the potential, not only of bringing great good to mankind, but also of threatening it with untold harm.\textsuperscript{20} This emphasizes the recent plea of Zinder of Rockefeller University to the Senate Subcommittee on Health that this legislative control be carried out with extreme care and without haste.\textsuperscript{21}

The committee on Life Sciences and the Law of the American Bar Association is engaged in evaluating questions relating to recombinant DNA legislation. The ethical considerations raised by members of the committee and others are many and varied, and include imponderables such as what will actually happen if the advance of this particular science is restricted by legislation. There is no instance in the history of man where legislation to restrict any form of scientific inquiry has advanced that form. If the same type of legislative restriction had been applied to atomic fission research in 1939, we might never have discovered fission. The judgment to retard the advancement of science will always find adherents, but the wisdom of such a course of action is difficult to assess.

In the April 1977 \textit{Hastings Center Report}\textsuperscript{22} which is the journal of the Institute of Society, Ethics, and the Life Sciences, there were three articles on the ethics of recombinant DNA, and more appear everywhere one looks. Cohen\textsuperscript{23} reflects on the problem and concludes that there is no legitimate basis for slowing or stopping research on recombinant DNA. A few pages later, Goldstein,\textsuperscript{24} in an editorial in the same journal, calls for the slow, thoughtful approach of a temporary slowdown for 5 to 10 years. He feels that the "Go" signal should be the result of careful evaluation by decision-making bodies democratically appointed and representative of the rich diversity of ethical and scientific points of view.

Our old ethics are our ethics today and will continue to be our ethics in the future. They are the distillate of our philosophic thinking. In deciding what we can and cannot do to acquire new information, we must be in possession of as many scientific facts as possible. Our ethical decisions are based upon such knowledge as we have, and our best informed guesses about what we do not know. Cornfield\textsuperscript{11} touched very briefly on an ethical-legal decision with relation to sugar substitutes; this of course is the saccharin decision based on the Delaney Amendment. Here we see the tensions when one attempts to make an ethical decision in the presence of inadequate evidence. There is evidence that a significant number of the saccharin-fed offspring of rats who were themselves on diets containing 5 per cent
saccharin developed bladder tumors. The quantity of saccharin, when translated into human terms, is equal to 800 cans of diet soda per person per day. Compare this to the average consumption by humans in the United States of approximately 1½ cans per day.

Cornfield has indicated that certain assumptions are necessary in order to apply statistics to such a problem. In the case of the saccharin-treated rats, we must make two assumptions. The first is that what is so in rats is so in humans, and second is that we are dealing with a straight line curve that has no zero toxicity level (that is, the curve goes back to a baseline of zero). Treating those assumptions as facts, we can project in the U.S. population of 220 million a urinary bladder cancer rate of 1200 cases a year. We do not have to consider whether these two assumptions are correct because, as Cornfield noted, we have the Delaney Amendment which eliminates our need to think about the subject, since it states that if any substance in any animal is associated with the development of any cancer, it may not be added to human food; that is, it states that the law is that our two unproven assumptions are proven facts.

Still central to ethical controversies is the concept of informed consent, about which a great deal has been written; I reviewed that 2 years ago in the context of the use of drugs that have possible undesirable side effects. A major ethical and legal question is, “Is there any such thing as informed consent?” The reason for this question is twofold: (1) if a subtle form of coercion is involved, as, for example, in the consent of a prisoner, or the consent of a less knowledgeable person to one he perceives as more knowledgeable, is that consent? and (2) if the patient is told everything appropriate for him to be told, is he then informed?

Regarding this second point, a recent study at Montefiore Hospital in the Bronx demonstrated that a majority of surgical patients denied after surgery that they had been told about all the possible undesirable outcomes prior to the surgery, even though discussion of possible undesirable outcomes ran for 1½ hours prior to the surgery and was tape-recorded. If the brain does not record, store, or recall the information supplied to it, or suppresses that information, has there been informed consent? Is the concept of informed consent really a legalistic rather than an ethical one, with the legalisms being used instead of ethics rather than in support of ethics? Surely, informed consent should mean that the right thing is being done, as the patient would have wanted it to be done had he truly understood, rather than that the wrong thing has been done and has been justified to the patient.

At the 1977 annual meeting of the American Bar Association, the section on science and technology had a program covering the subjects, regulation of experimentation on human subjects, the federal role in regulation of scientific research, and regulation of experiments in recombinant DNA. One of the major legal considerations in that symposium was, what disclosure
standards should exist, that is, what should the patient be told in coded experiments, which are considered by some critics as inherently deceptive because the participants do not know whether or not they are in the control group. Similarly, according to Milgrim, "a majority of the experiments carried out in social psychology use some degree of misinformation" (p. 19), and thus "subvert the possibility of informed consent" (p. 21). "Prior general consent" or "presumptive consent" have been proposed to deal with this ethical problem.

Recombinant DNA research makes it at least theoretically possible to combine the genetic characteristics of plant and mammal, to produce a "plamental" or a "mant." We need to find a balance between possibly inadvertently producing the means to cause catastrophe to mankind, and potentially high beneficial developments. The genetic splicing of recombinant DNA technology has already been used to transfer the rat gene for insulin production to bacteria. This development has the potentially high beneficial consequence of making possible massive commercial production of human (instead of other species) insulin for diabetics. It also has, in the eyes of some, the possibility of catastrophe should insulin-producing bacteria get out of the laboratory into the body of a human, to multiply and throw the person into insulin shock.

One argument is that knowledge is power, and if we do not acquire the knowledge, other countries will. Remember that in World War II the other side was also working on an A-bomb. If we acquire the knowledge, we can also acquire the means to control the knowledge. If we do not, the controls may be in other hands. These too, are ethical considerations.

As Jonas notes, generally there is something experimental because tentative about every individual treatment, beginning with the diagnosis itself. He would be a poor doctor who would not learn from every case for the benefit of future patients, and a poor member of the profession who would not make any new insights gained from his treatments available to the profession at large.

In summary, we recognize that acquiring new information while retaining old ethics demands adherence to the fundamental rule that a person should not be subjected to avoidable risk of death or physical harm unless he freely and intelligently consents. The problem is to balance rights against benefits with respect for human dignity in the quest for the cure of human diseases.

References and Notes


10. Black, H. C.: Black’s Law Dictionary, Revised (St. Paul, Minnesota, ed. 4, 1968). In “United States of America v. Articles of Food and Drug Consisting of...apricot kernels...amygdalin...,” Civil No. 77-C-285 (U.S. District Court, Eastern District of Wisconsin, 29 July 1977), Judge Reynolds closed a laetrile factory after holding as a Finding of Fact that, “Anecdotal and testimonial evidence as to cures or effects of treatments on cancer victims as described by lay persons, or persons possessing either an M.D. or Ph.D., but who are not qualified by scientific training and experience as experts in the field of cancer therapy, is not probative or substantial evidence of the safety and efficacy of cancer treatments.” Judge Reynolds held as a Conclusion of Law, “The testimony of lay witnesses as to the existence of cancer and the safety and efficacy of an alleged cancer treatment based on their personal experience with the treatment is entitled to no weight and is therefore inadmissible as irrelevant and non-probative evidence.” As precedents for this Conclusion of Law, Judge Reynolds cited United States v. Hoxsey Cancer Clinic, 198 Fed. Rep., 2nd ser. 273 (5th Cir. Ct., 1952); United States v. Wier, 281 Fed. Rep., 2nd ser. 850 (5th Cir. Ct., 1960), and Federal Rules of Evidence 401, 402, 403, and 701.


Medical, Legal and Ethical Considerations in the Use of Drugs having Undesirable Side Effects

*Primum non nocere—above all, do no harm.*¹ This ancient maxim captures the essence of the medical, legal, and ethical considerations in the use of drugs having undesirable side effects. This maxim is implemented by using a drug only after its potential assets are balanced against its potential liabilities, as weighed against alternative courses of action (or inaction). The underlying considerations in such balancing are on the one part for the physician alone (assessing the medical considerations and accurately reflecting them to the patient), on another part for the physician and the patient (does the patient choose or not to accept the physician’s best judgment?), and finally for physician, patient, and the social order (assessing the legal and ethical considerations).

Fundamental to the medical assessment is an adequate understanding of the general principles of the pharmacological basis of therapeutics. Fingl and Woodbury² review this subject in the opening chapter of the fourth edition of Goodman and Gilman’s classic textbook of pharmacology, “the most widely read and generally respected book in its field.”³ As they point out, “No drug is free of toxic effects... Clinicians have long been aware of the drug-induced diseases. However, with the introduction into therapeutic practice of drugs of greater and broader efficacy, the problem of drug toxicity has increased, and it is now considered the most critical aspect of modern therapeutics. Not only is a greater variety of serious toxicity being uncovered, but also the average incidence of adverse effects of medication is increasing, and unexpected toxic effects are occurring relatively frequently. ... However, adverse effects do not arise solely because of the inherent toxicity of drugs and the limitations of the methods for early detection of this toxicity. Many of the adverse effects could be avoided if drugs were used

---

¹ Supported in large part by Public Health Service grant AM15163, by a Veterans Administration Medical Investigatorship (3570-01 and 3570-02), and by Health Research Council of the City of New York Career Scientist Award I-683.
more carefully and more wisely. The physician should avoid a toxic drug if a less toxic one will suffice; and he should, if possible, avoid the use of concurrent medication and especially the use of drug mixtures, as one drug may affect the toxicity of another. Moreover, he must be aware of the potential hazards of the drugs that he uses, and he must be prepared to act promptly if toxicity occurs. He must be especially alert for the unexpected."

A broad range of effects of oral contraceptive (OC) hormones on nutrient metabolism has been observed, but the significance of some being possibly undesirable is difficult to evaluate. Many of the effects of OC hormones on nutrient metabolism are similar to the effects of the alterations in hormone metabolism induced by pregnancy; indeed, it is the mimicking of a facet of the hormonal state of pregnancy by inducing a kind of pseudopregnant condition which underlies the efficacy of OC hormones.  

Thus, medical considerations in the use of oral contraceptives revolve largely around the question of whether the known and potential undesirable side effects of inducing a kind of pseudopregnant condition for a protracted period of time are likely to be greater or less than allowing pregnancy to occur, with its known health dangers, including a rate of mortality from hemorrhage, toxemia of pregnancy, infection, heart disease, and less frequent causes of 28 mothers/100,000 live births, not counting the long-term effects of pregnancy complications on women who survive.

The gradually accumulated evidence of definite or possible relationship of OC hormones to increased incidence of thromboembolic disorders, cholestatic jaundice, and estrogen-dependent neoplasia, has led to the insertion of a brief description of these possible hazards of OC hormones in each package dispensed to the patient.

Perhaps the most difficult question to grapple with is that of unforeseen and possibly unforeseeable long-term undesirable effects. Again drawing our analogies from the use of OC hormones, the most recent allegation of an undesirable effect is that OC hormones may be associated with the rare development of liver adenoma, a tumor both rare and benign, but potentially fatal. It has been indicated that, treated correctly, the tumor should not be fatal and would not recur. The two potentially fatal errors are in medical judgment: misdiagnosing the tumor as cholecystitis, or hesitating to excise it.

This leads us directly to medical ethics, as related to OC hormones. Let us say it is the judgment of the physician that for a combination of medical reasons and his own ethical standards he refuses to prescribe OC hormones for a patient who desires them, and the patient insists on such therapy, secures it elsewhere, develops one of the undesirable side effects, and this side effect is inadequately recognized and inadequately treated. The physician
who initially rejected the patient may be on sound medical and legal ground; is he on sound ethical ground? This is a philosophical question I leave you to ponder.

The legal considerations in the use of drugs having undesirable side effects primarily fall under the rubric of malpractice. The April 1974 issue of *Resident and Staff Physician* is a special issue subtitled “A Malpractice Manual for Hospital Doctors,” containing sixteen articles on malpractice, including one by Don Harper Mills, M.D., J.D., on “Malpractice and Drugs.” As Mills states, “Issues raised in malpractice claims have included the decision to use the drug, the manner of administration, the dosage and duration of use, the performance of laboratory tests during prolonged use, the timeliness of diagnosis of reactions and of other untoward results, and their management.” Thus, no possible issue related to drug usage is immune from medicolegal scrutiny. The decision of the physician to prescribe drug A rather than drug B will usually stand up to legal scrutiny provided the decision of the physician was a decision which a substantial minority of other physicians might also have made in the circumstances. However, the physician is on unsafe ground if he employs a novel and unorthodox procedure with “risks incident to or possible in its use,” and these were not disclosed, which was the case in an analogous situation of a nonemergency surgical procedure used on an infant patient who died after suffering an exsanguinating hemorrhage as a result of the operation.

Because the Food and Drug Administration exercises controls on the use of drugs, if the plaintiff could demonstrate that the physician used the drug in a way that was proscribed by the FDA, and the court accepted the proposition that the physician knew or should have known of the proscription, in the eyes of the jury the burden of proof might well shift from the need for the plaintiff to prove the culpability of the physician to the need of the physician to prove his lack of culpability. The physician who must defend himself against both the plaintiff and governmental pronouncements will need strong support from medically knowledgeable colleagues if he is to sustain his position.

It has been alleged that many physicians have been prompted to prescribe unnecessary diagnostic tests as a means of insulating themselves against possible malpractice claims, thereby contributing to the spiraling costs of medical care. Since the primary purpose of a malpractice suit is to redress the injuries suffered by the plaintiff, much can be said in favor of extending the no-fault concept, now well-established in the automobile injury field, to health care. Exemption laws on guarantee of purity for blood transfusions and tissue and organ transplants appear to be constitutional, and health care no-fault laws would probably prove the same. The very broadly worded Tennessee statute which covered all contracts “for the sale, procurement, processing, distribution or use of human tissues (such
as corneas, bones, or organs), whole blood, plasma, blood products, or blood derivatives" was held not to violate either the due process right to sue for injury or the equal protection right against laws which unfairly discriminate in favor of hospitals, physicians, and medical-anatomic banks.

Probably opposed to introducing the no-fault concept to medical care would be those members of the Association of Trial Lawyers of America who believe that only litigation can frighten the medical profession into improving the quality of care, and only litigation provides the necessary stimulus for reform. The question at issue here appears to be that of whether or not any professional group can be expected to adequately police its own ranks and if not, whether the policing should be by private litigation or by state action (such as concurrent enactment of no-fault health care laws and laws requiring adequate review of medical actions resulting in injury, and containing adequate teeth to prevent recurrence). What is sauce for the goose is sauce for the gander: the tools to attack medical malpractice should not differ from those to attack legal malpractice. Private malpractice litigation does not root out incompetents. Adequately drawn and enforced statutes can. Lawyers draw up statutes, and lawyers enforce them; it is here that the lawyer, working with rather than against the physician, can make significant contributions to improving the quality of health care.

A major legal consideration in the use of drugs having undesirable side effects is that of informed consent. The doctrine of informed consent states in essence that, under normal circumstances the patient should be given the opportunity to make an intelligent choice about whether he will permit or refuse a proposed drug or other treatment or procedure. Informed consent has been likened to "obtaining consent after the patient has been apprised of the risk/benefit ratio; i.e., what are the risks entailed by the proposed treatment as compared to the expected benefits: do the latter outweigh the former?"

In the words of Rubsamen, "In 1972, the high courts in California, Rhode Island, and Washington, D. C. dropped bombshells labeled 'Informed Consent'." As Rubsamen notes, in the past the law required an expert witness to answer the question: How much information should have been given this plaintiff in this particular situation, applying the standard of disclosure of that particular community? The three 1972 decisions have the effect of eliminating the medical standard established by an expert witness and replacing it with a legal standard for informed consent to be used by the jury to measure the defendant physician's conduct. The Canterbury court (J. Robinson) stated "...it is normally impossible to obtain a consent worthy of its name unless the physician first elucidates the options and the perils for the patient's edification," and further, "Some have measured disclosure by...what medical custom in the community would demand.
... We have explored this body of law and are unprepared to follow it.... The patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice.... Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked... a risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk... in deciding whether or not to forego the proposed therapy.” In Cobbs also, the court stated that the test of what to tell the patient is what the patient needs to know to make up his mind whether or not to proceed, although “A medical doctor need not make disclosure of risks when the patient requests that he not be so informed.” Rosenberg suggests that, if the patient waives his right to know in writing, physicians may rely on this Cobbs exception, but Mills suggests they should not, in part because the jury will decide what should or should not have been disclosed, possibly irrespective of a waiver by the patient.

The soft-cover book “Medicolegal Forms with Legal Analysis” provides an up-to-date review, with pertinent case citations, of the subject of informed consent. That document cites the Kansas Supreme Court statement in Williams vs. Menehan that: “It is the duty of a doctor to make a reasonable disclosure to his patient of the nature and probable consequences of the suggested or recommended treatment, and to make a reasonable disclosure of the dangers within his knowledge which are incident or possible in the treatment he proposes to administer. But this does not mean that a doctor is under an obligation to describe in detail all of the possible consequences of treatment.... The duty of the physician is to disclose... is limited to those disclosures which a reasonable clinical practitioner would make under the same or similar circumstances.” The physician may tailor the extent of his disclosure to a particular patient to avoid unnecessary anxiety or apprehension on the part of the patient. His primary duty is to do that which is best for the patient. Except in the case of experimental drugs, the patient’s consent to drug therapy is customarily implied consent or oral consent. As recommended by the Office of the General Counsel of the AMA, “generally, drugs under clinical investigation should be administered only where: 1) the informed consent of the patient or his authorized representative has been obtained; 2) the physician is convinced of the reasonable accuracy of his diagnosis and, if necessary, has confirmed it by adequate consultation; and 3) existing methods of treatment have proven unsatisfactory. The voluntary participation of the patient will not excuse a deviation from the physician's obligation to exercise his best skill in rendering the care re-
quired of a reasonable practitioner. Furthermore, the physician is advised to confine his clinical investigations of new drugs to those furnished by reputable sources who have supplied him with comprehensive written information concerning: 1) animal experimentation; 2) previous clinical investigation, if any; 3) recommended dosages; 4) contraindications; 5) possible side effects to be watched for; and 6) the safety and possible usefulness of the drug, from existing data.”

HEW in 1974 was developing and formalizing in the Federal Register guidelines with the status of formal regulations on human experimentation. Among the topics under review were those of informed consent and no-fault insurance for clinical investigations.

Finally, we turn more directly to ethical considerations in the use of drugs having undesirable side effects. Edmund Burke wrote, “It is not what a lawyer tells me I may do; but what humanity, reason, and justice, tell me I ought to do.” While there are generally accepted guidelines for clinical research, there is no printed code of professional medical responsibility governing all forms of therapy equivalent to the Code of Professional Responsibility adopted by the House of Delegates of the American Bar Association. The ABA Code of Professional Responsibility contains nine canons, holding that a lawyer should assist in maintaining the integrity and competence of the legal profession, assist in making legal counsel available, assist in preventing unauthorized law practice, preserve the confidences and secrets of a client, exercise independent professional judgment on behalf of a client, represent a client competently and zealously within the bounds of the law, assist in improving the legal system, and avoid even the appearance of professional impropriety. Each canon is followed by a section on ethical considerations and another on disciplinary rules. Much of this code could easily be made applicable to physicians, often by simply replacing the word “lawyer” with the word “physician” and the word “client” with the word “patient”. However, Bar associations seem as reluctant to discipline attorneys for violations of this written code as medical associations are to discipline physicians.

Thus a written code of ethics not only does not guarantee ethical behavior, but it does not guarantee that unethical behavior will be punished. However, it is a start. As part of this start, let us look at Canon 6 of the Code of Professional Responsibility of the ABA, reproduced below. For application as an ethical code to physicians, almost all that need be done is to replace the word “lawyer” with “physician”, the word “client” with “patient”, and the phrases “the Bar” and “the Law”, with “Medicine”.

The official adoption of such an ethical code governing therapy by appropriate agencies can serve as both an inspirational guide to members of the profession and a basis for disciplinary action when the conduct of a physi-
cian falls below the required minimum standards stated in the Disciplinary Rules. Ethics, after all, is "a system of moral principles," "the rules of conduct recognized in respect to a particular class of human actions." Law is nothing more than the formalization of the ethics of a society.

**CANON 6**

*A Lawyer Should Represent a Client Competently*

**ETHICAL CONSIDERATIONS**

**EC 6-1** Because of his vital role in the legal process, a lawyer should act with competence and proper care in representing clients. He should strive to become and remain proficient in his practice and should accept employment only in matters which he is or intends to become competent to handle.

**EC 6-2** A lawyer is aided in attaining and maintaining his competence by keeping abreast of current legal literature and developments, participating in continuing legal education programs, concentrating in particular areas of the law, and by utilizing other available means. He has the additional ethical obligation to assist in improving the legal profession, and he may do so by participating in bar activities intended to advance the quality and standards of members of the profession. Of particular importance is the careful training of his younger associates and the giving of sound guidance to all lawyers who consult him. In short, a lawyer should strive at all levels to aid the legal profession in advancing the highest possible standards of integrity and competence and to meet those standards himself.

**EC 6-3** While the licensing of a lawyer is evidence that he has met the standards then prevailing for admission to the bar, a lawyer generally should not accept employment in any area of the law in which he is not qualified. However, he may accept such employment if in good faith he expects to become qualified through study and investigation, as long as such preparation would not result in unreasonable delay or expense to his client. Proper preparation and representation may require the association by the lawyer of professionals in other disciplines. A lawyer offered employment in a matter in which he is not and does not expect to become so qualified should either decline the employment or, with the consent of his client, accept the employment and associate a lawyer who is competent in the matter.

**EC 6-4** Having undertaken representation, a lawyer should use proper care to safeguard the interests of his client. If a lawyer has accepted employment in a matter beyond his competence but in which he expected to become competent, he should diligently undertake the work and study necessary to qualify himself. In addition to being qualified to handle a particular matter, his obligation to his client requires him to prepare adequately for and give appropriate attention to his legal work.

**EC 6-5** A lawyer should have pride in his professional endeavors. His obligation to act competently calls for higher motivation than that arising from fear of civil liability or disciplinary penalty.

**EC 6-6** A lawyer should not seek, by contract or other means, to limit his individual liability to his client for his malpractice. A lawyer who handles the affairs of his client properly has no need to attempt to limit his liability for his professional activities and one who does not handle the affairs of his client properly should not be permitted to do so. A lawyer who is a stockholder in or is associated with a professional legal corporation may, however, limit his liability for malpractice of his associates in the corporation, but only to the extent permitted by law.
DISCIPLINARY RULES

DR 6-101 Failing to Act Competently.
(A) A lawyer shall not:
   (1) Handle a legal matter which he knows or should know that he is not competent to handle, without associating with him a lawyer who is competent to handle it.
   (2) Handle a legal matter without preparation adequate in the circumstances.
   (3) Neglect a legal matter entrusted to him.  

DR 6-102 Limiting Liability to Client.
(A) A lawyer shall not attempt to exonerate himself from or limit his liability to his client for his personal malpractice.

NOTES

1. "[W]hen a citizen is faced with the need for a lawyer, he wants, and is entitled to, the best informed counsel he can obtain. Changing times produce changes in our laws and legal procedures. The natural complexities of law require continuing intensive study by a lawyer if he is to render his clients a maximum of efficient service. And, in so doing, he maintains the high standards of the legal profession; and he also increases respect and confidence by the general public." Rochelle & Payne, The Struggle for Public Understanding, 25 Texas B.J. 109, 160 (1962).

   "We have undergone enormous changes in the last fifty years within the lives of most of the adults living today who may be seeking advice. Most of these changes have been accompanied by changes and developments in the law.... Every practicing lawyer encounters these problems and is often perplexed with his own inability to keep up, not only with changes in the law, but also with changes in the lives of his clients and their legal problems.

   "To be sure, no client has a right to expect that his lawyer will have all of the answers at the end of his tongue or even in the back of his head at all times. But the client does have the right to expect that the lawyer will have devoted his time and energies to maintaining and improving his competence to know where to look for the answers, to know how to deal with the problems, and to know how to advise to the best of his legal talents and abilities." Levy & Sprague. Accounting and Law: Is Dual Practice in the Public Interest?, 52 A.B.A.J. 1110, 1112 (1966).

2. "The whole purpose of continuing legal education, so enthusiastically supported by the ABA, is to make it possible for lawyers to make themselves better lawyers. But there are no nostrums for proficiency in the law; it must come through the hard work of the lawyer himself. To the extent that that work, whether it be in attending institutes or lecture courses, in studying alter hours or in the actual day in and day out practice of his profession, can be concentrated within a limited field, the greater the proficiency and expertness that can be developed." Report of the Special Committee on Specialization and Specialized Legal Education, 79 A.B.A., Rep. 582, 588 (1954).

3. "If the attorney is not competent to skillfully and properly perform the work, he should not undertake the service." Degen v. Steinbrink. 202 App. Div. 477, 481, 195 N. Y. S. 810, 814 (1922), aff'd mem., 236 N. Y. 669 142 N. E. 328 (1923).
References

To the Editor:

The vehement and emotional reaction of the editorial staff of The New York Times to the publication "Toward Healthful Diets," which was released last week by the Food and Nutrition Board of the National Research Council/National Academy of Sciences, verges on the hysterical.

The board had the temerity to conclude that, because the scientific evidence was inadequate, it could not propose a general recommendation concerning consumption of cholesterol for the U.S. population as a whole. Both the American Medical Association and the Canadian Health Protection Branch reached this conclusion three years ago. The board also concluded that it was inappropriate to make a general recommendation concerning fat consumption for the public at large. It suggested instead that recommendations with regard to fat consumption should be made specifically for different age and population groups.

A June 3 editorial condemned the board for not endorsing the view that a recommendation to reduce consumption of cholesterol and fat is an appropriate public policy action for lowering the incidence of chronic degenerative diseases. Has the board been subjected to this coercive attack because it has had the effrontery to disagree with the established opinions of the editors? Are we to assume that The Times does not condone differences of scientific opinion?

Discovery of new scientific knowledge depends upon the freedom of scientists to evaluate as critically as possible information that may be used as the basis for establishing public policy, regardless of the coercion that may be exerted to inhibit such efforts. It is a responsibility of the communications media to provide the public with as objective and unbiased an analysis of the news as is possible.

In moments when I reflect on the emotional and vituperative reaction to the board's report, I recall that after the Nazi occupation of the Netherlands in World War II the Dutch Medical Association was asked to add only a few words to the oath required of physicians: Their obligation to "restore the individual to health" was to become an obligation to "restore the individual to health and the ability to work." They recognized the implications of this request and that acceptance of it would destroy their integrity. They refused and were persecuted.

I hope that future Food and Nutrition Boards will resist efforts to coerce them into conformity and will stand firm against attacks on their integrity by powerful representatives of the press.

(Prof.) ALFRED E. HARPER, University of Wisconsin-Madison. The writer is chairman of the Food and Nutrition Board.

(Reprinted from The New York Times, June 16, 1980.)
**III. NUTRITION FACTS**

**What Is A Vitamin?**

A *Vitamin* is a chemical compound that the human body needs in small amounts. Vitamins make up one of the major groups of *nutrients* (food substances necessary for growth and health). Vitamins regulate chemical reactions by which the body converts food into energy and living tissues. There are 13 vitamins. The body produces only 5 of them itself, and it does not make these vitamins in sufficient quantities to meet its needs, with the possible exception of biotin, pantothenic acid and vitamin K, which are made by bacteria in the human intestine. Therefore, vitamins must be supplied in a person’s daily diet.

Each vitamin has such specific uses that one of the compounds cannot replace, or act for, another. But the lack of one vitamin can interfere with the function of another. The continued lack of one vitamin in an otherwise complete diet results in a *vitamin deficiency disease*. Such diseases include beriberi, pellagra, rickets, or scurvy. Investigators first discovered vitamins while searching for the causes of such diseases. In order to be considered a vitamin, a substance must be required in the diet to prevent a deficiency disease.

The best way for a healthy individual to obtain vitamins is to eat a balanced diet. A daily diet that includes a variety of foods from each of the basic food groups provides an adequate supply of all the vitamins. A *Recommended Dietary Allowance* (RDA) has been established for most vitamins. In order to provide a margin of safety, the RDA is considerably greater than the amount of a vitamin needed daily for good health. The RDA was established by the Food and Nutrition Board of the National Research Council. The council is a branch of the National Academy of Sciences, which serves as a scientific adviser to the United States government.

Some people take daily vitamin supplements, mostly in the form of vitamin tablets. Most supplements contain doses of one or more vitamins in the range of their RDA’s. The vitamins in such preparations are equivalent to those in food. But a person who eats a balanced diet has no need for daily supplements.

A person with a vitamin deficiency disease may be helped by taking one or more preparations that contain large doses of a certain vitamin or of a combination of several vitamins. But individuals should use such preparations only if they are prescribed by a physician. Self-diagnosis and treatment with *megadoses* (doses ten or more times larger than the RDA) can be dangerous.

**Kinds of Vitamins**

The 13 vitamins are vitamins A; B complex, which is actually a group of
8 vitamins; and vitamins C; D; E; and K. Scientists divide vitamins into two general groups, fat-soluble vitamins and water-soluble vitamins. The fat-soluble vitamins—vitamins A, D, E, and K—dissolve in fats. The water-soluble vitamins—the B-complex vitamins and vitamin C—dissolve in water.

Vitamin A, also called retinol, occurs naturally only in animals. Egg yolk, liver, and milk provide much vitamin A. Some plants contain substances called carotenes, or provitamins A, which the body converts into vitamin A. These plants include cantaloupes, carrots, sweet potatoes, and green and yellow vegetables.

Vitamin A is essential for the development of babies before birth and the growth of children. It is especially needed for the growth of bones and teeth. Vitamin A keeps the skin healthy and helps produce mucous secretions that build resistance to infection. People who do not get enough vitamin A may develop a condition called xerophthalmia, in which the surface of the eye becomes dry and likely to develop infection. Vitamin A also forms part of the two pigments that help the eyes to function normally in light that varies in intensity. Night blindness is an early symptom of a deficiency of vitamin A.

Vitamin B Complex was first believed to be only one vitamin. Researchers later discovered that it consists of eight vitamins—thiamine, riboflavin, niacin, B₆, pantothenic acid, biotin, B₁₂, and folic acid.

Thiamine, or vitamin B₁, prevents and cures beriberi, a disease of the nervous system. It contains sulfur and nitrogen. Sources of thiamine include green vegetables; meat, especially pork; nuts; soybeans; yeast; and whole-grain and enriched breads and cereals. This vitamin, like vitamin A, is needed for growth. The body also needs thiamine to change carbohydrates into energy.

Riboflavin, or vitamin B₂, is most abundant in such foods as eggs, fish, liver, milk, poultry, yeast, and green and leafy vegetables. Direct sunlight destroys riboflavin in milk. This vitamin is needed for growth and for healthy skin and eyes. It promotes the body's use of oxygen in converting food into energy. If a person does not get enough riboflavin, cracks may develop in the skin at the corners of the mouth. The person also may have inflamed lips and a sore tongue, and scaly skin around the nose and ears. The eyes may become extremely sensitive to light.

Niacin, or nicotinic acid, helps prevent pellagra. The best sources of niacin are fish, green vegetables, lean meat, poultry, and whole-grain and enriched bread and cereal. Milk and eggs, even though they have little niacin, are good pellagra-preventive foods because they contain tryptophane, an amino acid. The body converts some tryptophane into niacin.

Niacin is essential for growth, for healthy tissues, and for the conversion of carbohydrates into energy. It also helps produce fats in the body. With-
out niacin, thiamine and riboflavin cannot function properly. A person who
does not get enough niacin may develop ailments of the skin and of the
digestive and nervous systems.

**Vitamin B₆, Pantothenic Acid, and Biotin.** A deficiency of these vitamins
has never been reported in people who have a healthful diet. Vitamin B₆, or
pyridoxine, helps the body use amino acids. Lack of this vitamin damages
the skin and nervous system. Pantothenic acid is converted by the body into
coenzyme A, a vital substance that helps the body produce energy from
food. Biotin helps the body change fats into fatty acids, which also aid in
producing energy.

**Vitamin B₁₂ and Folic Acid.** Vitamin B₁₂, or cyanocobalamin, contains co­
balt and is essential for the normal functioning of folic acid, also called
folacin. Vitamin B₁₂ and folic acid are necessary for the production of de­
oxynucleic acid (DNA) in the body’s cells. DNA carries the “master plans” that govern each cell’s activities. A deficiency of either vitamin B₁₂
or folic acid produces anemia. Physicians may advise a pregnant woman to
supplement her diet with folic acid to prevent anemia. Doctors inject min­
ute amounts of vitamin B₁₂ to treat persons with pernicious anemia. Lack of
vitamin B₁₂ also damages the nervous system.

Eggs, liver, milk, and other animal sources of proteins, as well as some
microbes, supply vitamin B₁₂. People who eat only vegetables may lack this
vitamin. Almost all uncooked foods contain folic acid, but cooking destroys
varying amounts of it.

**Vitamin C, or ascorbic acid.** Physicians call vitamin C the antiscorbutic
vitamin because it prevents and cures scurvy. The body stores little vitamin C,
and so this vitamin must be supplied daily in the diet. Good sources of it
include cantaloupe, citrus fruits, raw cabbage, strawberries, and tomatoes.
Vitamin C is essential for healthy blood vessels, bones, and teeth. People who
lack this vitamin may have sore gums and suffer bleeding under the skin.
Vitamin C also helps form collagen, a protein that holds tissues together.

**Vitamin D helps prevent rickets.** Either a deficiency or an excess of this
vitamin can seriously affect the bones. There are several forms of vitamin
D. One form, calciferol, or vitamin D₂, is produced in plants. It is produced
from a sterol, a type of chemical compound, when a plant is exposed to
ultraviolet light. Another form, cholecalciferol, or vitamin D₃, occurs in the
tissues of animals, including human beings. It has been called the “sunshine
vitamin” because it forms in the skin when the body is exposed to sunlight.
Fish-liver oils contain large amounts of vitamin D₃, and manufacturers may
enrich milk and other animal food products with this vitamin.

**Vitamin E, or tocopherol, helps protect polyunsaturated fatty acids in cell
membranes and elsewhere in the body against oxidation.** Vitamin E thus
plays an important role in maintaining cell membranes, which contain sub-
## VITAMINS ESSENTIAL FOR HUMAN HEALTH

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>What It Does</th>
<th>Recommended Dietary Allowance</th>
<th>Adults</th>
<th>Children (ages 1-14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (retinol)</td>
<td>Helps maintain skin, eyes, urinary tract, and lining of the nervous, respiratory, and digestive systems. Needed for healthy bones and teeth.</td>
<td>Sweet potatoes, milk, liver, fish liver oils, eggs, butter, green and yellow vegetables.</td>
<td>1000 mcg R.E. (men) 800 mcg R.E. (women)</td>
<td>400-1000 mcg R.E.</td>
</tr>
<tr>
<td>Thiamine (B₁)</td>
<td>Needed for carbohydrate metabolism and release of energy from food. Helps heart and nervous system function properly.</td>
<td>Yeast, meat, whole-grain and enriched breads and cereals, nuts, peas, potatoes, most vegetables.</td>
<td>1.2-1.4 mg (men) 1.0-1.1 mg (women)</td>
<td>0.7-1.4 mg</td>
</tr>
<tr>
<td>Riboflavin (B₂)</td>
<td>Helps body cells use oxygen. Promotes tissue repair and healthy skin.</td>
<td>Milk, cheese, liver, fish, poultry, green vegetables.</td>
<td>1.4-1.7 mg (men) 1.2-1.3 mg (women)</td>
<td>0.8-1.6 mg</td>
</tr>
<tr>
<td>Niacin (nicotinic acid)</td>
<td>Essential for cell metabolism and absorption of carbohydrates. Helps maintain healthy skin.</td>
<td>Liver, yeast, lean meat, whole-grain and enriched breads and cereals.</td>
<td>16-19 mg N.E. (men) 13-14 mg N.E. (women)</td>
<td>9-18 mg N.E.</td>
</tr>
<tr>
<td>B₆ (pyridoxine)</td>
<td>Needed for healthy teeth and gums, blood vessels, nervous system, and red blood cells.</td>
<td>Yeast, whole-grain cereals, meat, poultry, fish, most vegetables.</td>
<td>2.0-2.2 mg (men) 2.0 mg (women)</td>
<td>0.9-1.8 mg</td>
</tr>
<tr>
<td>Pantothenic Acid</td>
<td>Helps the body convert carbohydrates, fats, and proteins into energy.</td>
<td>Egg yolk, meat, nuts, whole-grain cereals.</td>
<td>4.0-7.0 mg*</td>
<td>3.0-7.0 mg*</td>
</tr>
<tr>
<td>Vitamin</td>
<td>Description</td>
<td>Foods</td>
<td>R.D.A.</td>
<td>Estimated Safe and Adequate Dietary Intake</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
<td>-------</td>
<td>--------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>B12</td>
<td>Essential for proper development of red blood cells. Helps proper function of nervous system.</td>
<td>Eggs, meat, milk, milk products.</td>
<td>3.0 mcg</td>
<td>2.0-3.0 mcg</td>
</tr>
<tr>
<td>Biotin</td>
<td>Needed for healthy circulatory system and for maintaining healthy skin.</td>
<td>Egg yolk, nuts, liver, kidney, most fresh vegetables, made by intestinal bacteria.</td>
<td>100-200 mcg*</td>
<td>65-200 mcg*</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>Needed for production of red blood cells.</td>
<td>Green leafy vegetables, yeast, meat, poultry, fish.</td>
<td>400 mcg</td>
<td>100-400 mcg</td>
</tr>
<tr>
<td>C (ascorbic acid)</td>
<td>Essential for sound bones and teeth. Needed for tissue metabolism and wound healing.</td>
<td>Citrus fruits, tomatoes, raw cabbage, potatoes, strawberries, cantaloupe.</td>
<td>60 mg</td>
<td>45-50 mg</td>
</tr>
<tr>
<td>D</td>
<td>Essential for calcium and phosphorus metabolism.</td>
<td>Fish liver oils, fortified milk, eggs, tuna, salmon, sunlight.</td>
<td>5-10 mcg</td>
<td>10 mcg</td>
</tr>
<tr>
<td>E (tocopherol)</td>
<td>Helps prevent the oxidation of polyunsaturated fatty acids in cell membranes and other body structures.</td>
<td>Whole-grain cereals, lettuce, vegetable oils.</td>
<td>10 mg T.E. (men) 8 mg T.E. (women)</td>
<td>5-8 mg T.E.</td>
</tr>
<tr>
<td>K</td>
<td>Needed for normal blood clotting.</td>
<td>Leafy vegetables; made by intestinal bacteria.</td>
<td>70-140 mcg*</td>
<td>15-100 mcg*</td>
</tr>
</tbody>
</table>

mcg = micrograms; mg = milligrams; R.E. = retinol equivalents; N.E. = niacin equivalents; T.E. = tocopherol equivalents

*Estimated Safe and Adequate Dietary Intake. Because there is less information on which to base allowances, these figures are not classified as RDA's. Bacteria in the human intestine make substantial amounts of this vitamin, and we probably absorb a major part of our daily need for this vitamin from this source.

stantial amounts of polyunsaturated fatty acids. The best sources of vitamin E are lettuce and wheat-germ oil. Meat, milk, eggs, liver, whole-grain cereals, and most vegetables also contain this vitamin. A deficiency of vitamin E occurs rarely and produces few symptoms.

**Vitamin K** is essential for blood clotting. Green leafy vegetables, such as cabbage, cauliflower, kale, and spinach, are rich in Vitamin K. Pork liver is also an excellent source. Intestinal bacteria manufacture vitamin K in the body, and so deficiencies of this vitamin rarely result from a poor diet. Doctors sometimes give women vitamin K before childbirth to prevent bleeding in the newborn baby. Babies do not have enough intestinal bacteria to produce adequate amounts of the vitamin until they are about 2 weeks old.

**How Vitamins Work**

Vitamins function as *catalysts* in the body. A catalyst is a substance that increases the speed of a chemical reaction without being consumed by the reaction. Vitamins help accelerate certain chemical reactions that are essential for health. Without vitamins, these reactions would occur very slowly or not at all.

Most vitamins play the role of either enzymes or organic compounds called *coenzymes*. Enzymes are catalysts that contain protein and regulate certain body processes. An enzyme alters molecules in the body and combines with the molecules to cause a chemical reaction. The enzyme remains unchanged by the reaction, and so it can repeat the process again and again.

Some vitamins occur in inactive forms that do not influence chemical reactions. The body converts such vitamins into their active forms. Vitamin D is unique because it functions not only as a vitamin, but also as a "chemical messenger," or hormone.

**History**

Such nutritional diseases as beriberi, pellagra, rickets, and scurvy have been known for centuries. But the idea that they might result from a dietary deficiency is comparatively new. One of the first persons to study the effect of diet on human health was James Lind, a Scottish physician. As early as the 1740's, Lind used lemons and oranges to cure scurvy in sailors, who rarely ate fresh fruits on long voyages. In 1882, a Japanese physician named Kanehiro Takaki cured beriberi among naval crews by adding meat and vegetables to their diet of rice. Christiaan Eijkman, a Dutch scientist, studied beriberi in the Dutch East Indies (now Indonesia). About 1900, he showed that people who ate *polished rice* (rice with the hulls removed) developed the disease. Those who ate whole rice, including the hull, did not. Eijkman concluded that rice hulls contained an *antiberiberi factor* that was essential for health.

In 1912, a Polish biochemist, Casimir Funk, tried but failed to extract the
What is a Vitamin?

pure antiberiberi factor from rice hulls. Funk thought the substance belonged to a group of chemical compounds called amines, and he named it vitamine, meaning amine essential to life. Meanwhile, research on the effect of diet on the growth of rats was published in 1906 by the British biochemist Frederick G. Hopkins. He demonstrated that certain foods contain substances that are vital for the growth and development of the body. Hopkins called these substances “accessory food factors,” to distinguish them from the well-established “basic food factors”—carbohydrates, fats, proteins, minerals, and water. Later, the word vitamin (with the e dropped) came to be used for all such accessory substances. Together, Hopkins and Funk developed the vitamin theory of deficiency disease.

At first, scientists thought there were only two vitamins, a fat-soluble one and a water-soluble one. By 1922 the American biochemist Elmer V. McCollum had proved that the fat-soluble vitamin actually consisted of a mixture of vitamins. About the same time, Joseph Goldberger, an American physician, showed that the water-soluble vitamin was also a mixture. Since then, vitamins of both types have been identified. Although it is possible that more may be discovered, none of the compounds proposed as vitamins since 1948, when vitamin B₁₂ was isolated, has met the required scientific qualifications.

In Defense of the Cholesterol Report


by VICTOR HERBERT

An article in the June 29, 1980, New York Times by Charles E. Rodgers Jr. described his confusion after the “bombshell” when “the National Academy of Sciences announced it found no reason for anyone to cut down on cholesterol.” That statement made clear to me that, like most people who have commented in print about the document, “Toward Healthful Diets,” Mr. Rodgers had not read the report but had simply read the misrepresentations of its content by 90 percent of the news media.

When I became a member of the Food and Nutrition Board of the National Academy of Sciences a year ago, “Toward Healthful Diets” was already in its seventh rough draft, and we put it through three more careful evaluations before all 15 of us agreed to every facet of the wording. After that it was sent to outside experts for review, in accordance with National Academy of Sciences policy, and only then was it published.

Cholesterol is a fatty substance found in all animals but not in plants, and it is therefore in most food derived from animals. Cholesterol is an important component of the walls of nearly all the cells of the human body. The body also uses cholesterol to make male and female sex hormones, and the brain is particularly rich in cholesterol.

“Toward Healthful Diets” makes a careful distinction between blood serum cholesterol and food cholesterol, a distinction the media have largely ignored. It is high serum cholesterol that is associated with increased risk of heart disease, although we do not know the reasons for this association.

Food cholesterol is not a risk factor for heart disease in an individual whose serum cholesterol is normal. However, what is a normal serum cholesterol for one person is high for another. When one considers cholesterol in food, it is necessary to be aware of the fact that food contains many substances other than cholesterol that can affect the
serum cholesterol level. For example, whole milk contains cholesterol, and yet if you drink whole milk, your serum cholesterol falls rather than rises. The reason for this is believed to be that whole (and skim) cow milk contains two substances that reduce the production of cholesterol by the human liver to such an extent that they more than counterbalance the amount of cholesterol absorbed.

As we pointed out in our report, Americans eat an average of 450 milligrams of cholesterol a day, with a range in American diets of 200 to 1,500 milligrams of cholesterol daily. We also pointed out that the human body makes between 800 and 1,500 milligrams of cholesterol a day.

People fall into three categories with respect to cholesterol synthesis in their own bodies. Some have a "thermostatic control," which reduces their cholesterol synthesis in exact proportion to the amount of cholesterol absorbed from their diet, with the result that their serum cholesterol changes not one iota because of cholesterol in the diet. At the other extreme are people with no "thermostatic control" at all, so that all the cholesterol absorbed from their diet increases the total body cholesterol burden. These are the people at greatest risk from cholesterol in their diet. The majority of people are between these two extremes in the ability of their livers to reduce production of cholesterol in response to cholesterol absorbed from the diet.

Another factor which must be taken into account is that only 10 percent to 50 percent of the cholesterol in the diet is absorbed. Various substances in the diet, such as certain forms of fiber, bind cholesterol so that it cannot be absorbed, and carry it out as body waste.

Yet another factor which must be considered is that prospective epidemiologic studies by Dr. Abraham Kagan and associates of the John A. Burns School of Medicine of the University of Hawaii and by Dr. Mario Garcia-Palmieri of San Juan, P.R., and Dr. R. Beaglehale and associates of New Zealand suggest that a low serum cholesterol is associated with an increased frequency of cancer. This is probably coincidence rather than cause and effect. As we also pointed out, there is some laboratory evidence that polyunsaturated fats can promote the development of certain laboratory cancers.

The path of rational scientific judgment appears to be to recommend moderation and variety in diet, and that is exactly what "Toward Healthful Diets" recommends. This recommendation of moderation and variety as the keys to healthful diets is identical to the statement on page 3 of the Dietary Guidelines for Americans published by the United States Department of Health and Human Services and the United States Department of Agriculture earlier this year.

In his article on cholesterol in diets, Mr. Rodgers has attempted to draw conclusions from quotations (and, in the case of the National Academy of Sciences, misquotations) of conclusory statements from various authorities. Conclusory statements are worthless as evidence; it is the underlying facts which led to the conclusory statements which must be weighed to make an intelligent judgment.

Intelligent judgment, based on the underlying facts, requires that you know the underlying facts. For each individual, one basic underlying fact is his serum cholesterol level. If you have not yet had it measured, and you are worried about cholesterol, you should have that measurement made and interpreted for you in the context of other laboratory tests and of a complete physical examination by a physician respected by both you and his or her colleagues. With that information, that physician can tell you that you do or don't need a low-cholesterol diet.

Victor Herbert, M.D., is Professor of Medicine at the State University of New York's Downstate Medical Center in Brooklyn and Chief of the Hematology and Nutrition Laboratory of the Veterans Administration Medical Center in the Bronx. He lives in Scarsdale.
Water Soluble Vitamins: Diagnosing Deficiencies

There are nine water soluble vitamins: vitamin C and the eight B vitamins (thiamine, riboflavin, niacin, vitamin B₆, vitamin B₁₂, folic acid, pantothenic acid, and biotin).¹⁻⁶ These nine, plus the four fat soluble vitamins A, D, E, K are probably all the vitamins that exist for humans; the last vitamin (B₁₂) was discovered in 1948, and not only have the last three decades of intensive research not discovered new ones, but patients have now lived quite well for years on total parenteral nutrition (i.e., intravenous solutions containing the known nutrients) without developing any deficiency state which would suggest the existence of any vitamin in addition to the known thirteen (unless it is one made in adequate quantities by bacteria in the human intestine⁷). In addition to the thirteen vitamins for humans, there are substances which are growth factors (vitamins) for bacteria and some other forms of life, but not for humans. These substances include PABA (para-aminobenzoic acid), bioflavonoids ("vitamin P")—including hesperidin, choline, inositol, lipoic acid, and ubiquinone. Some are not needed at all by humans. Others are made in the human body as needed. Far from being of value to humans (other than as the active ingredient in some sun-screen lotions), PABA, as a growth factor for microorganisms, can harm patients by reversing the anti-bacterial action of sulfonamides, and some bioflavonoids contain quercetin, a mutagen. Of the two essential fatty acids, linoleic acid must be supplied in the diet, but arachidonic acid can be formed from linoleic acid.¹

Because of the prevalence of megavitamin cultism and the power of megavitamin industry propaganda involving millions of gullible Americans, adequate nutrition assessment now requires evaluation by diet and symptom history, physical examination and laboratory testing for vitamin excesses and undesirable effects⁷ and for vitamin deficiencies and their undesirable effects.

In addition to the basic sources for information on assessing nutritional status cited above,\(^1\text{-}^5\) the April 1979 "Special Issue on Nutrition of the *Journal of the Florida Medical Association* contains a number of articles relating to nutritional assessment, particularly those by Christakis\(^8\) and Kafatos.\(^9\)

Particularly useful is Christakis'\(^8\) delineation of the specific questions that should be asked when taking a diet history, his table of questions which should be asked in symptom history, his table of the physical signs of nutrient deficiencies, and his table of current guidelines of the significance of laboratory test results when evaluating for nutrient deficiencies.

**VITAMIN C**

**Diet history:** Citrus fruits provide about a quarter of the vitamin C in the American diet, other fruits about 10%, potatoes almost 20%, dark green and deep yellow vegetables about 10%, and other vegetables about 25%.\(^4\) Thus, ascorbic acid deficiency is highly unlikely in anyone eating a minimum of one serving daily of a fruit or vegetable, particularly if the serving is fresh. In the United States, vitamin C deficiency is seen almost exclusively in infants fed diets deficient in ascorbic acid (such as diets exclusively of cow milk) and in adults in association with poverty, alcoholism, famine, and nutritional ignorance.\(^1\) Sellers of unneeded vitamin C supplements justify themselves by referring to the fact that the 1965 U.S. Department of Agriculture Household Food Consumption Survey showed that 13% of the households surveyed had diets providing less than two-thirds of the Recommended Dietary Allowance (RDA) for vitamin C\(^10\), and the 1971-72 U.S. Health and Nutrition Examination Survey (HANES)\(^11\) suggested this figure might be as high as 38% of American diets. However, the RDA for ascorbic acid is 60 mg,\(^*\) two-thirds of that is 40 mg, and a daily intake of 10 mg is sufficient to alleviate and cure the clinical signs of scurvy in human subjects.\(^1\) Similarly deceptive and misleading is the claim by purveyors of vitamin C supplements that the lowering of vitamin C plasma levels by smoking\(^4\) means supplements are needed. In fact, no case has yet been reported of any individual who ate daily one fruit or vegetable and yet developed scurvy because he smoked. The effectiveness of the purveyors of vitamin C supplements in inducing millions of Americans to take unnecessary megadoses of vitamin C now requires us as part of the diet history to ask the patient whether he or she is taking any vitamin C supplements daily and, if so, in what quantity.

**Symptom History and Physical Examination for Signs:** Scurvy is the result of inadequate intake of vitamin C, and a similar phenomenon, "rebound scurvy," can occur on the sudden discontinuance of megadoses of vitamin C.\(^5,12\) The symptoms are those of weakness, lassitude, irritability,

\(^*\)60 mg in the 1968 and 1980 RDA, producing almost complete saturation of body stores.
and occasional vague aches and pains in joints and muscles. The signs are those of bleeding brought about by unknown factors. Traditional views hold that bleeding results from weakening of the intercellular cement known as collagen, since ascorbic acid is necessary for normal collagen formation. Widespread capillary hemorrhaging may occur. The characteristic lesion is the perifollicular hemorrhage surrounding a hyperkeratotic hair follicle; when the keratin plug is lightly scraped away, a corkscrew-shaped hair springs into view. There may hemorrhagic spongy gums, subperiosteal hemorrhages, diffuse ecchymoses, and even hematuria. In childhood, there is impaired growth and deformity, and at all ages there is impaired wound healing and decreased resistance to infection. Blood clotting studies are usually normal in patients with scurvy. Electron microscopy of skin and subcutaneous tissues fails to show disruption of capillary endothelium. Hence the intracellular cement theory may not explain the bleeding.

**Laboratory Testing for Vitamin Levels and Vitamin Function:** Although serum (or plasma) levels of ascorbic acid are most commonly used for determining vitamin C nutritional status, such levels are unreliable for diagnosing vitamin C deficiency since it becomes negligible long before tissue deficiency is present. Assay of the ascorbic acid content of the “buffy coat” (white blood cell and platelet layer) of anticoagulated centrifuged whole blood is more helpful, with the normal level being 20-30 mg per 100 ml, falling to below 2 mg per 100 ml in deficiency. Accurate delineation of nutritional stores of vitamin C can only be measured using radioactively labelled L-ascorbic acid which is ingested or injected, after which the body pool size is estimated by determining the specific radioactivity in plasma or blood, with determination of the daily rate of urinary excretion of radioactivity to estimate the rate of catabolism of ascorbic acid. Although smokers have lower mean “buffy coat” vitamin C levels than non-smokers, the levels of smokers remain more than ten-fold those of persons with vitamin C deficiency, and provide no legitimate basis for recommending that smokers take vitamin C supplements, if they eat a balanced diet.

Most of the “bleeding gums” syndromes in the United States are in people who are not deficient in vitamin C and whose problem is periodontal and gum disease. The “lingual ascorbic acid test” promoted to dentists as a measure of tissue vitamin C status has not been demonstrated to have any validity, according to Hodges (personal communication). The many articles published on this test by its two main promoters lack adequate comparison with reliable tests of ascorbate status.

---

*A low serum ascorbate merely means negative balance, not deficiency. Low cell ascorbate means deficiency.*
THIAMINE (VITAMIN B₁)

Diet History: Thiamine deficiency is unlikely unless there is a history of polished rice as the staple cereal in the diet, or a history of chronic alcoholism or generalized intestinal malabsorption. Sources of the vitamin include yeast, wheat, whole-grain and enriched breads and cereals, nuts, peas, potatoes and most vegetables. Daily ingestion of one or more servings of grains usually rules out thiamine deficiency. The RDA for adults is 1.2-1.5 mg for men and 1.0-1.1 mg for women.¹

Symptom History: The classic syndrome of thiamine deficiency is beri-beri, manifest in its mildest stages with peripheral neuritis ("dry beri-beri"), and in its later stages as "wet beri-beri," with edema and cardiac failure of the high output type. Severe deficiency is often associated with Wernicke's encephalopathy or Korsakoff's syndrome.²,⁵,¹⁶,¹⁷

Physical Examination: Neurologic and cardiac abnormalities, muscle tenderness and atrophy²,⁵,¹⁶,¹⁷ are found.

Laboratory Diagnosis: Measurement of erythrocyte transketolase is the most utilized procedure in the diagnosis of thiamine deficiency, and is sensitive to mild degrees of depletion. Neal and Sauberlich² consider the best methods currently in use to be the erythrocyte transketolase method of Brin as modified by others, and the urine thiamine measurement with the modified thiochrome procedure of Hennessy and Cerecedo.

RIBOFLAVIN (VITAMIN B₂)

Diet History: Dairy foods and animal protein are the main sources of riboflavin, so a diet history indicating daily ingestion of a portion of a dairy food or of another animal protein source would essentially eliminate riboflavin deficiency as a possibility. Conversely, absence of all animal protein from the diet would make riboflavin deficiency a distinct possibility. The vitamin is abundant in eggs, fish, liver, milk, poultry, yeast, and green and leafy vegetables. The RDA of riboflavin is 1.5-1.8 mg for men and 1.1-1.4 mg for women.¹

Symptoms and Signs of Deficiency: Ariboflavinosis is characterized by a syndrome of angular stomatitis, glossitis, seborrheic dermatitis about the face (particularly the nose) and the trunk and extremities (particularly the scrotum), and sometimes vascularization of the cornea. Riboflavin deficiency usually occurs with other nutrient deficiencies, and the stomatitis as well as the anemia and neuropathy sometimes present may be due, in part or completely, to these other nutrient deficiencies.¹⁶,¹⁷
Water Soluble Vitamins

Laboratory Diagnosis: The two most commonly used measures of riboflavin status are urinary excretion of riboflavin (which correlates with dietary intake), and erythrocyte glutathione reductase activity, which is a functional test of nutritional adequacy with respect to riboflavin.\textsuperscript{14} Sauberlich et al. have proposed the use of riboflavin load tests and measurement of blood riboflavin levels, but these procedures require further evaluation.\textsuperscript{14}

NIACIN (NICOTINIC ACID AND NICOTINAMIDE)

Diet History: Meats and grains are the main sources of niacin, with the exception of corn (maize), because this cereal grain has not only a low tryptophan content but also a low niacin content but also a low tryptophan content, and the body is able to convert some tryptophan into niacin.\textsuperscript{1-2,16} Sixty mg of tryptophan is defined as equivalent to 1 mg of niacin; the RDA for males is 16-20 and for females 12-16 mg of niacin or niacin equivalents per day.\textsuperscript{1,16} Niacin deficiency is unlikely unless the history is of a diet exclusively of corn or mainly of pork fat and hominy grits (made from degenerated corn) or of Indian jowar (millet, Sorghum vulgara), so deficiency in the United States is seen almost exclusively in alcoholics.\textsuperscript{16}

Symptoms and Signs: Pellagra is the clinical syndrome of niacin deficiency. The early signs include lassitude, anorexia, weakness, digestive disturbances, anxiety, irritability, and depression. As the deficiency progresses, chronic dermatitis occurs, with thickening, scaling, hyperkeratinization, and pigmentation. The mucous membrane inflammation is manifest as glossitis, stomatitis, esophagitis, diarrhea, urethritis, proctitis, and vaginitis. The tongue may be scarlet and swollen with papillary atrophy. There may be severe weight loss, and disorientation, delirium, dementia, and hallucinations.\textsuperscript{16}

Laboratory Diagnosis: Although appreciable amounts of nicotinic acid are present in white cells and red cells, measurement of the vitamin level in these blood components has not yet been demonstrated to be a reliable and satisfactory method for evaluating niacin status.\textsuperscript{14} Sauberlich and associates have assessed niacin status by measuring two major metabolites of nicotinic acid in the urine, namely, N\textsuperscript{1}-methyl-nicotinamide and N\textsuperscript{1}-methyl-2-pyridone-5-carboxylamide (2-pyridone), and by use of the excretion ratio of these two metabolites.\textsuperscript{14} The ratio of the latter to the former is 1.3 or more to 1 under normal conditions, with a ratio of less than 1 indicating latent niacin deficiency.\textsuperscript{14}

VITAMIN B\textsubscript{6} (PYRIDOXINE, PYRIDOXAL, PYRIDOXAMINE)

Diet History: In the American food supply, meat, poultry and fish account for about half the available vitamin B\textsubscript{6}, potatoes and vegetables about a quarter, dairy products about 10%, and grains about 10%.\textsuperscript{4} Because of these main sources of the vitamin, vitamin B\textsubscript{6} deficiency has not been clearly defined as a problem attendant upon poor nutrition, although there
are a number of special situations in which an inadequate vitamin B₆ state has been implicated.¹ These special situations include the use of drugs which antagonize vitamin B₆, such as isonicotinic acid hydrazide (INH) used in the treatment of tuberculosis, and penicillamine, used in the treatment of Wilson's disease and of cystinuria.²,⁴

**Signs and Symptoms:** A syndrome of nervous irritability and convulsive seizures, along with anemia, vomiting, weakness, ataxia, and abdominal pain was reported in infants receiving a commercial formula in which the pyridoxine was inadvertently destroyed during the processing of the milk; these convulsive seizures responded dramatically to administration of pyridoxine.⁴ No clear-cut symptoms of pyridoxine deficiency occurred in college students given a vitamin B₆ deficient diet for seven weeks, despite biochemical (laboratory) evidence of deficiency.⁴ However, when the B₆ antagonist deoxypyridoxine was added to the deficient diet, facial seborrheic dermatitis appeared, which was counteracted by the vitamin.⁴

**Laboratory Diagnosis:** Vitamin B₆ levels fall rapidly in plasma and red cells during depletion and rise following supplementation; measurements of pyridoxal phosphate in serum and red cells have been used to evaluate vitamin B₆ status.¹⁴

Increased excretion of various metabolites of tryptophan after a tryptophan load test occur when tissues are not saturated with vitamin B₆; a number of these are measured as indices of B₆ deficiency. Xanthurenic acid is easiest to measure, but the results of these tests have to be interpreted with caution because of many interrelated metabolic and hormonal factors other than B₆ status involved in tryptophan metabolism.¹⁴ Urinary excretions of less than 20 µg of B₆ per gram of creatinine have been considered indicative of marginal or inadequate dietary intakes of vitamin B₆ by Sauberlich et al.¹⁴

Measurements of erythrocyte transaminases (EGOT, erythrocyte aspartate aminotransferase, and EGPT, erythrocyte alanine aminotransferase), are tests of biochemical functional status with respect to B₆, but considerable individual variation occurs in normal subjects with or without addition of pyridoxal phosphate, and these tests need further evaluation.¹⁴

Although some of the above tests provide results which are considered abnormal and which correct with vitamin B₆ administration in women taking oral contraceptives, there is considerable question as to whether vitamin B₆ supplementation for women taking oral contraceptives has any physiologic benefit.¹,¹⁸

**VITAMIN B₁₂**

**Diet History:** Vitamin B₁₂ is found only in animal protein and the microorganisms which synthesize the vitamin. Thus, a diet history of strict vegetarianism (a diet devoid not only of meat, fish, and fowl, but also of milk products) should trigger the probability of vitamin B₁₂ deficiency.
Symptoms and Signs: The clinical picture is primarily of slowed DNA synthesis, resulting in ineffective hematopoiesis (with anemia, leucopenia, and thrombocytopenia) and inadequate myelin synthesis resulting in deterioration of myelinated nerves.\textsuperscript{2,16}

Laboratory Diagnosis: A low serum vitamin $B_{12}$ level is diagnostic for deficiency.\textsuperscript{16} This assay may be carried out either microbiologically or using radioassay, provided that the binder used in the radioassay is specific for vitamin $B_{12}$ rather than being a non-specific binder for all corrin nuclei.\textsuperscript{19,20} A high urinary excretion of methylmalonic acid occurs in vitamin $B_{12}$ deficiency, but the procedure is more complicated and less useful than direct determination of the serum vitamin $B_{12}$ level.\textsuperscript{14} Since heating vitamin $B_{12}$ in the presence of a megadose of ascorbic acid and in the absence of a protective agent such as cyanide may destroy the vitamin, when a low serum $B_{12}$ level is reported in the absence of clinical evidence of vitamin $B_{12}$ deficiency, it should be ascertained whether the patient has been taking megadoses of ascorbic acid.

Abnormal binders for vitamin $B_{12}$ are released into the serum in liver disease and in myeloproliferative disorders, causing the serum $B_{12}$ level to be normal in some patients who actually have tissue depletion. In this circumstance, as well as in instances of selective nutrient deficiency in one cell line and not another, the "dU suppression test" can provide the diagnosis of vitamin $B_{12}$ deficiency.\textsuperscript{21,22}

FOLIC ACID (FOLACIN; FOLATE)

Diet History: Folate is ubiquitous in uncooked foods, and dietary deficiency of the vitamin is not found in persons eating each day one fresh uncooked fruit or vegetable or fresh or fresh-frozen fruit juice. Conversely, deficiency is common in persons whose diet is exclusively of thoroughly-cooked foods, particularly foods consisting of relatively small individual particles, such as beans and rice.\textsuperscript{2,16,23} In addition, many beans may contain a substance activated by heat which inactivates intestinal folate conjugase, thereby reducing the absorbability of food folate which is generally in polyglutamate form.\textsuperscript{23}

Symptoms and Signs: These are due to the ineffective hematopoiesis producing anemia, leucopenia, and thrombocytopenia, and are indistinguishable from the hematologic manifestations of vitamin $B_{12}$ deficiency. The two vitamin deficiencies differ in their clinical presentation in that only vitamin $B_{12}$ deficiency results in damage to myelin and the neurologic damage resulting therefrom; folate deficiency does not damage myelin.\textsuperscript{2,16}

Laboratory Diagnosis: Low levels of both serum and red cell folate are necessary to diagnose folate deficiency. A low serum level occurs long before tissue depletion, and therefore is inadequate to make a diagnosis of defi-
ciency. A low red cell folate by itself is inadequate to diagnosis folate deficiency since it also occurs in vitamin B₁₂ deficiency (vitamin B₁₂ is necessary for folate to get across cell walls and be retained within the red cell).¹⁶

In liver disease and myeloproliferative disorders, serum folate may be kept in the normal range despite tissue depletion due to release into the serum of folate binding proteins. In such a circumstance, as well as in other situations (such as iron deficiency and selective nutrient deficiency in one cell line and not another), serum and red cell folate may be normal despite deficiency of the vitamin in other tissues, and the diagnosis of such deficiency can then be made by the "dU suppression test" using peripheral blood lymphocytes.¹⁶,²¹-²³

**PANTOTHENIC ACID AND BIOTIN**

Nutritional assessment for these two vitamins is unnecessary since dietary deficiency has never been reported. This is probably not only because of the wide availability of these two vitamins in foods but also because they are both synthesized by bacteria in the human intestine, and there is evidence for absorption of such synthesized vitamin.¹²-⁴ Unless a person is eating a dozen raw egg whites a day (which contain the biotin antagonist avidin), the probability of biotin deficiency is essentially nil.

**References**

Summary of “Nutritional Anemias” (pages 189-198).

The American diet is marginal in absorbable iron content for infants and children under age 5, for children at the growth spurt of puberty, and for women in the child-bearing years. Folate deficiency is common among people not eating each day one fresh or fresh-frozen uncooked fruit or vegetable or fruit juice. Vitamin B₁₂ deficiency is common on a dietary basis only among pure vegetarians (no meat, milk, eggs, etc.). Iron deficiency anemia and folate (folic acid) deficiency anemia are more common in women than men both because of the monthly loss of these two nutrients in blood during the menstrual years and the taking up of these nutrients by the fetus at the expense of the mother during pregnancy. During the menstrual years, because of the monthly blood loss, women have approximately twice the daily iron need of men. For them, the American diet is marginal in iron, and approximately 40-50% of premenopausal women may have iron depletion, and about 15% have iron deficiency anemia. After age 50, only about 13% of women have iron depletion. Iron depletion is present in about 50% of infants, and iron deficiency anemia in about 25%. Iron depletion is present in about 10% of children at the growth spurt of puberty.

Both the Committee on Maternal Nutrition and the Committee on Dietary Allowances of the Food and Nutrition Board, National Research Council (USA) recommend that oral supplements of 0.3 mg folic acid and 30-60 mg of elemental iron should be taken throughout pregnancy. The Committee on Dietary Allowances’ recommendation was that the recommended dietary folate allowance be doubled in pregnancy, up to 800 µg.
daily. Data presented at the Folate Workshop of the Food and Nutrition Board (published 1977) suggest that such an amount could not easily be achieved without supplementation. Oral contraceptives reduce monthly blood loss, thereby reducing the frequency of iron deficiency. The question of whether the existing iron fortification of American flour should be increased (AMA Council on Foods and Nutrition, 1972; Wintrobe, 1973) has been decided in the negative on grounds of inadequate information to make an adequate risk:benefit assessment. In this connection, it should be noted that American breads are now mainly fortified with ferrous sulfate, with a trend to ferrum reductum, and American spaghettis and pastas with the less absorbable ferrous pyrophosphate (Dudley Titus, personal communication). Canada requires that more than 90% of ferrum reductum fortification be the more absorbable less than 10 micron particle size, but the U.S.A. has no size requirements.

Several surveys have shown lower serum and red cell folate in women taking oral contraceptives, but a daily fresh or fresh-frozen uncooked fruit or vegetable, or fruit juice would probably prevent folate deficiency in this group as well as many other groups.
Nutritional Anemias

Anemia is defined as a reduction below normal in the amount of red blood which occurs when the equilibrium between blood production and loss (through bleeding or destruction) is disturbed (Dorland's Medical Dictionary, 1974). By World Health Organization criteria (1968; Baker and DeMaeyer, 1979), anemia is considered to exist when the non-pregnant adult female has a hemoglobin below 12, and the pregnant adult female has a hemoglobin below 11 g/100 ml of venous blood (when at sea level; normal values are higher at higher altitudes). The observations of Scott, Pritchard and associates (1970) indicate that the hemoglobin concentration of healthy, non-pregnant young women without iron deficiency will almost always be 12 g/100 ml or more; that at mid-pregnancy, this value will practically always be at least 10 g/100 ml, but fairly often may be less than 11 g/100 ml; and that late in pregnancy, this figure will almost always be 10 g/100 ml or more, and most often 11 g/100 ml or more, in the absence of iron deficiency. The normal fall of hemoglobin during pregnancy is simply pregnancy hypervolemia (which increases both the plasma and red cell volume, with a greater increase in the former).

Nutritional anemia is defined as a condition in which the hemoglobin content of the blood is lower than normal as a result of deficiency of one or more essential nutrients. To delineate a given anemia as nutritional, two criteria must be met: lack of the nutrient must produce, and providing the nutrient must correct, the anemia. By these two criteria there are only three unequivocal nutritional anemias: those due to lack of iron, folate or vitamin B_{12} (Herbert, 1970). These three anemias reflect an important nutritional problem affecting large population groups, particularly the poverty-stricken and those under metabolic stress.

Iron deficiency and folate deficiency are more common in women because of two forms of metabolic stress peculiar to women: the monthly blood loss in premenopausal women and the drain on maternal nutrient stores imposed by pregnancy. The fetus will take from the mother whatever it needs in order to be normal at birth, even if this produces severe nutrient deficiency in the mother (Committee on Maternal Nutrition, 1970). Since

anemia is a relatively late manifestation of nutritional deficiency, those patients diagnosed as having nutritional anemia are the “tip of the iceberg”; part of a larger group suffering from nutrient depletion of more moderate degree which is not yet manifest by unequivocal anemia.

The metabolic stress of menstrual blood loss is increased by the use of some intrauterine contraceptive devices (Medical Letter, 1974; 1975) and decreased by the use of oral contraceptives (Medical Letter, 1973). In fact, advertising of “unique vitamin-mineral formulas for the special needs of patients taking oral contraceptives” are misleading because it has not been established that there is any such special need (Medical Letter, 1973; Symposium, 1975).

Iron Deficiency Anemia

Fairbanks et al. (1971) tabulated the approximate frequency of iron depletion as 50% of infants, 50% of premenopausal women, and 100% of pregnant women. They tabulated the frequency of iron deficiency anemia (the end product of prolonged negative iron balance) as 25% of infants, 0 to 5% of children (higher frequency in economically deprived children), 15% of premenopausal women, and 30% of pregnant women not receiving iron supplementation.

About one-third to one-half of apparently healthy young American women have laboratory evidence of iron depletion (Monsen et al., 1967; Scott and Pritchard, 1967; Sturgeon and Shoden, 1971). Sturgeon and Shoden (1971) found less than 5 mg of iron/100 g liver tissue in 40% of women age 20 to 50, indicative of iron depletion. This was true of only 13% of women over age 50 (and less than 10% of all men). It should be noted that iron depletion (loss of body iron stores) precedes anemia. While a majority of women who are anemic have iron deficiency, this is not always the case, so self-administration of medicinal iron is unwise, and blanket treatment of every anemic woman with iron, without ascertaining that she does, in fact, have iron deficiency, can do positive harm (for example, in women with sickle cell or other hemolytic anemias with increased iron stores, in whom the giving of iron may produce “iron overload” syndrome). Nevertheless, the incidence of anemia in various groups of American pregnant women has ranged from 10 to 60%, most of which could be prevented by prophylactic iron therapy (AMA Council on Foods and Nutrition, 1968).

Menstrual loss of iron is the main source of the iron losses in non-pregnant women in the fertile age group (Rybo, 1970; Fairbanks et al., 1973). The average menstrual blood loss is about 40 ml/cycle (Fairbanks et al., 1973), representing a loss of about 20 mg of iron per cycle. About 10% of women have menorrhagia, with a blood loss exceeding 80 ml/cycle (Hallberg et al., 1966), making them particularly susceptible to iron deficiency. The use of more than 12 pads during a menstrual period, or the damming up of blood behind tampons, often suggests excessive menstrual bleeding.
Nutritional Anemias

191

(Moore and Dubach, 1956; Fairbanks et al., 1973).

An understanding of the situation of American women with respect to iron balance is more clearly shown in Tables 1 and 2, which present the estimated dietary iron requirements of Americans (Table 1) and the iron requirements of pregnant American women (Table 2). The absorbability of iron from different food sources is highly variable, averaging about 10% of iron in the total diet being absorbed (Layrisse, 1975; Cook, 1978). Therefore, the amount of iron ingested must be ten times the daily requirement, as indicated in Table 1. Since the average American diet provides about 6 mg of iron per thousand kCal (Monsen et al., 1967), iron intake from dietary sources is borderline for teenage girls and women, and may be inadequate for infants and pregnant women (AMA Council on Foods and Nutrition, 1968; Food and Nutrition Board, 1974). Nevertheless, a woman who has sufficient iron stores to provide for her increase in hemoglobin mass during pregnancy, and who breast-feeds her infant for six months (thereby delaying the return of menstruation), will have her iron needs covered by adequate intake of dietary iron (FAO/WHO Expert Group, 1970).

As stated in the footnote to Table 1, the amount of iron required to meet the needs of pregnancy should usually be met by iron supplementation in the latter half of pregnancy, since it cannot usually be derived from diet. The Committee on Maternal Nutrition (1970) recommends supplementation with 30 to 60 mg of iron daily (i.e., 150 to 300 mg of ferrous sulfate) during pregnancy. The physician should use his judgment in this regard, based on knowledge of the patient, the dietary habits, the fact that iron deficiency is frequent in pregnant women, and on his evaluation of the blood and iron status of the particular patient (Herbert, 1975). He may administer iron routinely (Wallerstein, 1973). The baby tends to attain a normal iron status even if it has to deplete the mother completely to do so (Murray, 1975).

In general, oral ferrous sulfate, the least expensive iron preparation, is the drug of choice for treating iron deficiency. A detailed discussion of iron therapy is presented elsewhere (Herbert, 1972; Herbert, in Goodman and Gilman, 1975). It is important to remember that the duration of oral therapy for iron deficiency should be approximately six months, since a lesser duration will not adequately replete body iron stores. The physician must remember that the iron deficiency may have developed in association with menorrhagia; if that menorrhagia persists, iron therapy may have to persist as well so that the iron loss in blood does not again produce a negative iron balance.

About 3 to 4% of the iron in vegetable foods and 15 to 20% of the iron in animal foods are absorbed. Heme iron accounts for about one-third of the iron in animal tissues, but may supply up to one-third of the daily requirement because it is 5 to 10 times as absorbable as inorganic iron in food (Cook, 1978). Non-heme iron absorption is enhanced by vitamin C and a "meat tissue fac-
Table 1. Estimated Dietary Iron Requirements

<table>
<thead>
<tr>
<th></th>
<th>Absorbed Iron Requirement (mg/day)</th>
<th>Dietary Iron Requirement* (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal men and nonmenstruating women</td>
<td>0.5-1</td>
<td>5-10</td>
</tr>
<tr>
<td>Menstruating women</td>
<td>0.7-2</td>
<td>7-20</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>2-4.8</td>
<td>20-48†</td>
</tr>
<tr>
<td>Adolescents</td>
<td>1-2</td>
<td>10-20</td>
</tr>
<tr>
<td>Children</td>
<td>0.4-1</td>
<td>4-10</td>
</tr>
<tr>
<td>Infants</td>
<td>0.5-1.5</td>
<td>1.5 mg/kg†</td>
</tr>
</tbody>
</table>

*Assuming 10% absorption

†This amount of iron cannot be derived from diet and should be met by iron supplementation in the latter half of pregnancy.

‡To a maximum of 15 mg. (After Council on Foods and Nutrition, 1968. Courtesy of the Journal of the American Medical Association.)

Table 2. Iron Requirements for Pregnancy

<table>
<thead>
<tr>
<th></th>
<th>Average mg</th>
<th>Range mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>External iron loss</td>
<td>170</td>
<td>150-200</td>
</tr>
<tr>
<td>Expansion of red-blood-cell mass</td>
<td>450</td>
<td>200-600</td>
</tr>
<tr>
<td>Fetal iron</td>
<td>270</td>
<td>200-370</td>
</tr>
<tr>
<td>Iron in placenta and cord</td>
<td>90</td>
<td>30-170</td>
</tr>
<tr>
<td>Blood loss at delivery</td>
<td>150</td>
<td>90-310</td>
</tr>
<tr>
<td>Total requirement*</td>
<td>980</td>
<td>580-1340</td>
</tr>
<tr>
<td>Cost of pregnancy†</td>
<td>680</td>
<td>440-1050</td>
</tr>
</tbody>
</table>

*Blood loss at delivery not included.

†Expansion of red-cell mass not included.


Iron absorption is affected by the proportion of heme and nonheme iron, and its content of ascorbic acid and animal food.

Folate Deficiency Anemia

Studies carried out under the aegis of the World Health Organization (1968; 1970; 1972; Baker and DeMaeyer, 1979) in various countries suggest that up to one-third of all of the pregnant women in the world have folate deficiency. In a recent study in a New York City municipal clinic, our group (Herbert et al., 1975) found tissue deficiency of folic acid, as measured by a red cell folate level below 150 ng/ml, present in 16% of 110 sequential pregnant women at the time of their first prenatal visit to the clinic. A further
14% had red cell folate levels in the range "suggestive but not conclusive for tissue folate depletion" (150 to 199 ng/ml). It was suggested that daily ingestion of one fresh or fresh-frozen uncooked fruit or vegetable or fruit juice could have prevented this folate deficiency.

These studies add to a growing body of evidence that nutritional deficiency of folic acid is prevalent among Americans of poor economic status. Based on findings up to 1970, Pritchard, writing for the Committee on Maternal Nutrition of the Food and Nutrition Board (1970) recommended that folic acid supplements be taken throughout pregnancy. Subsequently data of the Ten-State Nutrition Survey of 1968-1970 became available. Although that survey found that "the mean serum folate values were, with few exceptions, above the acceptable level of 6 ng/ml, and the mean red cell folate values were in the acceptable range of 150-650 ng/ml," a more detailed evaluation indicates a real problem does, in fact, exist, obscured by the use of mean values alone (Herbert et al., 1975). The mean values obscured the existence of a substantial number of actual values sufficiently below the mean to suggest widespread folic acid deficiency. This is indicated by the data from the Survey Director for Massachusetts of the Ten-State Nutrition Survey (Edozien, 1972).

In Massachusetts, serum and red cell folates were measured on most of the samples collected. Of all the 1,087 Massachusetts blood samples from females on which such estimations were made, 25.6% had red cell folate values below 150 ng/ml. This includes 115 pregnant women (all of whom were receiving prenatal clinic care) in the economically poor Roxbury-Dorchester area, most of whom were receiving vitamin supplements presumably containing folic acid. Among these pregnant women, 7.1% had red cell folate values below 160 ng/ml and 7.1% had serum folate levels below 3 ng/ml. It is probably relevant that the over 10,000 individuals surveyed in Massachusetts were randomly selected from enumeration districts with the lowest average income (lowest quartile) according to the 1960 census (Ten-State Survey, 1968-1970); poverty and folate deficiency tend to run hand in hand (Herbert, 1968; Kahn et al., 1970). As the Massachusetts report noted (Edozien, 1972), "The results suggest that the diets currently eaten by a large segment of the population cannot provide the allowance of folic acid recommended for optimal health and, therefore, that dietary deficiency of folic acid may pose a major nutritional problem. Considered together with the finding of a high prevalence of low plasma vitamin A levels, it would appear that these diets contain insufficient amounts of green leafy vegetables which are major sources of both folic acid and provitamin A. Current processes for preservation, storage, and preparation of foods may also destroy a high proportion of the folate in foods."

The hazard to mother and fetus of folate deficiency in the absence of
frank anemia is unclear, and has been extensively reviewed (Rothman, 1970). Studies from South Africa suggest that folate supplements in this situation decrease the incidence of prematurity (Baumslag et al., 1970) and cause significant elevation of hemoglobin levels (Colman et al., 1975), suggesting that even mild deficiency may limit DNA synthesis. Prospective studies of the effects on the fetus are difficult to interpret because folate administration invariably starts only after the period of maximum fetal susceptibility in the first trimester. However, animal experiments demonstrate a consistent teratogenic effect of folate deprivation from the time of conception, dependent on the duration of the experiment (Herbert et al., 1975).

Thus, in the light of present knowledge, it appears appropriate to correct folate deficiency in pregnancy. The implementation of this principle by improving the quality and quantity of available food is a longterm ideal limited by custom and economic circumstances. For this reason, the Joint FAO/WHO Expert Committee on Nutrition has recommended that food fortification be considered an immediate possibility for the improvement of intake of any deficient nutrient (Joint FAO/WHO Expert Committee, 1971). A series of studies indicates that fortification of staple foods with folic acid is feasible, safe, effective, and in accordance with the recommendations of the Expert Committee (Colman et al., 1974, 1975). With adequate fortification, possible hazards of folate deficiency in early pregnancy would be averted. Until such fortification is practiced, administration of folic acid tablets, 200 to 400 µg/day, is appropriate for all pregnant women, with 300 µg probably adequate for any pregnant population group (Herbert, 1977).

The evidence relating folate deficiency in pregnancy to the presence in offspring of mental retardation and other defects in central nervous system function and development is reviewed elsewhere (Herbert and Tisman, 1973). This evidence is far from conclusive as yet, but does constitute one more slight increment in the balance favoring the concept of daily folate supplementation throughout pregnancy.

In 1976, there was a National Academy of Sciences “Workshop on Human Folate Requirements” whose proceedings were published in 1977. That workshop included papers presenting the latest information on distribution of folates in food, food folate availability, results of several surveys to detect folate deficiency in certain American population groups, and reviews of the folic acid requirement in children, adults, and in situations of increased need. In summary, the findings most pertinent to nutritional anemias are: measurement of serum and red cell folate together constitutes the best method for delineating the existence of folate deficiency; food folate availability is affected by various constituents present in different foodstuffs; pregnancy increases folate requirement.

The minimal daily adult requirement for folic acid which must be absorbed from food to sustain normality is in the range of 50 µg daily (Her-
Nutritional Anemias

bert, 1968), and the Food and Nutrition Board (1980) recommends that the diet of adults contain 400 µg daily. This requirement appears to be approximately doubled by pregnancy. Thus, if a woman is absorbing from her food around 100 µg of folic acid daily from the start of pregnancy, she may not need supplementation, but assuming lesser stores than normal at the start of pregnancy, and supplementation beginning later than the start of pregnancy, 200 to 300 µg of folate supplementation daily may be necessary (Herbert, 1975; Herbert, in Food and Nutrition Board, 1977). The Food and Nutrition Board (1980) recommends a daily dietary intake of 800 µg during pregnancy and 600 µg during lactation.

Although serum and red cell folate may be lowered by the use of oral contraceptives (Smith et al., 1975; Prasad et al., 1975), it is not yet clear that folate supplementation is needed by women taking such products (Medical Letter, 1973; Lindenbaum, 1975). This folate need would probably be adequately met by one fresh uncooked vegetable, fruit, or fruit juice daily (Herbert, 1975).

Vitamin B₁₂

Although serum vitamin B₁₂ level falls in pregnancy (Cooper, 1973) and may also fall with the use of oral contraceptives (Wertalik et al., 1972; Smith et al., 1975), tissue levels of vitamin B₁₂ may remain normal, so that vitamin B₁₂ deficiency anemia has not seemed to be a problem (Wertalik et al., 1972). From the evidence so far, vitamin B₁₂ deficiency is rarely a dietary problem in the United States (Herbert, 1975). In population groups where vitamin B₁₂ deficiency is common due to vegetarianism, such vitamin B₁₂ deficiency would be increased by the metabolic stress of pregnancy, including the fetal drain on maternal stores of about 0.3 µg/day (Herbert, 1968; WHO, 1970), and by a mean of 0.3 µg B₁₂/day lost in breast milk during lactation (WHO, 1970). It is for these reasons that the Recommended Dietary Allowance (Food and Nutrition Board, 1974) for vitamin B₁₂ was raised from 3 µg for adults in general to 4 µg for pregnant or lactating adults.

Bibliography


a population study: Variation at different ages and attempts to define normality.


Herbert, V. 1970. Introduction to the nutritional anemias. Seminars Hemat. 7:2-5.


Moore, C.V. and Dubach, R. 1956. Metabolism and requirements of iron in the human, JAMA 162:197-204.


AMA Concepts of Nutrition and Health*

Report of the
Council on Scientific Affairs
American Medical Association

Adopted by the House of Delegates
July 26, 1979

The effort by physicians, nutritionists and other health professionals to educate the public about food and nutrition is no easier today than it was in 1938 when the observation was made that:

"More food notions flourish in the United States than in any other civilized country on earth, and most of them are wrong. They thrive in the minds of the same people who talk about their operations; and like all mythology, they are a blend of fear, coincidence and advertising."1

Most people have little genuine knowledge about the science of nutrition; what they call "nutrition" is not likely to be founded in science at all.

The public is continuously distracted by announcements of hazards associated with foods, food additives, or given dietary practices. Many warnings are unfounded or premature, but the fears thus engendered adversely influence attitudes about foods. The public is also misled by extravagant claims of health benefits derived from the use of certain foods or nutrient supplements.

An Adequate Diet

Research and clinical experience continually confirm the lack of absolutes in human nutrition. While the human need for many different nutrients is well established, the exact amounts required are not known. Requirements for nutrients are influenced by genetics, environment, the nature of the diet, and by the homeostatic demands under changing physiological conditions expressed as growth, reproduction and response to the stress of injury or disease.

The establishment of standards or guidelines for nutrient and energy needs is a difficult procedure. Such standards are in fact estimates, or the

judgments of expert committees. In the United States, the Recommended Dietary Allowances (RDA) serve as standards for achievement. It should be understood that the RDA are not standards of minimum requirements; they are amounts of nutrients and calories that should adequately nourish most healthy people.

For the most part, man is able to maintain health with a rather large range of nutrient intake. Short-term deficits in nutrient and energy intakes will not jeopardize health since small deficits are easily repleted. Long-term consumption of an inadequate diet, however, will lead to nutrient deficiencies; the most common one in the U.S. is iron deficiency.

The effects of excessive intake of nutrients and other components of food will depend upon the particular compound, the extent and duration of excessive intake, the efficiency of liver and kidney function, and on the presence or absence of appropriate compensatory and detoxification mechanisms. There are no known advantages to the ingestion of quantities of nutrients greatly in excess of need other than for the correction of deficiency diseases or satisfaction of exaggerated requirements caused by metabolic or absorptive abnormalities.

Two advantages of a widely varied diet are the low probability of excessive exposure to any one noxious compound and the high probability of receiving all essential nutrients.

The Daily Food Guide developed by the U.S. Department of Agriculture is a very helpful guide to food selection. It permits people to plan adequate diets by selecting foods rather than calculating amounts of nutrients (the latter procedure being impossible in any practical sense) and has proven to be effective in teaching illiterate persons. Foods are divided into four groups on the basis of similarity in composition and nutritive value: milk and its products; meats, fish, poultry, dry beans and other excellent protein sources; vegetables and fruits; and bread-cereals. The key to the plan is in the recommended numbers and sizes of daily servings from each group. In fact, the plan may be viewed as a model of moderation in developing dietary habits, but this feature is often ignored. A few examples of serving size for the adult illustrate this point: Milk Group—2 or more servings (eight ounces of whole or skim milk equals one serving); Meat Group—2 or more servings (3 ounces of meat equal one serving); Vegetable-Fruit Group—4 or more servings, with emphasis on valuable sources of vitamins A and C (¾ cup of most vegetables constitutes a serving); Bread-Cereal Group—4 or more servings (1 slice of bread equals one serving). Perhaps the most often overlooked aspects are the number and size of the servings in the meat group. Note that only 3 ounces is considered a serving!

Adhering literally to the minimum servings recommended by the Daily Food Guide will provide about 1300 calories and from 80% to 120% of the
RDA for nutrients. It is, therefore, a good basic guide for weight reduction or for very sedentary people who can subsist on about that number of calories. Normal, more active individuals with more conventional nutrient and energy requirements can meet their needs by way of more or larger servings and by way of utilization of foods not specifically mentioned in the guide, namely, fats, oils, and sugars. Foods such as table spread, salad dressings, jams, gravy, most desserts, unenriched cereal products, etc. provide some nutrients and they certainly provide calories. Moderation does not imply avoidance of such foods; moderation suggests that good sense be used in deciding the frequency and size of servings consumed. The exercise of good judgment is doubly important in the case of alcohol consumption. Alcohol is a liver toxin and is second only to fat as a concentrated source of calories. Appreciation of what constitutes appropriate serving sizes is one of the imperatives of good nutrition. The normal individual rarely needs to avoid any item of food. The prudent person will learn the amounts of various foods that can be eaten for good nutrition and weight maintenance or weight loss.

Maternal and Infant Nutrition

Maternal Needs: The proper nourishment of pregnant and lactating women is the vital first step in assuring well-nourished infants. Ideally, nutrition counseling and appropriate dietary modifications should be accomplished well before pregnancy begins. Couples anticipating their first child may be quite receptive to dietary and health guidance for their own welfare and that of the child. Teenage pregnancy poses special problems in that the nutritional stress of pregnancy may be superimposed on an immature and already inadequately nourished adolescent.

It is accepted that weight gain during pregnancy should be at least 22 to 26 pounds (10-12 kg), gained at a steady rate of just under a pound per week after the first trimester of pregnancy. When a woman has gained excessive weight during the first trimester or so, however, it would be ill-advised for her to attempt to keep her weight constant during the remainder of the pregnancy. Calorie restriction would have to be such that both mother and fetus would be at risk of nutritional deprivation.

Nutrient and energy needs are considerably increased during pregnancy and lactation. Requirements are greater for protein, calcium, phosphorus, iron and folic acid in particular and there are modest increases in the need for other vitamins and minerals. In order to counsel the pregnant or lactating woman about her diet and make a judgment about the need for dietary supplements, the physician must consider the increased needs for nutrients as well as the patient's diet history and current nutritional status. Particular attention should be given to iron and folic acid intakes because of the increasing demands on the maternal hematopoietic system. The malnourished woman may require
considerable nutritional rehabilitation as quickly as possible and as early as possible in the pregnancy. It is not appropriate, however, to recommend weight reduction during pregnancy or lactation.

Infant Needs: Infants experience their most rapid growth during the first four to six months. Full-term, newborn infants should be breast fed, unless there are specific contraindications or breast feeding is unsuccessful. The breast fed infant has health advantages that are not shared by infants who are formula fed, even though modern commercial formulas are skillfully designed to meet nutritional needs. Nutrient absorption from human milk is generally superior, especially for fat and iron. The amino acid composition of human milk is particularly suited to the metabolic requirements of newborns. Many of the immunologic advantages of breast feeding are credited to the presence in human milk of bacteriostatic proteins (lactoferrin and transferrin) and secretory IgA plus lysozymes. Breast feeding also protects the newborn against the introduction of foreign food antigens. The AMA urges that better efforts be made to educate the public and the profession about the advantages of breast feeding.

The decision to breast feed should be made well before the birth of the infant. This gives prospective parents time to learn about the physiological and psychological aspects of breast feeding and time to prepare for personal and social adjustments that may be necessary.

The transitional period in infant feeding begins between the fourth and sixth months of life. Single-ingredient foods are introduced in small amounts one at a time in order to isolate food sensitivities. Hypoallergenic foods such as rice cereal are first offered; the usual progression is iron-enriched cereals to vegetables to fruits to meats. Human milk or formula provides the primary nourishment during the initial part of the transition. At about 12 months of age, most infants are able to eat a good variety of modified adult-foods.

The proper and gradual introduction of the infant and young child to varied and nutritious meal patterns can pay dividends throughout life. Immoderate habits learned early in life may be difficult to change later on. Normal weight for height is the goal. Family counseling of the children about good health and nutrition practices is quite important. Since today's children eat so many meals away from the home, they must be educated to make good food choices.

Some eating patterns, e.g., overeating, can become established early in life and thereafter are difficult to change unless individuals are highly motivated. Consequently, the establishment of good food habits based upon the judicious use of a wide variety of foods is important. Although responsibility for encouraging good food habits among children rests primarily with the parents, physicians should take advantage of every opportunity to educate their young patients.
Nutrition in Maturity

Energy balance may be the most pressing nutritional challenge to be faced in late childhood and once maturity is achieved. Weight gain after maturity is related as much to lack of exercise as to overeating. Since basal metabolic rate and energy expenditure in physical activity decline with age, total food intake must be gradually reduced with time. The nutrient and caloric densities of foods then take on added significance for the person who is conscientious about weight control. Physicians should also be alert for patients who practice the extreme in calorie control, subsisting on energy intake of a few hundred calories above their basal metabolic requirement. The stress of illness, injury or pregnancy may compromise marginal nutritional reserves, and place the person in jeopardy of malnutrition.

Nutritional anemias are unnecessarily common in women and older men. The anemias are often related to inadequate dietary intake of iron, folic acid or perhaps vitamin B₁₂. Osteoporosis is a frequent problem among older women and some men. Although the precise etiology is unknown, there is some agreement that adequate calcium intake and continued physical activity are important in prevention.

Calorically and nutritionally inadequate diets of the elderly are of growing concern. Although food energy needs decline with age, requirements for the essential nutrients do not decrease appreciably. The nutrition of older people is influenced by factors common to all age groups: income, social status, isolation, marital status, presence of disease, and earlier training in food habits.

In addition, there are physiological factors that affect senior citizens, such as their state of dentition; diminished sensitivity to taste and smell, which reduces food acceptance; reduction in basal metabolic rate, and physical activity; moderate reduction in digestion, which may make older persons more susceptible to nutrient deficiency; and incapacitation. Psychological factors also play a part. Feelings of rejection and imposition on family, lack of incentive for health, and loneliness, all may lead indirectly to malnutrition.

Diet and Disease

Many problems associated with the “usual American diet” and “American food habits” reflect abandonment of the dictum of moderation. Immoderate habits, namely, overeating, may exacerbate or contribute to the development of degenerative diseases. Contemporary concerns about diet and disease center on the kinds and amounts of fatty acids and carbohydrates in the diet, the amounts of sodium, plant fibers, cholesterol, alcohol and total calories, and also the level of energy expenditure in physical activity.

A common denominator of the various dietary guidelines proposed to modify the risks of chronic and degenerative diseases is the emphasis on restraint or moderation. Few would argue against the concept of “all things
in moderation,” though many would say that it is paltry advice in an era unsurpassed in advances in biomedical research. In time, when our knowledge of the relationships, if any, of specific food components to the development of chronic diseases reaches maturity, it may be feasible to make more refined recommendations. Until then, the AMA recommends that the American public give primary emphasis to the achievement and maintenance of the most desirable body weight and further recommends that this be accomplished through the combination of dietary control and exercise.

This recommendation is considered the most appropriate for healthy people but is also applicable to large numbers of Americans who are at greater risk of developing certain diseases and to those who must contend with specific dietary modifications instituted for the management of hypertension, diabetes, coronary heart disease and other medical problems.

Hypertension: Weight control and sodium restriction are often indicated in the management of hypertension and in some instances obviate the need for drug therapy. An increase in weight during adulthood correlates positively with an increase in blood pressure. Individuals with a family history of hypertension should avoid excess weight gain and also restrict their sodium intake.

Whether the amount of salt in the diet bears a direct relationship to the development of hypertension is not known. Prudence suggests that moderation in salt intake is desirable for the entire population. For the healthy population, total dietary exposure of less than 12 grams of salt a day is suggested as a tentative definition of moderation. The “usual” intake of salt appears to be on the order of 4.3 gm per 1000 calories, of which 27% is discretionary addition by the individual.*

Greater attention must be given to controlling salt intake of the more vulnerable, including cardiac and hypertensive, populations.

It is important to identify persons who are at particular risk of developing hypertension and might benefit from early preventive measures.

Diabetes: The most constant feature of individuals who develop diabetes after age 40 is excess body fat. In the majority of diabetics who are overweight, the first aim of dietary management is to reduce weight to the level considered ideal for the individual. Diet therapy should be based on caloric needs. Although not all obese individuals will develop diabetes, obesity and diabetes are often inseparably linked. In families with a history of diabetes, emphasis should be given to the maintenance of desirable body weight.

Coronary heart disease: A number of risk factors associated with susceptibility to coronary heart disease can be manipulated. These include elevated plasma lipids, hypertension, cigarette smoking, obesity and physical inactivity. Measurement of plasma lipid concentrations should be carried out

when indicated in physical examinations, especially in patients from families with histories of early onset or death from cardiovascular diseases. The National Heart, Lung and Blood Institute guidelines for dietary treatment of hyperlipidemias emphasize that in overweight individuals the first step is weight reduction to desirable weight. Dietary regimens developed for reduction of plasma cholesterol call for regulation of the amount of cholesterol and saturated fatty acids, as well as total calorie intake. *The AMA recommends that persons falling into risk categories on the basis of their plasma lipid profiles be given individualized dietary advice based upon the type of hyperlipidemia diagnosed and that physicians encourage their patients to achieve or maintain desirable weight.*

There is considerable variability among the population as to risk of developing heart disease. It cannot be assumed that the proportions of saturated and unsaturated fat and the levels of cholesterol in the diet are of universal importance. For healthy people, moderation in fat intake should become the rule of thumb. Fats, regardless of their source, are of high caloric value.

*The AMA recommends that the medical profession assume a more active role in teaching people how to achieve and maintain good health habits.* This may require specific attention to behavioral patterns and attitudes about food and nutrition, physical fitness, smoking, the use of addictive drugs and alcohol, and the management of debilitating stress of life and work. Assisting patients to achieve their desirable weight and to develop appropriate patterns of exercise are among the most important goals.

References


To the Editor:

As a member of the Food and Nutrition Board of the National Academy of Sciences, I take exception to publication by The Times, under the defamatory heading "Food, Nutrition and Special Interests," of a defamatory letter by Samuel Epstein, which states that "the membership of the Food and Nutrition Board reflects persisting and generally undisclosed special interests" [June 28].

Dr. Epstein attacks Professor Harper for being a consultant to "Kraft, the meat industry and others" and Professor Olson for being a consultant to the "egg, dairy and other industries." He omits the facts that they (and other board members) consult only on what constitutes sound nutrition science and that they are consultants to consumer-advocacy organizations as well. And from whom else than nutrition scientists should industry seek advice about what constitutes sound nutrition?

I am a consultant to consumer-advocacy organizations. I have written a book, soon to be published, on nutrition frauds by elements of the food industry. I am currently engaged with other board members, in their individual capacities, in a battle to protect the public from a mutagen being sold as a nutrient by certain elements in the health-food industry. Dr. Epstein, author of the lucrative book "The Politics of Cancer," has yet to join in this battle.

Of the 15 members of the board, not one has "persisting and generally undisclosed special interests." All 15 were selected because of eminence as nutrition scientists. To say that Professors Harper and Olson are industry consultants without pointing out that they earn their living as full-time nutrition scientists at universities denigrates their professional stature.

With respect to the "food industry" smear-by-buzz-word, both Dr. Epstein and The Times appear blind to the fact that the low-cholesterol, low-fat industry is part of the food industry.

Both Dr. Epstein and the writer of your June 3 editorial which Dr. Epstein supported are untrained in nutrition science and therefore incompetent to attack us as professionals. So they resort to personal defamation.

As nutrition scientists, rather than nutrition cultists, we must consider all the scientific evidence. This includes the fact that dietary cholesterol is only 10 to 50 percent absorbed, the fact that some foods contain factors which may inhibit liver cholesterol synthesis (such as milk, which because of these factors and despite its cholesterol content lowers rather than raises serum cholesterol in humans), the fact that our livers produce about four times as much cholesterol as we absorb from food on average and the fact that some people have a "thermostat" which can reduce the daily cholesterol synthesis by their own livers in response to cholesterol absorbed from food, while other people lack this thermostat.

We feel it unwise to recommend low-cholesterol diets for all Americans as part of a program to reach those with elevated serum cholesterol. That conclusion has been misrepresented as a recommendation for those at risk of heart attacks to abandon low-cholesterol diets. It was not. We recommended reduced food and fat intake for the many Americans more than 20 percent overweight. Losing weight lowers the serum cholesterol level.

Moderation and variety are the two fundamental tenets of healthful diets. The two basic canons of nutrition and diet therapy are:

• No proposed dietary therapy is safe until proved safe.
• No proposed dietary therapy is efficacious until proved efficacious.

VICTOR HERBERT, M.D.
Bronx, June 30, 1980

The writer is professor of medicine at Downstate Medical Center and chief of the Veterans Administration's Hematology and Nutrition Laboratory in the Bronx.
Toward Healthful Diets

Food and Nutrition Board

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institutes of Medicine. The members of the Committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering and the Institute of Medicine.

Food and Nutrition Board

Chairman
Alfred E. Harper, Department of Biochemistry, University of Wisconsin, Madison

Vice-Chairman
Henry Kamin, Department of Biochemistry, Duke University Medical Center, Durham, North Carolina

Members
Roslyn B. Alfin-Slater, Division of Environmental and Nutritional Science, University of California School of Public Health, Los Angeles
George K. Davis, Nutrition Laboratory, University of Florida, Gainesville
Richard L. Hall, Science and Technology, McCormick and Company, Inc., Hunt Valley, Maryland
Gail G. Harrison, Department of Family and Community Medicine, University of Arizona, Tucson
Victor Herbert, Veterans Administration Medical Center, Bronx, New York
Ogden C. Johnson, Scientific Affairs, Hershey Foods Corporation, Hershey, Pennsylvania
David Kritchevsky, The Wistar Institute, Philadelphia, Pennsylvania
Robert A. Neal, Department of Biochemistry, Vanderbilt University School of Medicine, Nashville, Tennessee
Robert E. Olson, Department of Biochemistry, St. Louis University School of Medicine, St. Louis Missouri
George M. Owen, School of Public Health, University of Michigan, Ann Arbor
Introduction

Since its inception in 1941, the Food and Nutrition Board of the National Research Council has striven to encourage sound nutritional practices by the U.S. population. A fundamental element of any national nutrition policy, inherent in the recommendations of the Board, is to ensure the provision of a supply of diverse, safe and attractive foods that will meet the nutritional requirements of the population at reasonable cost.

The first action of the Board, taken in 1941 on the basis of information from the scientific literature, was to recommend allowances of essential nutrients that would assure adequate nutrition in the U.S. population. These *Recommended Dietary Allowances* (RDA) were calculated to exceed average nutritional requirements by a "safe margin", taking into consideration the difference in requirements among individuals in a basically healthy population. The allowances are defined as levels of intake of essential nutrients considered, in the judgment of the Food and Nutrition Board on the basis of available scientific knowledge, to be adequate to meet the known nutritional needs of practically all healthy persons. The RDA have been reevaluated and revised at regular intervals as new scientific information has become available (Olson, 1978). The ninth edition was published in 1980 (FNB, 1980).

The RDA have been accepted by both governmental and nongovernmental agencies as the basis for planning and procuring food supplies for population groups, interpreting food consumption records, establishing standards for food assistance programs, developing nutrition education programs, developing new products by industry, and establishing guidelines for nutritional labeling of foods by the Food and Drug Administration. The General Accounting Office (GAO) has recently concluded that the RDA provide the basis for current national policy in nutrition, and urged the Secretaries of Agriculture and of Health, Education, and Welfare to identify research needs and priorities in clinical nutrition, particularly as they relate to concerns about given "food components, lifestyle factors, and diet and health" (Comptroller General of the U.S., 1978). The Food and Nutrition Board recently addressed this issue in response to a request from the National Institutes of Health (FNB, 1979).

The food guides developed by the U.S. Department of Agriculture (USDA, 1957, 1979) have been used in nutrition education to assist people in planning adequate diets that will meet the RDA set by the Board. The
RDA are met by selecting servings of foods in given food groups, rather than by calculating amounts of nutrients. In the recent guide, foods are divided into five main groups on the basis of their similarity in nutrient composition. The five groups are 1) milk and other dairy products, 2) meat, fish, poultry, dry beans and other high protein foods, 3) vegetables and fruits, 4) cereals and breads, and 5) fats, oils, sugars and alcoholic beverages. This guide (USDA, 1979) provides information to help consumers identify components from the different food groups in complex foods, such as pizza. The recently published Canadian food guide (Health and Welfare Canada, 1979) is particularly valuable for this purpose. The key to the guides is the information they provide about the number and sizes of daily servings from among the different food groups that will meet the major requirements of given population groups. On the average, 80-120 percent of the RDA for several selected nutrients for adults can be obtained in a diet consisting of about 1200 kilocalories of properly selected foods. If a diet meets the requirements for these nutrients, it is unlikely to be deficient in others. The recommended selections provide the foundation for a nutritionally adequate diet. It is a sound guide, particularly for sedentary people who have low energy needs and for overweight persons on weight-reducing diets. Active individuals, who have higher nutrient and energy requirements, can meet their needs with additional or larger servings from among the first four groups and may include additional foods from the fifth group, which consists of calorie-rich foods.

The Food and Nutrition Board is concerned about the flood of dietary recommendations currently being made to the American public in the hope that a variety of chronic degenerative diseases may be prevented in some persons. These recommendations, which have come from various agencies in government, voluntary health groups, consumer advocates, and health-food interests, often lack a sound scientific foundation, and some are contradictory to one another. In an effort to reduce the confusion in the mind of the public that has resulted from these many conflicting recommendations, the Board has prepared the following statement.

**Quest for Guidelines Toward Healthful Diets**

Associations between dietary patterns and disease prevalence have been observed in a variety of epidemiological investigations of coronary heart disease, hypertension, and diabetes. These observations have raised the question whether it is possible to develop additional nutritional guidelines for improving health. In fact, general recommendations to alter consumption of dietary fat, cholesterol, complex carbohydrates, sugar, salt, and fiber have been made to the public by a number of organizations. Such nutritional guidelines for improved health deal not with requirements for essen-
tial nutrients but with the pattern of intake of nonessential nutrients or with the intake of essential nutrients in amounts that greatly exceed requirements.

The Board considers it scientifically unsound to make single, all-inclusive recommendations to the public regarding intakes of energy, protein, fat, cholesterol, carbohydrate, fiber, and sodium. Needs for energy and essential nutrients vary with age, sex, physiological state, hereditary factors, physical activity, and the state of health. The nutritional needs of the young growing infant are distinctly different from those of the inactive octogenarian; those of the vigorous active young person differ from those of the sedentary, obese person of middle age. Variations in requirement due to age, sex, physical activity and individual variability are taken into account in the formulation of the RDA. Guidelines for a healthful diet must also take into account these same variables if they are to be realistic.

The recent Surgeon General's Report on Healthy People (DHEW, 1979) has stated that the population of the United States has never been healthier. It reported that age corrected mortality rates have been falling throughout this century, that life expectancy at birth is continuing to rise, and that the mortality rate for coronary heart disease has declined 20 percent during the last 20 years and is currently falling at a rate of 2 percent per year. Likewise, death rates from cancers not associated with excessive cigarette smoking have not been rising, and some have been falling. Nonetheless, heart disease and cancer continue to be the leading causes of death in the U.S., together accounting for about 66 percent of total mortality. Both are diseases of multiple etiology. Some argue that because there are associations between dietary practices and the incidence of these diseases, it should be possible to reduce death rates from them by proper nutritional practices. Others question that as nutritional deficiency diseases have essentially been eliminated by better availability of foods containing protective nutrients, is it now possible to reduce the incidence of the chronic degenerative diseases by altering the diet of the population at large?

Although the Board considers it appropriate to set dietary guidelines beyond those implicit in the RDA, in the hope of correcting metabolic patterns in susceptible individuals in such a way as to prevent or delay the onset of chronic degenerative diseases, it is concerned about the adequacy of the scientific undergirding on which these recommendations are based. The Board recognizes that epidemiology establishes coincidence, but not cause and effect. Epidemiologic findings, however, lay the groundwork for further studies to test given hypotheses. Many such studies are in progress. The Board believes that advice should be given to the public when the strength, extent, consistency, coherence, and plausibility of the evidence
from lines of investigation ranging from epidemiology to molecular biology converge to indicate that certain dietary practices or other aspects of lifestyle promote health benefits without incurring undue risks.

The American food supply on the whole is nutritious and provides adequate quantities of nutrients to protect essentially all healthy Americans from deficiency diseases. The excellent state of health of the American people as documented in the Surgeon General's report could not have been achieved unless most people made wise food choices. It is clear, however, that appropriate selections are not made and equitable distribution of nutrients is not currently attained by a portion of the population because of economic, educational and cultural factors. Inappropriate selection or uneven distribution of nutrients that result in intakes appreciably above or below needs affects nutritional status. The high prevalence in the United States of obesity, which is a form of malnutrition, is due in part to the abundance of appetizing foods. It is not only undesirable physiologically for persons to be too fat, but obesity increases for many persons the risk of developing a number of chronic degenerative diseases.

The Board has considered the current evidence pertaining to relationships between dietary practices and the occurrence of obesity, hypertension, atherosclerosis and its complications (coronary heart disease, stroke, and peripheral vascular disease), cancer, and diabetes. It did not consider dental caries to be a member of this group of chronic degenerative diseases, but endorses fluoridation of water supplies as the most effective preventive measure against this disease (Mogren, 1979).

The ensuing discussion includes specific dietary recommendations that the Board feels are justified at this time.

Obesity

Obesity, or excess fatness, is the commonest form of malnutrition in the Western nations of the world. It has a multiple etiology and is influenced by neurohumoral, endocrine, metabolic and social factors. In the United States, according to the recent HANES survey, approximately 30 percent of middle aged women and 15 percent of middle aged men are obese, i.e., they weigh more than 120 percent of desired weight (Abraham and Johnson, 1979). It is generally recognized that in many persons obesity is associated with significant increases in morbidity and mortality from such diseases as hypertension, diabetes, coronary heart disease, and gallbladder disease and that mortality from these diseases is reduced with weight reduction (Dublin and Marks, 1952).

Obesity occurs in those who fail, for various reasons, to match energy intake to energy expenditure. Energy balance is most difficult to achieve when energy expenditure is low, as is generally the case in the U.S. popu-
lation. Energy requirements vary widely among persons depending upon their age, sex, body size, and physical activity. The fixed component of energy expenditure (basal metabolic rate or BMR) is a function of body surface area and, for a given body size, varies less among individuals than does total energy expenditure. The amount of physical activity varies greatly among individuals. Furthermore, energy expenditure among individuals doing similar amounts of work is variable, suggesting that different persons perform work with different efficiencies. As people age, energy requirements decrease because of a modest fall in basal metabolic rate and a general tendency toward less physical activity. Modern life and work styles as a consequence of mechanized aids in the workplace and household, dependence on the automobile, and the popularity of such sedentary leisure activities as television viewing and spectator sports, have reduced energy expenditure by the U.S. population. A recent USDA survey estimates that, in the United States, the current mean energy intake for adult men is 2200 kilocalories and for adult women 1500 kilocalories (Hegsted, 1979). When these data are considered in the light of the prevalence of obesity in these same groups, it appears that energy expenditure is not only low but is decreasing, on the average, in this country despite increased participation by many in exercise programs.

Achievement of weight control and reduction in the incidence of obesity should be a major objective of any set of dietary guidelines. Achievement of this objective, however, is difficult for a large number of people who resist changes in lifestyle. This is attested to by the continued high prevalence of obesity in our population despite the proliferation of weight control programs and the continuous publication of books and articles that promise an easy road to weight reduction through diet. The high rate of failure underscores the complexity of the problem and the need for new strategies to produce sustained negative caloric balances in obese persons without undue risk. Nationwide attempts to prevent obesity in children and adolescents might provide a new approach to this difficult problem.

Slimming to achieve and maintain desired weight involves long-term discipline. Fad diets promising "quick" weight loss through the use of special dietary formulas are to be avoided, because they are potentially harmful. Short-term effects observed with these diets provide no assurance of long-term attainment of desired weight. Diets restricted in energy content to below 1200 calories per day should be employed only under the guidance of a physician or other health professional.

The USDA food guides (USDA, 1957, 1979) explain how to select foods so that essential nutrient needs can be met from a diet providing only 1200 to 1500 kilocalories. This is an excellent starting point for persons who wish to avoid gaining weight or for overweight persons who wish to reduce. Moderation should be the watchword in deciding the frequency and size of
servings that will be needed to maintain energy balance and desired weight in sedentary persons. Moderation does not imply avoidance of any particular food, but it should be recognized that fats provide over twice as much energy per gram as do carbohydrates and proteins. Also, those who drink alcoholic beverages must recognize that alcohol is a high-calorie food as well as a drug and that it supplies more calories (7 Cal/g) than does carbohydrate. Many Americans who drink do not do so moderately and take the equivalent of more than six drinks per day. Prudent individuals should not consume more than half that amount (Ahrens et al., 1979). This is particularly true for those for whom weight control proves difficult.

A moderate increase in physical activity is equally important in slimming. Increases in energy expenditure improve physical fitness (American Medical Association, 1979), as well as contribute to mobilization of stored fat. Additional energy expenditure will permit those who are not seriously overweight to liberalize their diets without becoming obese. For those who are more obese, a consistent program of physical activity will not only increase energy expenditure, but may also facilitate control of appetite and hence food intake.

Cardiovascular Disease

Atherosclerosis and its complications, i.e., coronary artery disease, stroke, and peripheral vascular disease, are the leading causes of death in the United States. Although the age-adjusted mortality rate from cardiovascular disease has declined 20 percent since 1960, this disorder still accounts for about 50 percent of the deaths in this country and is the leading health problem. As is true for other degenerative diseases, mortality rates from cardiovascular disease increase sharply with increasing age; 78 percent of deaths from this disease occur among those over 65 years of age (DHEW, 1979).

The causes of atherosclerosis are unknown. A number of hypotheses are being investigated in both animals and man in search of a better understanding of the factors affecting atheroma formation. High concentrations of low density lipoproteins (LDL), enhanced platelet aggregation, transformation of smooth muscle cells, altered prostaglandin metabolism, and effects of various androgenic and estrogen steroid hormones on arterial metabolism are implicated as possible causative factors. A number of risk factors for cardiovascular disease have been identified from epidemiologic studies. These include male sex, positive family history of cardiovascular disease, hypercholesterolemia, hypertension, obesity, diabetes, cigarette smoking, and physical inactivity. Risk factors are those factors found to be statistically associated with an increased incidence of disease. They cannot, without independent evidence, be considered to be causative agents of the disease. Risk factors are “fellow travelers” that may aggravate some event
in the overall pathogenesis of the disease. At the present time only 50 per-
cent of the risk of persons in the United States for coronary artery disease
can be accounted for as stemming from currently recognized risk factors.
Thus much additional research is necessary to understand fully the multiple
etiology of coronary atherosclerosis. Nonetheless, in our present state of
knowledge, sound medical and public health practice should be aimed at
reducing the known risk factors to the extent possible.

Diet modification as recommended for the prevention of atherosclerosis
is based upon the assumption, not yet adequately tested, that reduction of
high serum cholesterol levels, i.e., those greater than 250 mg/dl, will reduce
the probability of cardiovascular disease (Ahrens, 1976, 1979). Total serum
cholesterol is distributed among three classes of lipoproteins that accom-
plish the transport of cholesterol within the body. These are the very low
density lipoproteins (VLDL), low density lipoproteins (LDL), and high
density lipoproteins (HDL). In both normal and hypercholesterolemic indi-
viduals, LDL carry the highest level of the serum cholesterol, about 65 per-
cent. High density lipoproteins carry the next largest quantity, about 25
percent, and the very low density lipoproteins carry about 10 percent (Fred-
rickson and Levy, 1972). These lipoprotein fractions are considered to have
inherently different risk values for coronary heart disease. VLDL is essen-
tially neutral, high LDL is a positive risk factor for atherogenesis, and high
HDL is a negative risk factor, i.e., protective against atherogenesis. The
concentration of HDL, which appears to be protective against atherogene-
sis, is higher in females and athletes, although individual responses to in-
creased physical activity are highly variable. Heredity is important in deter-
mining the levels of various lipoprotein fractions in a given individual and
the variability of the serum cholesterol response to diet. In general, dietary
modifications that reduce the concentration of serum cholesterol reduce
LDL concentrations.

It has been shown that modification of the diet with respect to level of fat,
kind of fat, and amount of dietary cholesterol of subjects in metabolic
wards under rigid dietary control, can result in alterations in their serum lip-
id and lipoprotein concentrations (Ahrens et al., 1979). A high intake of sat-
urated fat as a percent of calories is a major factor in elevating serum cho-
lesterol and LDL levels. A high intake of polyunsaturated fat is important
in the lowering of serum cholesterol and LDL levels. Dietary cholesterol
has the least impact, particularly in the range of intake of 300-600 mg per
day. In order of importance, without respect to direction of effect, the die-
tary factors affecting serum cholesterol concentration are saturated fat,
polyunsaturated fat, and cholesterol (Keys et al., 1965). In the Diet-Heart
Feasibility study carried out in six medical centers in the United States,
using free-living populations with a controlled food supply, the effect of a
low-saturated fat, high-polyunsaturated fat, low cholesterol diet was only about 60 percent as effective in lowering serum cholesterol as it was in subjects in metabolic units (American Heart Association, 1968). Clearly, other factors influence serum lipid values of free-living persons in an as yet unpredictable manner.

Intervention trials in which diet modification was employed to alter the incidence of coronary artery disease and mortality in middle aged men have been generally negative. Seven large-scale studies were carried out in London, Oslo, Helsinki, New York City, New Jersey, and Los Angeles, for 2 to 10 years on 3,060 men, 20 to 59 years of age, with or without previous myocardial infarction. In these studies, comprising about 20,000 man-years of observation, in which decreases in serum cholesterol concentrations of 7 to 16 percent occurred, there was a marginal decrease in coronary disease incidence but no effect on overall mortality. In addition, five trials involving 18,000 men for 5 years have been carried out with hypocholesterolemic drugs in England, Scotland, Europe, and the United States. The effects of the drugs on incidence of coronary artery disease were not impressive, and some unpredicted toxicities were observed (Ahrens, 1976, 1979; Report from the Committee of Principal Investigators, 1978). It appears, therefore, that although high serum cholesterol and LDL levels are positive risk factors for coronary heart disease, it has not been proven that lowering these levels by dietary intervention will consistently affect the rate of new coronary events.

Despite these generally unimpressive results, some organizations (American Heart Association, 1961, 1978; Select Committee on Nutrition and Human Needs, 1977) have recommended that dietary lipids be reduced from 40 percent to about 30 percent of calories, and that the ratio of polyunsaturated to saturated fat (P/S ratio) be changed from the present value in the American diet of 0.4 to 0.5 to a ratio of about 1.0, in order to achieve lower serum cholesterol levels in the population generally. Unfortunately, the benefit of altering the diet to this extent has not been established. As noted, other studies employing diets containing 35-40 percent of calories from fat and higher P/S ratios have shown equivocal effects on coronary disease, and have been accompanied by a somewhat greater incidence of gastrointestinal disease.

In the light of these observations, the Board recommends that the fat content be adjusted to a level appropriate for the caloric requirements of the individual. Infants, adolescent boys, pregnant teenage girls, as well as adults performing heavy manual labor, probably have no need to reduce the fat level of their diets below 40 percent of calories. On the other hand, sedentary persons attempting to achieve weight control may be well advised to reduce the caloric density of their diets by reduction of dietary fat. It does not seem prudent at this time to recommend an increase in the dietary
P/S ratio except for individuals in high risk categories. The average intake of polyunsaturated fatty acids in this country is 6-7 percent of calories, which is about five times the nutritional requirement for essential fatty acids.

The intake of dietary cholesterol by the U.S. population averages about 450 mg per day at the present time, ranging from 200 to 1500 mg (Nichols et al., 1976; Hegsted, 1979). From 1900 to 1970, the average intake varied from 509 to 576 mg/day (Gortner, 1975; Ahrens and Boucher, 1978). The present lower value reflects a drop in total caloric intake by the U.S. population during the past decade. Cholesterol is an essential metabolite and is actively synthesized by the human body in amounts of 800 to 1500 mg daily. In contrast to many species, man absorbs cholesterol poorly, permitting the entry of only 10-50 percent of that in the diet (Dietschy and Wilson, 1970). There is a curvilinear relationship between dietary cholesterol intake and serum cholesterol concentrations in man, as evidenced by a slope that decreases with increasing cholesterol intake from about 12 mg/dl of serum cholesterol/100 mg dietary cholesterol/1000 calories at low levels to less than 2 mg/dl/100 mg/1000 calories at high levels (Keys et al., 1965; Ahrens et al., 1979). This effect is due to the poor absorption of cholesterol at high levels, plus feedback mechanisms in the body that adjust biosynthesis to body needs. No significant correlation between cholesterol intake and serum cholesterol concentration has been shown in free-living persons in this country (Kannel and Gordon, 1970; Nichols et al., 1976). For these reasons, the Board makes no specific recommendations about dietary cholesterol for the healthy person. Similar conclusions were reached by the Canadian Health Protection Branch (Dept. of National Health and Welfare, 1977).

For persons with a positive family history of heart disease and other risk factors, such as obesity, hypertension, and diabetes, concentrations of blood lipids and lipoprotein fractions should be determined and, if any are abnormal, therapy should be undertaken under a physician’s guidance.

Hypertension

A relationship between the intake of salt and the development of hypertension was emphasized as early as 1904 by Ambard and Beaujard (1904). In 1950 Dahl and a group of collaborators at the Rockefeller Institute carried out a series of investigations demonstrating that the reason for the effect of the rice diet (Kempner, 1948) in reducing hypertension was its low salt content (Dole et al., 1951; Dahl, 1972). According to Freis (1976), increased extracellular fluid volume is the initiating factor in the sequence of events leading to chronic hypertension. Low sodium diets reduce extra-
cellular fluid volume, and the chlorothiazide diuretics appear to act in a similar manner.

The nutritional requirement for sodium for growth and for unavoidable losses from skin and feces is in the range of 4-8 mEq or 100-200 mg of sodium per day (equivalent to 250-500 mg of salt per day). Hypertension is absent in some nonindustrialized populations in the Solomon Islands, the Amazon basin, and the Coco Islands of Polynesia where the salt intake is about 2 g per day (Food and Nutrition Board, 1979). The incidence is high in populations in northern Japan where salt intake commonly exceeds 20-25 g/day. Available evidence indicates that sodium restriction to approximately 3.8 g of salt per day will effect a slight reduction (5 mm Hg) in blood pressure among moderately hypertensive adults (Parijs et al., 1973). Several very carefully controlled studies of severely hypertensive adults have shown that sodium must be restricted to 200 mg (0.5 g salt) per day in order to achieve a significant reduction in blood pressure (Kempner, 1948). The level of dietary sodium chloride that will permit the development of hypertension in the 15-20 percent of the population that have a genetic predisposition for this condition is unknown. Studies in animals show that genetically predisposed rats develop hypertension when fed high levels of sodium chloride (Meneely and Battarbee, 1976). Genetic variations in man are large, however, and an association between blood pressure and salt intake has not been demonstrated within selected U.S. populations. The average sodium chloride intake in this country is about 10 g per day, with a range of 4-25 g. This average intake of salt is 20 times the nutritional requirement.

Hypertension is also known to be associated with obesity and a number of studies have demonstrated that weight reduction is associated with a decrease in blood pressure. The extent to which decreased sodium intake is a factor in these cases is still controversial, although it has recently been reported that weight reduction exerts an independent effect (Reisin et al., 1978). In a study of 10,900 persons, the National Heart, Lung and Blood Institute recently reported that concerted antihypertensive drug therapy, combined with advice to avoid salty food, resulted in a 17 percent reduction in mortality from those chronic diseases for which hypertension is a risk factor (National Heart, Lung and Blood Institute, 1979).

The Board believes that sodium chloride intakes of many people in this country are excessive, particularly in that 15 percent of the American population at risk for hypertension. There is no reason to believe that reduction of sodium chloride intake to levels of 3 g per day would be harmful for healthy persons, and it may be helpful for the prevention of hypertension in susceptible individuals for whom salt is a permissive factor. Achieving an intake of 3 g of salt per day would require elimination of salt in cooking and at the table since nondiscretionary salt intake in foods amounts to at least 3 g per day (FASEB, 1978).
Cancer

Cancer is the second leading cause of death in the United States. A putative relationship between diet and cancer is based upon both epidemiologic and experimental observations, but, for the most part, these investigations do not identify specific causative agents. Foods contain both nutritive and nonnutritive components. Most of the latter are present naturally, but some are added during formulation, processing, and cooking. Studies have shown that some specific nonnutritive substances can promote tumor development in animals. For example, aflatoxin, a potent carcinogen derived from mold on grains, legumes, or nuts is a "naturally occurring" toxin in these foods. For decades, sodium nitrite has been added to cured meats at levels of about 200 parts per million to prevent botulism. Since nitrite can react with secondary amines to form carcinogenic nitrosamines, the question of the safety of nitrites in amounts present in cured meats has been raised (Issenberg, 1976) and is currently under review. The average nitrate intake from mixed diets in the U.S.A. is 100-200 mg daily and the intake of preformed nitrite as food additives is about 3 mg. Bacteria in the mouth or intestine, however, reduce nitrate to nitrite in appreciable amounts, so that up to 100 mg may be formed daily (National Academy of Sciences, 1979).

The situation regarding nutritive elements in the U.S. diet is complex. Certain tumors, such as those of the breast and uterus, are associated with obesity in human beings (MacMahon et al., 1970). Studies have shown that tumor incidence in animals may be decreased in some circumstances by restricting calories, fats (particularly polyunsaturated fats), and protein (Tannenbaum and Silverstone, 1953; Carroll and Khor, 1971). From epidemiologic observations, associations between high calorie, high fat, and low fiber diets and cancer of the colon have been reported (Wynder, 1978). These effects are assumed to be related to metabolites produced by intestinal bacteria that can be modified by a change in the composition of the diet. Further study of bacterial metabolism in the gut under various dietary conditions favoring tumorigenesis is needed.

The Board believes that in the absence of evidence of a causal relationship between the macronutrients of the diet and cancer, there is no basis for making recommendations to modify the proportions of these macronutrients in the American diet at this time. Although the recommendations reflected therein are slightly different, the recent statement on Diet and Cancer from the National Cancer Institute also recognized that no direct cause-effect relationship has been observed for nutrition and cancer in humans (Upton, 1979). It is possible that the correlation between high fat diets and colon cancer may reflect a high energy intake leading to overweight or some other diet-related variable. Clearly, a nutritious diet providing adequate amounts of all nutrients and the proper energy content to achieve desirable weight is important for general health and for vigorous defense mechanisms against cancer as well as other diseases.
Diabetes Mellitus

Diabetes mellitus is not a single disease but rather a syndrome of hyperglycemia and glycosuria, accompanied by varying degrees of ketosis and acidosis, with or without weight loss. It has several causes and mechanisms of inheritance. Juvenile diabetes occurs in young people because of a failure of the pancreas to secrete insulin in adequate amounts and represents an insulin deficiency. Ketoacidosis and weight loss due to catabolism of fat and protein are common in this form of the disease. Late onset of diabetes in adults after age 40 does not usually result from insulin deficiency, but is strongly associated with obesity and appears to result from an alteration in insulin receptors. Severe ketosis is not common in this form of diabetes.

Epidemiological studies are not consistent with the hypothesis that high sugar consumption is a cause of diabetes mellitus (Medalie et al., 1975). The Pima Indians of Arizona, for example, have a prevalence of adult-onset diabetes that is among the highest in the world, but their intake of sugar is considerably lower than that of the average American (Bennett et al., 1976). There is evidence that genetic factors are important in the development of diabetes in the Pima and in the development of noninsulin-dependent diabetes generally. High carbohydrate diets have been reported to increase the glucose tolerance of mild late-onset diabetics (Brunzell et al., 1971). It has been shown that increasing the ratio of "complex" carbohydrates to simple sugars in the diet improves glucose tolerance in diabetic individuals (Crapo et al., 1976). In addition, it has been shown that such viscous soluble fibers as metamucil, pectin and guar further improve glucose tolerance and control of insulin secretion in diabetics (Jenkins, 1979). For this reason, persons with factors predisposing to diabetes, including obesity, might well increase the consumption of foods containing "complex" carbohydrates and soluble plant fibers. A ratio between "complex" carbohydrates and simple sugars of between 1:1 and 2:1 should be sought. Excessive caloric intake should be avoided and an adequate level of physical activity maintained. In juvenile diabetics, blood sugar levels should be maintained within normal limits by judicious use of insulin, diet, and exercise. Late-onset, obese diabetic subjects in general do not require exogenous insulin and should be regulated with diet and a program of physical activity (Cahill et al., 1976).

Even though coronary artery disease and other manifestations of atherosclerosis are more common in diabetic persons than others, there is no convincing evidence that fasting serum cholesterol levels are higher in well-regulated diabetic men than in normal men (Bennion and Grundy, 1977).

The Board recommends that careful regulation of diabetes with diet containing more complex carbohydrates, insulin (if necessary), and exercise to achieve normal weight and blood sugar levels is important to extend life and minimize the complications of the disease, including atherosclerosis.
Decision-making in Public Health

Good public health practice depends upon the application of sound principles of preventive medicine to population groups. One of these principles is that primary prevention of disease is preferable to treatment, provided the preventive intervention is effective and safe. Another is that primary prevention is preferable to secondary prevention, i.e., the prevention of the progression of a disease, once established. Immunization of healthy persons against preventable infectious diseases is a classic example of primary prevention and constitutes good public health practice. It is clear that risk-benefit considerations for proposed new interventions constitute an important aspect of decision-making in public health.

Any public official considering a new public health program for disease prevention must evaluate the potential effectiveness of the proposed action before recommending its adoption. If there is uncertainty about its effectiveness, there must be clear evidence that the proposed intervention will not be harmful or detrimental in other ways. In the case of diseases with multiple and poorly understood etiology, such as cancer and cardiovascular disease, the assumption that dietary change will be effective as a preventive measure is controversial. These diseases are not primarily nutritional, although they have nutritional determinants that vary in importance from individual to individual. Authorities who resist recommendations for diet modification express a legitimate concern about promising tangible benefits from controversial recommendations that alter people’s lives and habits. Many also have an equally valid concern about diverting attention and resources away from investigation of the underlying causes of these diseases toward unproven action programs. Those experts who advocate a more aggressive approach and seek to change the national diet in the hope of preventing these degenerative diseases assume that the risk of change is minimal and rely heavily on epidemiologic evidence for support of their belief in the probability of benefit. The degree of neither risk nor benefit can justifiably be assumed in the absence of suitable evidence.

The Board has debated its recommendations in light of these considerations. It believes that an extensive and critical evaluation of assumptions underlying any recommendations for dietary change should be carried out, including risk-benefit analyses. It is aware that changes in the American food supply are occurring spontaneously and continuously due to innovations by the food industry, advertising and consumer preferences. The subject of dietary guidelines will be under continuing study and reports will be issued by the Board periodically in the future.

Conclusions and Recommendations

In a sound program of preventive medicine, appropriate nutritional guidance is an essential part of a comprehensive plan involving immunization,
improvement of physical fitness, prevention of accidents, and avoidance of cigarette smoking and alcohol abuse. Individual variation in human populations with respect to susceptibility to the chronic degenerative diseases is large; therefore, surveillance of risks by health professionals is recommended for all healthy persons. Each individual should be aware of his personal metabolic risk factor profile, which includes assessment of hyperglycemia, hypercholesterolemia, hypertension and family history.

The Board expresses its concern over excessive hopes and fears in many current attitudes toward food and nutrition. Sound nutrition is not a panacea. Good food that provides appropriate proportions of nutrients should not be regarded as a poison, a medicine, or a talisman. It should be eaten and enjoyed.

In view of these premises, the Board makes the following recommendations to adult Americans. It believes that these guidelines will improve general nutritional status, may be beneficial in preventing or delaying the onset of some chronic degenerative diseases, and incur no appreciable risks. Additional recommendations for infants and children and for pregnant and lactating women have been made previously (FNB, 1980).

- Select a nutritionally adequate diet from the foods available, by consuming each day appropriate servings of dairy products, meats or legumes, vegetables and fruits, and cereal and breads.
- Select as wide a variety of foods in each of the major food groups as is practicable in order to ensure a high probability of consuming adequate quantities of all essential nutrients.
- Adjust dietary energy intake and energy expenditure so as to maintain appropriate weight for height; if overweight, achieve appropriate weight reduction by decreasing total food and fat intake and by increasing physical activity.
- If the requirement for energy is low (e.g., reducing diet) reduce consumption of foods such as alcohol, sugars, fats, and oils, which provide calories but few other essential nutrients.
- Use salt in moderation; adequate but safe intakes are considered to range between 3 and 8 g of sodium chloride daily.

References


Health and Welfare Canada. 1979. Can-
ada's Food Guide. Department of National Health and Welfare, Ottawa, Canada.


Comment on “Toward Healthful Diets”

D. MARK HEGSTED, PH.D.
Director, Human Nutrition Center
U.S. Department of Agriculture

“Toward Healthful Diets,” the recent statement issued by the Food and Nutrition Board of the National Academy of Sciences, contains many agreements with an earlier report of the United States Government.

It concurs with “Dietary Guidelines for Americans,” published jointly earlier this year by the Department of Agriculture and the Department of Health and Human Services, on the following points: 1) Dietary guidance must take into account the fact that nutritional needs vary depending on age, sex, physical activity, and other conditions such as pregnancy or illness. 2) Obesity is generally recognized as a risk factor in such chronic diseases as hypertension, diabetes, coronary artery disease, and strokes. 3) Gradual, steady weight loss, involving long-term eating discipline, is both safer and more likely to be successful than fad diets which promise quick results. 4) A moderate increase in physical activity is important and helpful in a weight-loss program. 5) A healthy diet means eating a variety of foods. 6) Most Americans eat more sodium than they need, and should reduce their sodium intake. 7) Alcohol should be consumed only in moderation. 8) Reductions in consumption of sugars, fats and alcohol are often necessary to maintain ideal weight and prevent obesity.

Our reports agree, further, that there is abundant evidence that dietary fat and cholesterol are factors which determine serum lipid levels, and serum lipid levels are risk factors of atherosclerosis and coronary artery disease.

Where the reports disagree is on the implication of the facts about dietary fat and cholesterol for the American public. The Food and Nutrition Board concludes that the evidence warrants no specific recommendations about dietary cholesterol for the healthy person, and that the average person does not need to be concerned about fat intake.

An “average person” is not defined, though the report does say, at one point, that “Infants, adolescent boys, pregnant teen-age girls, and adults performing heavy manual labor, probably have no need to reduce the fat level of their diets below 40 percent of calories,” while “sedentary persons attempting to achieve weight control may be well advised” to reduce calories by reducing fat.

The two U.S. government departments most concerned with food and health chose a more conservative, prudent approach. Based on evidence of a relationship between dietary fat intake and heart disease, as well as obesity, and lacking any evidence that a low-fat diet is harmful to anyone, we recommended that Americans avoid too much fat, saturated fat, and cholesterol, in their diets.

The Food and Nutrition Board accepted precisely that reasoning in recommending that Americans reduce their salt consumption, saying that “There is no reason to believe that reduction of sodium chloride intake…would be harmful for healthy persons, and it may be helpful for the prevention of hypertension in susceptible individuals…”

The board rejects, however, a similar risk-reduction approach in the case of cholesterol.

The board does not deal with the issue of sugar and dental caries, even though the American people spend more than $2 billion a year on dental care, and the
American Dental Association and the National Institute of Dental Health believe that much of the damage of dental caries is related to the consumption of sugary materials.

Forty to fifty percent—nearly half—of Americans die of heart attacks. More than 35 percent of adult Americans are obese and another 5 to 10 percent suffer from diabetes.

According to “Healthy People,” the Surgeon General’s Report on Health Promotion and Disease Prevention, about one-third of today’s obese adults were obese as children, and an obese child is at least three times more likely to be an overweight adult.

Statistics such as these clearly indicate that a substantial proportion of the American population is at risk of one or more of the chronic diseases which may be related to dietary factors.

It is small wonder that Americans are concerned about the food they eat and its effects on their health. Study after study has illustrated that concern, and there is fairly strong evidence that the concern is justified.

Last May, after an exhaustive study on the association between dietary factors and chronic disease, the American Society for Clinical Nutrition issued consensus papers which relate directly to this controversy.

The society found associations between alcohol consumption and liver disease, between sugar and dental cavities, between salt and hypertension, and between cholesterol and saturated fat and coronary artery disease.

Many national and international expert committees have reached similar conclusions.

Far from agreeing with the Food and Nutrition Board that general dietary guidance should not be made, we believe that many Americans are anxious to have dietary advice from reliable, unbiased sources. We believe that the preponderance of evidence suggests that recommendations can and should be made so that Americans can increase their awareness of the role of diet in health promotion and disease prevention.

USDA is the government’s food department and we believe that food is for nourishment and enjoyment. It was in this spirit that we presented the Dietary Guidelines—not as a panacea, a prescription, or a nutritional insurance policy, but as prudent advice, based on the best current scientific knowledge and a growing consensus of the scientific community. The Guidelines are: 1) Eat a variety of foods. 2) Maintain ideal weight. 3) Avoid too much fat, saturated fat, and cholesterol. 4) Eat foods with adequate starch and fiber. 5) Avoid too much sugar. 6) Avoid too much sodium. 7) If you drink alcohol, do so in moderation.
INDEX

Aangamik, 119-120
Absinthe, 59
Additives, food, 83
Allergy, cerebral, 145
AMA, Bureau of Investigation, guidelines of, for spotting quack, 46-47
“Concepts of Nutrition and Health,” 10, 199-205
and unmasking of questionable physicians, 47
Amblyopia, tobacco, 51
American Christian College, 18, 73
American Council Science & Health, 92
American Institute of Nutrition, 80
American Journal of Clinical Nutrition, letters to editor, 99-106
American Media laetrile promotion by, 36
American Media, publications of, 39
American Opinion, article by Larry McDonald in, 40
American Society for Clinical Nutrition, 80
A-mulsin, 60, 103, See Vitamin A, emulsified
Amygdalin. See Laetrile(s)
Anemia(s), definition of, 189
iron deficiency, 190-192
nutritional, 189-198
definition of, 189
Apricaps, cyanide poisoning following ingestion of, case illustrating, 63-64
Apricot kernel(s), and amygdalin poisoning, review of cases of, 24-32, 26, 63-64
as source of cyanide, 23-24
cyanide content of, 24
death following consumption of, case illustrating, 63-64
and laetrile consumption, warning concerning, 50, 94
milkshake, poisoning from, 26-27
Arachidonic acid, 179
Ariboflavinosis, 182
Arsenic, Cult of, 19-20
Ascorbic acid. See Vitamin(s), C
Atherosclerosis, possible causative factors in, 213
risk factors in, 213-214
Athletes, calories and, 12
Atkins, Robert, suits against, 91
Balancing body chemistry, 2, 43
Barrett, Steve, 1-3, 74
Behavior disorders, diet and, 12-13
Benzaldehyde, 59, 100, 104
Beri-beri, 182
Bioflavonoids, 84, 179
Biotin, 173, 186
“Bohanon affidavit,” 42, 56
Books, misleading, lack of FDA jurisdiction over, 88
misleading nutrition information in, legal action in, 64, 91
nutrition, sound, 13-14
Bradford, Robert, 51
Breast feeding, advantages of, 202
Brody, Jane, and Holleb, Arthur, “You Can Fight Cancer and Win” by, 39
Brown, Marco, 61
Burk, Dean, promotion of laetrile by, 17
Burton, Lawrence, 73
Butterworth, C. E., Jr., review by, of “New Hope for Incurable Diseases,” 81
Caffeine intoxication, 85-86
Calcium gluconate, in pangamic acid, 110
Calcium propionate, 83
Calories, daily requirements of, 12
Cameron, Ewan, 99-100, 103-139
Cancer, diet and, 218
laetriles may cause, 42-43
quackery, laetrile in, 38
terminal, drugs in, choice of, 42
and “incurable,” distinction between, 42
therapy, Committee for Freedom of Choice in, 20
victims, exploitation of, 38
vitamin C and, 139, 148
Candlelighters, 63
Cardiovascular disease, 213-216
Carson, and cornflakes, 9
Cederquist, Dena C., on fear of reputable doctors and journals of libel suits by quacks, 87-88
Cerebral allergy, 145
Charlatan, definition of, 78
Cheraskin, Emanuel, 131
and Ringsdorf, W. M., Jr., “New Hope...
for Incurable Diseases” by, 80-81
Cholesterol, body need for, 6, 177, 206
and cancer, 177
and cardiovascular disease, 214-215
intake, and serum cholesterol concentration, 92, 216
Choline, 179
Clark, John, on people who go into cults, 48
Cleckley, Harvey, “The Mask of Sanity” by, 44
Clinical trials, as source of reliable evidence, 152
ethical way of doing, 155
Code words, 22, 141
Coffee enemas, 60, 97
Cold, common, vitamin C and, 125, 133-134
Cole, Donald, 61
Consent, informed. See Informed consent
Consumer Reports, 84
Contraceptives, oral. See Oral contraceptives
Contreras, Ernesto, 55, 56
Contreras Clinic, laetrile therapy at, 27
Cult(s), childish existence in totalitarianism in, 54-55
definition of, 19
escape from reality in, 54, 59
fanaticism in, Chad Green case as illustration of, 55
gurus, psychiatric explanation of, 44
health, history of, 19-20
people who join, fanatical devotion of, to leaders, 48, 54
John Clark on, 48
propaganda, lethal effects of, 59-65
Cyanate, blood, in cyanide poisoning, 52
toxicity, clinical signs of, 30
Cyanide, absorption and diffusion, 24
apricot kernel as source of, 24
-containing foods, processing of, 25-26
cookbooks, 25
Cult of. See Laetrile(s), Cult
determinations, during laetrile therapy, 28-29, 51, 53, 61
exposure, chronic, symptoms of, 53
fatal dose of, 24
human toxicity of, Merck Index list of, 31
hydrogen. See Hydrocyanic acid(s)
in laetrile, 50
low doses of, conditions produced by, 94
olfactory perception of, 31-32
poisoning, acute, blood cyanide in, 51-52
in child, symptoms of, 31
chronic, of Chad Green, 53
following laetrile therapy, case illustrating, 63-64
from laetrile, 15, 23-28
health food store owner, 25
hospital reports of, 25
insidious, 52
in Laetrile Cult and People’s Temple, 49
nonfatal symptoms of, 24
symptoms of, 25, 138
release, from laetrile, 32
Cyanocobalamin. See Vitamin(s), B₁₂
Da Vinci Labs, 120
Davis, Adelle, 5, 131
“Let’s Have Healthy Children” by, 64, 91
Delaney Amendment, 156, 157
Deoxyribonucleic acid. See DNA
De Spain, June, 25
Diabetes mellitus, causes of, 219
diet therapy in, 219
excess body fat in, 204
vitamin C and, 133
Diagnosis, proof of, prior to claim of cure, 155
Dichloroacetaote, adverse effects of, 111-112
in pangamic acid, 111
Diet(s), adequate, 75-76, 199-201
books, sound, 13-14
and cancer, 218
change in, in disease prevention, 220
and disease, 205-206
fad, 212
healthful, toward, 207-223
quest for, guidelines in, 209-211
history, in vitamin intake assessment. See Specific Vitamin
low-protein, low-calorie, in cancer therapy, letter in support of, 99
modification, in behavior disorders, 12-13
“nutritional and metabolic antineoplastic,” 93-96, 105
recommendations, to adult Americans, 75-76, 221, 223
restricted calorie, 212
therapy, in diabetes mellitus, 219
vegetarian, and laetrile therapy, 31
well-balanced, 75-76, 130-131, 147, 200-201

Dietary Allowances, Recommended, 76-77, 121, 132, 142, 147, 148, 171, 200, 208-209
1979 food guide in, 209
Diisopropylamine, dichloroacetate, in pangamic acid, 105, 111
in pangamic acid, 111
Dimethylglycine, 113, 115-116, 119-120
Disease, primary prevention of, in public health, 220
DMG, see dimethylglycine
DNA, bill, federal proposed, 155-156
recombinant, ethics of, opinions on, 156
research, 158
Donsbach, Kurt, 7, 13, 55, 74
Drug(s), experimental, use of, conditions for, 165
information required prior to, 166
malpractice and, 163
prescription of, informed consent and, 164
therapeutic ratio of, determination of, 59
toxicity, as increasing problem, 161
avoiding of, 161-162
with side effects, medical, legal and ethical considerations in use of, 161-169
Duffy, John, on medical practice and folk medicine, 46

Endorphin, in placebo effect and in acupuncture, 140
Energy, balance, and obesity, 211-212
expenditure, weight control and, 213
Enzymes, and cancer, 6, 54, 60
Essential fatty acids, 179
Ethics, as oldest intellectual discipline, 153
code of, written, for physicians, 166-167
decisions in, and informed consent, 157
in inadequate evidence, 156-157
drugs with undesirable side effects and, 166
medical, 153-154
in new kinds of research, 155-158
retaining old, acquiring new information while, 151-159
in therapy, balance of rights and benefits in, 158
Experiments, on physicians, value of, 154

Fat, body need for, 6
intake, cholesterol levels and, 215
Fatty acids, essential, 179
Federal Communications Commission, and nutrition misinformation, 88-89
Federal Trade Commission, and nutrition misinformation, 88-89
Federation of American Societies for Experimental Biology, 80
Fertilizers, chemical and natural, 82
Fetus, laetrile and, 27
Fluoridation, 2, 82
Fluoride deficiency, 82
Folate. See Folic acid
Folic acid, 173, 185-186
deficiency, 185-186
in women, 189-190
deficiency anemia, 192-195
massive doses of, 139
minimum daily adult requirement for, 194-195
Food(s), additives, 83
"basic four," 75-76, 90
choice, religion influencing, 9
cyanide-containing, processing of, 25-26
and Drug Administration, and nutrition misinformation, 8, 9, 47, 88
regulations, nutrition and, 82, 88
Guide, Daily, four basic groups in, 130-131, 147, 200-201
habits, good, establishment of, 202
health, as racket, 8, 75, 84
"natural," molds on, 82
and Nutrition Board, functions of 208-209
members of, 206, 207-208
nutritive value of, processing and, 82-83
plant, with oral laetrile, causing cyanide poisoning, 32
toxicants in, 23
Food Science Labs, 120
Fraud, tests for, 45-47, 90
Fredericks, Carlton, 7, 131, 134
Fruit, 75
Ginseng, 85
Glucose 6-phosphate dehydrogenase deficiency, vitamin C and, 132-133
β-Glucosidase, foods containing, 93, 94
Glycosides, cyanogenic. See Laetrile(s)
Goiter, laetrile and, 27
Grain, 76
Green, Chad, case of, 52-54, 56-57
and laetrile, 6
Growth factors, for bacteria, 143-144, 179
Gurus, cult, psychiatric explanation of, 44
Hair analysis, 2, 145
Halstead, Bruce, 55, 56, 94
Hargis, Billy James, 73
Harper, Alfred E., 170, 206, 267
Harvard Medical School, evaluation of
medical information by, canons for, 45, 114
Health, care, no-fault laws, 163-164
Federation, National, 7
foods, 84, 97
foods, as racket, 8, 75, 84
foods, toxic, 27-28, 52-55, 107-117, 123-
126
hustlers, 75-92
information, medical profession and,
205
weakness of law governing, 88-91
public, decision-making in, 220
quack(s). See Quack(s)
research scientists, organizations of, 80
“Health Robbers, The,” edited by Stephen
Barrett and Gilda Knight. 8, 38, 131
Healthy People, Surgeon General’s Report
on, 210
Heart disease, coronary, dietary therapy in,
204-205
Hegsted, Mark, 224-225
Hemoglobin count, in anemia, 189
Hesperidin, 179
Hodgkin’s disease, laetrile in, 138
Hoefer-Janker, 61
Hofbauer, Joseph, 60-63
Hoffmann-LaRoche, vitamin C and, 11, 12,
146
vitamin sales promotion by, 12
Holleb, Arthur, and Brody, Jane, “You
Can Fight Cancer and Win” by, 39
Homeopathy, Cult of, 20
Homocystinuria, 123
Hopkins, Frederick G., 177
Hunzas, cancer and, 42
Hydrocyanic acid(s), lethal doses of, 24
released, 15-16
Hydrogen cyanide. See Hydrocyanic
acid(s)
Hydroxocobalamin, 19, 137
Hypertension, diet in, 204
and obesity, 217
and salt intake, 216-217
Hypotension, following intravenous laet-
trile therapy, 29
Infant, nutrition for, 202
Informed consent, 153, 164
as legalistic concept, 157
case citations concerning, 164-165
disclosure in, extent of, 165
drugs with undesirable side effects and,
164
ethical controversies and, 157
Inositol, 84, 179
Iron, absorption, 191-192
deficiency, anemia, 190-192
in women, 189-190
dietary, estimated requirements of, 191,
192
needs, average diet and, 84
requirements, for pregnancy, 191, 192
Irons, V. Earl, 55
John Birch Society, Laetrile Cult and, 20,
40
Jones, Jim, of People’s Temple, 44, 48
Journals, medical, fear of, of libel action
by quacks, 88
Kelley, William, 97
Kittler, Glenn, 102
Knowledge, control of, ethics and, 158
Krebs, Ernst T., 86, 108
Krebs, Ernst T., Jr., 18-19, 21, 51, 57-58,
61, 86, 95, 108
Krebs theory, 58
Korsakoff’s syndrome, 182
Label(s), and claims made orally or in
book, asking quack to verify, 90
food, nutrition, statements on, 8, 9, 13,
82, 88
Laetrile(s), actions of, 6
affidavits, from kin of deceased, 34
anecdotal and testimonial claims for,
worthlessness of, 33
and apricot kernels, consumption of,
warning concerning, 94
poisoning, review of cases of, 26
arguments for, “freedom of choice” and
“terminal cancer,” 41
as cancer cure, 35-41, 138, 155
chemistry of, 15-41, 138
contamination of, 62
Cult, devotee of, method for murder of, 43
and industry, 19-23
“metabolic therapy” of, 53, 54
and People’s Temple, similarities between, 49
religious overtones of, case illustrating, 63
support of, 20
cyanide in, 16-17, 32, 50, 137
cyanide poisoning from, 15, 23-28, 96, 137
“doctors,” 36-37
fetus and, 27
goiter and, 27
in Hodgkin’s disease, 138
in human anticancer therapy, letter in support of, 100
answer to, 102-106
illegality of, in most countries, 37
industry, article, typical, 55-56
creation of “metabolic physicians” by, 58
interlocking nature of, 22
promotion of, 20, 21, 55-59
injected, excretion of, 58
Larry McDonald and, 7, 21-22, 26, 40, 89
legal position of U.S. and Canada concerning, 50
liability of physician and, 49
may cause cancer, 42-43, 65
in “nutritional and metabolic antineoplastic” diet, 95
poisoning, cases illustrating, 15, 28, 29, 137
clinical signs of, 29-30
laboratory diagnosis of, 28
poisonous, knowledge of, history of, 23
positive results of, on tumors, study of, 37-38
processing of, 26
promoters of, demonstration of safety of apricot kernels by, 25, 26
language of, 22-23
-promoting “fringe” clinics, 36
promotion of, as vitamin, 17-19
by Dean Burk, 17
by E. T. Krebs, Jr., 18-19
promotional materials, 36
propaganda, effectiveness of, on judge, case illustrating, 60-63
reactions to, nonfatal, cases illustrating, 30-31
sales, 141
sources of, 23
synthetic, 15, 16, 17, 95, 104, 138
tablets, laetrile content of, 94
therapy, as killer where proper therapy may cure, 53, 63, 138
human experimentation with, 60-63
intravenous, hypotension following, 29
plasma and blood determinations during, 28-29
vegetarian diet with, 31
toxicity, actual cyanide concentration influencing, 32
admitted to by promoters, 27
factors affecting, 32
in tumor-bearing animals, 36
warning notice, 49, 50
“Laetrile Case Histories,” by Richardson and Griffin, 39, 93, 94
Lawyer, code of ethics for, for client representation, 167-168
Leber’s hereditary optic atrophy, 51
Legal action(s), by quacks, fear of reputable doctors and journals of, 87-88
recent, against self-styled nutritionists, 116-117
Letters to editor, American Journal of Clinical Nutrition, 99-106
Lifton, Robert Jay, on people who join cults, 48-49
Linoleic acid, 179
Lipoic acid, 179
Lipoprotein fractions, in coronary heart disease, 214, 215
Malpractice, and drugs, 163
suit, insulation against, diagnostic tests as, 163
Manner, Harold, 33-34, 54, 56-57, 60
“Mask of Sanity, The,” by Harvey Cleckley, 44
McCarty, Mark F., letter of, in defense of laetrile therapy, 99-101
McDonald, Larry, 7, 21-22, 89
Scott vs., 7, 40
McNaughton, Andrew, 17, 51, 70
McNaughton Foundation, 17, 36, 108
McQueen, Steve, 97
Meat, 76
Medical fraud, avoiding of, self-questions for consumer in, 46
Medical information, evaluation of, Harvard Medical School canons for, 45, 114
Medical treatment, questions concerning, public service organizations to contact with, 47
Megavitamin therapy, as term, 121, 129, 142, 144
See also Vitamin(s), therapy, massive-dose
Mencken, H.L., 43
Metabolic doctors, 56, 58, 60-62, 141
Metabolic stress, in women, anemias in, 189-190
Milk, 76, 92
Mills, Don Harper, on drugs and malpractice claims, 163
Miner, John, on Phillips case and medical quackery, 43
Monosodium glutamate, 83
Mosinee, U.S.A. vs., 41-42
Mother Jones, 13
Multivitamin "stress" products, 147
Murder, conviction of, in vitamin therapy instead of surgery, 138, 155
See nutrition quackery as, 43
National Academy of Sciences, "Toward Healthful Diets," 10, 170, 207-225
National Health Federation, 7, 20, 33-34, 55, 132
National News Council, 74
Natural foods, 1, 82, 92
New York, 13
Niacin, 172-173, 183
deficiency, 183
excess conditions associated with, 77
massive doses of, undesirable effects of, 124, 135
Nicotinamide. See Niacin
Nicotinic acid. See Niacin
Nitrilodoses, 15
Nitrite, intake, average, 218
No-fault concept in medical care, 163-164
Null, Gary, 88
Nutrients, requirements for, factors influencing, 199
standards for, 199-200
Nutrition, adequate, assessment of, 179-180
as science, 10
books, sound, 13-14
claims, evaluation of, scientific canons for, 141-142
cultism, advertising by, 8
code phrases of, 45, 141
demagogues in, first, 9, 44-49
distortion of decisions by, 10
scare tactics and sensationalism in, 9
cultists, recognizing of, 19
deficiencies, in U.S., 90
facts and fallacies, 130-132
FDA regulations concerning, 8, 9, 13, 82, 88
food notions and, 199
four basic groups in, 75-76, 130-131, 147, 200-201
frauds, publications lending authenticity to, 13
guidelines, for improved health, 209-210
and health, AMA statements on, 10, 199-205
infant, 202
maternal, 201-202
in maturity, 203
moderation in, 8, 10, 90
quackery, allure of, 44-49
as murder, 43
hallmarks of, 8
media promotion of, 9-10, 13
organizations promoting, 5, 7, 11
quacks. See Quack(s)
statements, on labels, 8, 9, 13, 82, 88
national nutrition bodies, 10
Nutrition Almanac, 13
Nutritionist(s), debates between, 11
deceptive, media and, 9-10
self-incorporation of, 8
honest, codes of, 8
responsible, and quacks, on same forum, 34
Obesity, as form of malnutrition, 211
cerebrovascular disease, 212
hypertension and, 217
morbidity or mortality associated with, 205, 211
Olson, Robert, 206-207
Oral contraceptives, ethical considerations in prescriptions of, 162-163
reducing iron need, 190
side effects of, 162
vitamin requirements and, 147-148, 190
Organic food, 83, 92, 131
Orthomolecular psychiatry, 77, 124, 135, 141, 145
Osuntokun, 104
Oxygen therapy, retrolental fibroplasia in, 151-152

PABA, see Para-aminobenzoic acid
Pancreatic enzymes, oral, in "nutritional and metabolic antineoplastic" diet, 94-95
Pangamate. See Pangamic acid
Pangamic acid, 6-7, 13, 60, 65, 86, 95, 105, 107-117, 119-120, 139, 141
as label, not product, 107
as latest health food rage, 107
background of, 108-109
calories and, 114
chemistry of, 109-111
clinical use of, 113-114
contents of, 107
dichloroacetate or dimethylglycine in, 105, 110
illegality of, in U.S. and in Canada, 113-114, 115
in "nutritional and metabolic antineoplastic" diet, 95
pharmacology of, 111-113
promoters of, 107
purported properties of, 108
supposed value of, 113
variety in composition of and names for, 110, 111, 114-115, 117
Pantothenic acid, 173, 186
Para-aminobenzoic acid, 84, 179
Pauling, Linus, 5, 13, 77, 100, 103, 131, 134, 135, 139
Institute of, 12, 146
Pellagra, 183
People's Almanac, 13
People's Temple, and Laetrile Cult, similarities between, 49
leader Jim Jones of, 48
Phillips, Marvin, murder conviction of, 43
Physician(s), as subject of experiment, value of, 154
"metabolic," creation of, by laetrile industry, 58
questionable, unmasking of, AMA and, 47
Placebo, definition of, 85
Placebo effect, 35, 85, 125, 139-140
Plant(s), cyanide release by, 23
foods, with oral laetrile, causing cyanide poisoning, 32
Potassium, toxicity, 91
Pregnancy, folate deficiency in, 193-194
iron requirements for, 191, 192
nutrition in, 201-202
Prevention Magazine, 5, 7, 11, 13, 27, 97, 132
Preventive medicine, comprehensive plan in, 220-221
Protein(s), apoenzyme, 129-130, 143
production, defect in, in vitamin-dependent genetic diseases, 123
Psychology, social, experiments in, consent in, 158
Pye, Jo Anne, 43, 63-64, 94
Pyridoxine. See Vitamin(s), B6
Quack(s), appeal of, to patient, 34
as legally belligerent, 87-88
as responsible for harm done, case illustrating, 89
attributing disease to bad diet, 81
bills promoted by, passing of, 45
buying advice to consumer by, 79
"Conspiracy Theory" and "Controversy Claim" espoused by, 86-87
credentials of, 78, 79-80
cures promised by, 84-85
definition of, 78
food additives and preservatives declared poisonous by, 83
inability of layman to recognize, 44
increased nutrient needs in stress and disease emphasized by, 83
malnutrition related to soil depletion and chemical fertilizers by, 82
"natural" vitamins touted above "synthetic" vitamins by, 84
poor nourishment of most people declared by, 81-82
pseudoscientific jargon of, 45
questions by, specious logic of, 44-45
recognition of, tips for, 79-87
removal of nutritive value from food in processing alleged by, 82-83
spotting of, AMA guidelines for, 46-47
studies by, 78-79, 90
support of case by, 78
testimonials to support claims of, 85
vitamin supplementation in poor eating endorsed by, 84
vitamins and health foods for everyone endorsed by, 84
“vitamins” offered by, 86
Quercetin, 179

RDA, see Dietary Allowances, Recommended
Reams, Carey, 57
Red cell hemolysis, in premature infants, vitamin E and, 135-136
Religion, influencing food choice, 9
Retinol, 124, 172
Retrolental fibroplasia, in oxygen therapy for premature infants, 151-152
Reynolds, Judge John, decisions of, in laetrile cases, 33, 36
Riboflavin, 172, 182-183
Richardson, John, 17, 38, 39, 51, 64, 70, 94
Ringsdorf, W. M., Jr., and Cheraskin, Emanuel, “New Hope for Incurable Diseases” by, 80-81
Roche, see Hoffmann La Roche
Rodale Press (Prevention Magazine), 5
Roszkowski, Stanley, 120
Rothblatt, Henry, 25, 26
Rubin, David, 33, 34
Rutherford vs. U.S.A., 41, 42
Rutin, 84

Saccharin decision, 156-157
Salt, intake, hypertension and, 204, 216-217
reduction of, 27
Schachter, Michael, 60-63
Schizophrenia, megalavitamin therapy for, 134-135
Scientific experiments, disclosure standards in, 157-158
Scientific inquiries, restriction of, ethics and, 156
Scientific studies, 10, 45
Scientist, nutrition. See Nutritionist(s)
Scott vs. McDonald, 7, 40, 89, 93
Scurvy, rebound, vitamin C and, 124, 132, 180-181
symptoms of, 180-181
Shute brothers, 5, 131
Sickle cell disease, vitamin C and, 133
Simeons, on religion and food choice, 9
Smith, Ralph Lee, on Carlton Fredericks as legally belligerent, 87
Smoking, thiocyanate excretion in, 51
vitamin C and, 147-148
Stang, Alan, 55-56
Statements, validity of, evaluation of, need for teaching of, 49
Stool, validity of, vitamin C and, 133
Stress, and increased nutrient needs, 83, 147
Sugar, body need for, 6
Symms bill, McDonald and, 22

Talk shows and quackery, 9, 11, 34, 89
Tennessee statute, 163-164
Testimonials, use of, by quack, 85, 134
Therapeutic ratio of drug, determination of, 52, 59
Thiamine, 172, 182
Thiocyanate, excretion, 28-29, 51
toxicity, signs of, 31
Thurston, Emory, 55
Tobacco amblyopia, 51
Tocopherol. See Vitamin(s), E
Treatment(s), existing, imposing clinical trial drugs on, 155
experimental nature of all, 158
new, consideration of alternative courses of action and, 154-155
risk associated with, 154

Ubiquinone, 179
U.S.A. vs. Mosinee, 41-42
US Magazine, 74

Vegetables, 75
Vegetarian diet, and laetrile therapy, 31, 93-106
Vitamin(s), A, 172
emulsified, 5, 65, 103, 144; See A-mulsin therapy, 53-54, 60-61
excess, conditions associated with, 77
massive doses of, 5
toxicity of, 53-54, 60-61, 91, 103, 124
therapy, letter in support of, 100
toxicity of, 105
absorption, inadequate, therapy in, 122
actions of, 176
as dietary supplements, situations requiring, 146
B complex, 172-173
B₁, 172, 182
B₂, 172, 182-183
B₁₂, 173, 183-184
  - deficiency, 184
  - massive doses of, undesirable effects of, 125, 139
B₁₂, 19, 137, 173, 184-185
  - addition of cyanide to, 19
  - in cyanide poisoning, prevention and treatment, 19
  - deficiency, 185, 195
  - massive dose vitamin therapies destroying, 78, 124-125, 126, 133
B₁₅. See Pangamic acid
B₁₇. See Laetrile(s)
C, actions and sources of, 173
  - and cancer, 139, 148
  - and common cold, 77, 125, 133-134
  - deficiency, symptom history and physical examination for, 180-181
  - excess, conditions associated with, 78
  - Hoffmann-LaRoche and, 11
  - intake, diet history of, 180
  - levels and function of, laboratory testing for, 181
  - Linus Pauling and, 5, 139
  - massive doses of, dangers of, in certain disease states, 132-133
  - letter in support of, 99-100
  - in “nutritional and metabolic antineoplastic” diet, 94
  - undesirable effects of, 124-125, 132, 146-147
  - vitamin B₁₂ and, 78, 124-125, 133
coenzymes, actions of, 129-130
craze, 141-150
D, 173
  - excess, conditions associated with, 77
  - massive doses of, toxicity of, 124
  - deficiency(ies), causes of, 121
  - laboratory diagnosis of. See Specific Vitamins
    - subclinical, 82
  - deficiency diseases, 171
  - definition of, 86, 129, 143, 171, 177
  - -dependent genetic diseases, 122-123
  - developed by quacks, 86, 95
  - doses, large, 5
E, 135, 136, 173-176
  - excess, conditions associated with, 77
  - massive doses of, in “nutritional and metabolic antineoplastic” diet, 94
  - undesirable effects of, 124, 126, 136
  - essential for human health, 174-175
  - excess, definition of, 76
use of, legitimate, 77
fat soluble, 143, 172
  - as metabolic regulators, 129
for everyone, recommended by quack, 84
functions of, as chemicals, 130, 143
  - as vitamins, 129-130, 143
“high potency stress formula,” 147
history of, 176-177
increased destruction, excretion, or requirement of, 123
ingestion, inadequate, therapy in, 121-122
“invented” by laetrile promoters, 103
K, 176
“natural” and “synthetic,” 84
poisoning, incidence of, 125
popular misconceptions about, 145-147
promotion of laetrile as, 17-19
Recommended Dietary Allowances of, 121, 142, 147, 148, 171, 200
supplementation, in poor eating, 84
supplements, use of, 147-148, 171
therapy, in cancer, instead of surgery, 138, 155
  - indication for, 121, 144
massive-dose, dangers of, 123-126
  - facts and fictions about, 84-85, 129-140
  - in inadequate vitamin utilization, 122-123
  - rationale of, 121-127
  - in schizophrenia, 134-135
  - toxicity of, 132
undesirable effects of, 132-137, 144, 179
United States Recommended Dietary Allowances of, 121
utilization, inadequate, massive-dose vitamin therapy in, 122-123
water soluble, 143, 172, 179-187
  - as coenzymes, 129
Weight, body, appropriate, guide to, 12
  - control of, in hypertension, 204
  - in obesity prevention, 212
Wernicke’s encephalopathy, 182
Wobe Mugos, 34, 57, 60, 65
Yogurt, 92
“You Can Fight Cancer and Win,” by Jane Brody and Arthur Holleb, 39
Young, James Harvey, and food choice, 9