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Current Issues in Protecting the Public from Health Fraud:

"DIETARY SUPPLEMENTS" AS A PUBLIC HEALTH PROBLEM

A Report Before the Special Committee on Aging
United States Senate
Washington, DC

September 10, 2001

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INTRODUCTION

Thank you very much for giving me the opportunity to be here today to share some of what I know on this very important subject.

Fifteen years ago, after graduating from Harvard University, after earning a medical degree at the University of Wisconsin, and after completing an internship and residency at the University of Colorado, I got out into the "real world" of medical practice. I had a solid education in the sciences, extensive training in the clinical applications of medicine and nutrition, and had practiced in my chosen specialty of Obstetrics and Gynecology under expert supervision for four years. I was very well prepared for almost everything.

What I was not prepared for were the "miracle breakthrough" products and services being promoted to my patients for the prevention and cure of a wide variety of ills both real and imagined. But it didn't take me long to find that the subject had been studied for years both as a social phenomenon and a law enforcement problem.

QUACKERY, "ALTERNATIVE MEDICINE" AND "DIETARY SUPPLEMENTS"

A principal contribution was made by this committee's counterpart in the U.S. House of Representatives. This was the 1984 report by Congressman Claude Pepper's Subcommittee on Health and Long-Term Care of the Select Committee on Aging: *Quackery: A $10 Billion Scandal*. That work referred candidly to a vast array of pills, potions, devices, and practices with the terms "worthless," "no scientific evidence," "no physiologic or pharmacologic basis," "no rational validity," and so on. It was also noted that most of these schemes, scams and frauds were perpetrated on America's elderly. So this is how I came to study, write and lecture about aberrant health and nutrition claims and practices and the windows they open on society and human nature, both innocent and corrupt.

In the 1980's, the business of unproven, disproven and irrational medical claims was a cottage industry on the fringe. Advocates called it "alternative medicine," really intending it as an "alternative" to scientific facts and principles, which they denigrated as a soulless "Western," "linear," "reductionist" system. The Pepper report used the word *quackery* in referring to this so-called "alternative medicine" and defined it as the *promotion* of "medical schemes or remedies known to be false, or which are unproven, for a profit."[1] So how did quackery, a $10 billion scandal, become "alternative medicine," a huge business that is at once a media darling, a feeder at the public trough, and, a threat to the public health?

A key catalyst was a deceptive 1993 report in *The New England Journal of Medicine* concerning "unconventional" medicine. This was a survey, funded by an advocacy group, that lumped together every conceivable form of health-related behavior "not taught *widely* at U.S. medical schools or *generally* available at U.S. hospitals." [emphasis added] This included vitamin use, commercial weight loss programs, self-help groups, "lifestyle diets" which could conceivably include keeping kosher or avoiding foods of any kind for personal reasons, and even massage and relaxation.[2] But "unconventional" quickly became "alternative" and so it has come to be falsely believed that a huge proportion of Americans are regular users of and are demanding unproven, disproven and irrational methods of medical care.

This belief was, in turn, used to support the imposition on the National Institutes of Health of the Office of Alternative Medicine (OAM) which subsequently became the National Center for Complementary and Alternative Medicine (NCCAM). The OAM/NCCAM was from the beginning and continues to be staffed and controlled by ideological advocates. The same is true of the White House Commission on Complementary and Alternative Medicine Policy. Its chairman, for example, has said that the devastating mental illness of schizophrenia should be considered merely a "different way of being." This same individual is also a supporter of alien-abduction therapy and a former devotee and apologist for the Bhagwan Shree Rajneesh, the Indian guru who took over the town of Antelope, Oregon in the early 1980's and was eventually deported. The other members of this commission, including the former head of OAM/NCCAM, are equally suspect.

Sadly, very few if any of the leaders in the "alternative medicine" movement appear to be interested in protecting the public from what the Pepper report properly called quackery. The result is that it serves as a cover for fraud. Interestingly, the NCCAM has been funding studies of prayer which, leaving aside the troublesome implications for religious liberty, was something that even the authors of the 1993 survey report said was "inappropriate" to delve into.

Meanwhile, the 1994 Dietary Supplement Health and Education Act opened the floodgates for the promotion of a new class of drugs outside of the FDA's regulatory jurisdiction. Included were all the remedies condemned as quackery only a decade earlier by the Pepper report as well as many others. These products may contain parts of animals, plants, minerals, and even heavy metals like silver, chromium and lead, either intentionally or unintentionally. As long as the constituents are found naturally somewhere in the universe, they are legally "foods." Theoretically, this could include coca leaf and opium poppies, a wide variety of toxic substances,

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[1] *Quackery: A $10 Billion Scandal: A Report by The Chairman of The Subcommittee on Health and Long-Term Care of the Select Committee on Aging*, US House of Representatives, 98th Congress, USGPO 1984.

[2] Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, Delbanco TL, "Unconventional medicine in the United States. Prevalence, costs, and patterns of use." *N Engl J Med.* 1993 Jan 28;328(4):246-52.

hormones of all kinds, and antibiotics or any other medication derived from natural sources. Under current law I could literally pack capsules full of grass clippings from my lawn and market them as just about anything I liked. In fact,

- Some products are claimed to contain tachyons, an imaginary faster-than-light subatomic particle,
- Microhydrin®, said to be "the ultimate antioxidant," is supposed to release hydrogen anions which, if true, would be like treating an upset stomach with lye,
- A California company sells a homeopathic X-ray product which is supposed to afford protection from electromagnetic fields, and
- Despite the Federal Trade Commission's crackdown on "Vitamin O" after full-page ads appeared in *USA Today*, quack "stabilized oxygen" products continue to be promoted.

DECEPTION TARGETS OLDER AMERICANS

One thing hasn't changed from the days when these schemes were recognized as *quackery* instead of "alternative medicine." Many of these products, if not the majority, target America's elderly or are claimed to prevent, treat, or cure medical conditions to which the elderly are particularly subject. The promotional gimmicks are legion:

- Television and radio ads and infomercials feature "doctors" and celebrities who extol the virtues of improbable remedies for a wide range of medical conditions. "Lose weight while you sleep" urges one of these. Others promise Viagra®-like benefits, relief from arthritis, and even the benefits of exercise from electrical stimulation.
- Fake newspapers and "journals" show up in the mailbox announcing "amazing discoveries" and "miracle breakthroughs." Among the claims made:
  - Vitamins can cure migraine headaches in minutes.
  - Forehead wrinkles and earlobe creases hint at ulcers and heart disease.
  - "The most nutrient dense food sources" are mandatory for good health.
  - Aluminum in deodorants and soft drink cans causes Alzheimer's Disease.
  - Chelation therapy – oral or intravenous – cures coronary artery disease as well as prevents cancer, arthritis, and "reverses senility."
  - Eating a balanced diet such as that recommended by the USDA "contains poisons that are KILLING YOU" and causes heart disease, cancer, diabetes, multiple sclerosis, appendicitis and hernias.
  - Dairy products cause arthritis and osteoporosis.
  - "Hormone replacement therapy … radically increases the risk of cancer."
  - Modern water treatment with chlorination causes diabetes.
- Ads are crafted to look like clipped newspaper articles with notes attached saying: "NAME, you've got to try this! –INITIAL." Naturally, they arrive in envelopes bearing no return address. Although most often these involve weight loss products, one recently trumpeted "IMMUNE SYSTEM BREAKTHROUGH" and offered protection from cancer, allergies, herpes, HIV, emphysema, diabetes, arthritis, heart disease and aging.
- Friends, coworkers, neighbors and family members involved in multi-level marketing schemes may push similar material, sometimes with audiotapes and free samples. Fraud in

these cases is particularly unlikely to be reported because people are reluctant to make complaints against their friends and relatives.

- Local distributors and "health food" stores hold lectures and seminars at churches and senior citizen centers. The promises and assurances made at these gatherings are almost as hard to pin down as those made by relatives and acquaintances.
- The Internet and email makes fraud particularly easy, cheap, and affords many protections for promoters of fraudulent products. One representative website [www.healthalert.com] prominently features the words: "Before you try dangerous prescription drugs or risky painful surgery … Discover my safer, more effective all-natural Miracle Healing Programs!" and solicits sales for scores of supplement products which it claims are superior to others. Another page on the same website begins with large type saying: "Here's How to Cure People With Heart Disease Without Dangerous Drugs or Surgery … With My *Safe, Natural* Secrets!" At the very bottom of that very long page, in very small type, are the words: "This publication is not intended to provide medical advice and nothing in it should be construed as a therapeutic recommendation or prescription for any disease or symptom." Such disclaimers, which are ubiquitous in advertising of this kind, are meaningless.

Regardless of the medium, these promotional campaigns are deliberately designed to exert a very strong psychological appeal. The strongest element of this, of course, is the promise of cures, of protection from serious illness, and even of super-health, all things that any reasonable person would surely want. To bolster their credibility, promoters almost always insist that their claims are based on solid science. Some do a better job than others at making the details sound plausible, at least to the untrained, who are encouraged to be independent – something else we all aspire to – and think for themselves.

Of course, the truth is that facts and principles that are rooted in credible evidence are widely known and relied on by medical professionals and that new discoveries that prove out are quickly incorporated into current practice. Most reasonable people know this. This is why promoters of the unproven, the disproven and the irrational often describe their advice and products as little-known or "secret." This appeals to the natural human desire to feel unique and to be singled out for special consideration. Everyone fantasizes about winning life's lottery.

To reinforce this seductive feeling, promoters of quackery portray themselves as under-appreciated but intrepid pioneers. To hear them tell it, each of them is a modern-day Galileo courageously battling an evil conspiracy of "conventional" medical doctors, the AMA, the pharmaceutical industry, and the FDA, all of them supposedly arrayed against the public for the sake of profit. Nowadays, though, promoters of quackery just as often – sometimes in the very next breath – point to the NCCAM and perhaps a "scientific research study" of some kind that will imminently refute the objections of all doubters.

As ridiculous as they may seem, these arguments, expressed in the right way, can have an overwhelming appeal. The erosion of the physician-patient relationship and the rise of managed care medicine has played a role in this as well.

There are at least five kinds of harm that arise where unproven, disproven and irrational health and nutrition claims are concerned:

- Direct harm from adverse effects,
- Indirect harm from the omission or delay of appropriate medical evaluation and treatment,
- Economic harm when people spend their money on worthless products,

- Psychological harm when people realize that they have been harmed directly, directly, or merely duped into wasting their money, and
- Social harm when Americans' understanding of the facts and principles of health and disease are undermined and corrupted, impairing their ability to make wise choices for themselves, their loved ones, and for their country when important health-related issues of public policy are at stake

THREATS TO THE PUBLIC HEALTH

These are all serious problems. But direct and indirect harm, or the potential for it, is certainly the most immediate concern. Given the huge number of different types of products and the various ways they are promoted, it is difficult to make general statements. Although we might hope that most are relatively harmless, the fact is that even a long history of relatively safe use in traditional cultures did not prevent such botanicals as opium, coca, and tobacco from becoming serious threats to public health in the U.S. and other industrialized nations. A reliance on simple facts and reasoning suggests that several kinds of "dietary supplements" pose a similar potential for major public health hazards.

- Ephedrine is probably the most obvious, if still not very widely known, of the public health hazards associated with "dietary supplements." Also known as ma huang (and Sida cordifolia, yellowhorse, sea grape), the FDA has received hundreds of reports of serious adverse events associated with the use of ephedrine-containing products. Most of these are promoted for weight-loss and "energy."

  Ephedrine is basically an amphetamine, acting like adrenaline in raising blood pressure, increasing the work of the heart, and heightening the activity of the central nervous system. Many ephedrine-containing products also contain caffeine, which enhances these effects further. So it should come as little surprise that these "dietary supplements" have been implicated in cases of heart attack, stroke, seizures, and other adverse effects both serious and minor. Although several such cases have been widely reported, it is older Americans who are at the greatest risk.

  Yet because these products are "all natural," it is widely assumed that they are completely safe. Even when side effects do occur, there is reluctance to make the connection. This makes it very difficult to assess the risks of these products, because the index of suspicion is low and side effects tend to be attributed to other causes.

  If these were OTC products or even prescription drugs under the regulatory authority of the FDA, they would have been withdrawn from the market long ago. Phenylpropanolamine was removed from store shelves on far less evidence of harm. Likewise, Baycol® (cerivistatin), was recalled by the Bayer company last month, even though it represented less of a public health threat than ephedrine-containing "dietary supplements." As U.S. population demographics continue to shift, adverse events associated with ephedrine products can be expected to increase.

- Different concerns are raised when we consider "dietary supplements" promoted for anxiety, depression, relaxation and sleep. Tryptophan was one of these that was taken off the market – a complicated story in itself – before the regulatory environment was relaxed. Then there was melatonin and now we have valerian, kava, and at least a dozen others of more doubtful effectiveness and questionable safety, particularly in combination with other supplements or prescription medications. To the extent that these products "work" as sedatives, it is also reasonable to ask what the public health impact may be in a society such as ours in which people are indulging in alcohol, driving, SCUBA diving, piloting aircraft loaded with hundreds of passengers, and so on. For the elderly, in particular, a simple fall can have catastrophic effects.

- Saint John's Wort is now known to interfere with the action of a wide variety of prescription medications: anti-AIDS medications, drugs taken to prevent the rejection of transplanted organs, digitalis, anticoagulant "blood thinners," and other medications taken by many older Americans. The problem of drug interactions is certainly much wider than this, though, and undoubtedly involves many herbal "dietary supplements." These products, let alone the various combinations in which they are taken, have a complex chemistry that almost assures unexpected effects that could not be sorted out even with an entire decade's budget for the NIH.

- Another potential public health threat is that of glucosamine, which is widely promoted for the treatment of arthritis on the basis of very scanty evidence. It is probably among the top ten best-selling "dietary supplements." Yet glucosamine is known to increase resistance to insulin at doses comparable to those recommended for these products. In layman's terms, glucosamine tends to cause diabetes, a disorder that many older Americans have or are susceptible to. Diabetes, in turn, is a risk factor for heart disease.

  Glucosamine bears a striking chemical resemblance to streptozotocin, a drug used in medical research to make animals diabetic. Streptozotocin has even been considered to have some potential as a chemotherapeutic agent in pancreatic cancer, because it kills pancreas cells. So it is all well and good to have limited scientific evidence for some possible benefit of glucosamine over placebo for arthritis symptoms in studies conducted over a few weeks or months. But it is also well to ask what the long-term risks may be for this particular agent used in this way.

  There is simply no way of knowing what the long term effects of passing large amounts of this substance through the stomachs and livers of elderly Americans for many years will be. In essence, there is a large uncontrolled and unmonitored clinical trial in progress, being conducted on unsuspecting and mostly older Americans. The results of this experiment will not be known for many years, and may never be known with any confidence because of confounding factors and the reluctance to consider that anything "natural" could be harmful.

- Yet another and perhaps the most serious public health threat in the making is the growing number of "dietary supplements" being marketed as "natural" treatments for menopause. These generally contain soy, black cohosh, red clover, or other "phytoestrogens." A few contain "natural progesterone" – which is produced in a lab, incidentally - or hormone

precursors with uncertain effects.

Most of these products are being promoted as substitutes for hormone replacement therapy (HRT), and fraudulently as well, because they either assert or imply that HRT is suspect, dangerous, or even that it causes cancer and other diseases. The most outrageous example that I have encountered was a "Medical Recall Notice" mailing from "Health Notification Service" of Henderson, Nevada. The official-looking contents purported to be a recall of all "Prescription Estrogens and Progestins" because of "Severe and Prolonged Life-Threatening Side Effects." Just how many of our wives, mothers or grandmothers, I wonder, received this ad, panicked, and threw out their prescription HRT? According to this mailing, the "Indicated Treatment" to be substituted was a "Natural Progesterone Cream" with "No Harmful Side Effects," with the order form conveniently enclosed. FDA-approved progesterone medications, incidentally, do not make the false claim of "no side effects."

In fact, although HRT is not necessarily for every woman, it offers significant benefits to most. We know, for example, that HRT prevents osteoporosis, which is itself a serious public health problem. Osteoporosis affects nearly 20 million American women and results in more than a million fractures annually. Of those with hip fractures, half never walk again and about 20% are die within a year. These numbers are expected to increase as the U.S. population grows older. There is also very strong theoretical and epidemiologic evidence for HRT's having cardiovascular benefits. Although the HERS study failed to show that it reduces coronary events in women who already have heart disease, HRT has been proven to reduce coronary risk factors in healthy women, particularly for those with Lipoprotein(a). HRT has also been shown to reduce the risk of colon cancer, the third leading cancer among women.

Although many women fear that HRT causes breast cancer, and promoters of "dietary supplement" products intended to treat menopause symptoms make an effort to arouse and increase those fears, the scientific evidence for a connection has never been compelling. Rather, the hormonal link with breast cancer appears to operate much earlier, with women who have early onset of menstrual periods, late or no childbearing, and late menopause showing a clear increased risk of breast cancer. Breast cancer mortality is not increased among women using HRT and, in fact, mortality from all causes is reduced. HRT also improves quality of life with users having more frequent and satisfying sexual relations, reduced tooth loss, and less risk of Alzheimer's disease.

It seems likely that appropriate uses may yet be found for "phytoestrogens." It's entirely possible that my grass clippings have medical benefits of some kind as well. But until the facts are sorted out, it is unconscionable that these products are promoted to menopausal women on the basis of speculative claims. Again, a vast uncontrolled and unmonitored experiment is in process. The unwitting subjects are menopausal American women who are being lied to with respect to the dangers of HRT and the unproven and even disproven benefits and unknown risks of so-called "natural alternatives." Most won't know it until they suffer fractures, heart attacks, or are diagnosed with colon cancer or Alzheimer's disease many years from now when it will be too late. But those who survive long enough may ask: how could my government allow this to happen?

- It should be remembered, too, that there are many Americans and others living in this country whose primary language is not English, who live in somewhat insulated communities and therefore are exposed to fraudulent promotional materials that do not readily come to the attention of already overburdened law enforcement authorities. There are those of us who are working to uncover this problem but it is clear from the limited information available that it represents a serious public health problem in these communities.

CONCLUSION

In conclusion, let me say simply and directly that the deceptive and fraudulent promotion of a entire class of drugs which have been renamed "dietary supplements," but which are promoted and sold on the basis of their alleged benefits in preventing, treating, and curing disease, is now a serious and growing problem in this country, particularly for older Americans. It is time to review the insights of the 1984 Pepper report, taking note of the fact that, promises to the contrary, none of the forms of quackery it identified have yet been proved effective and safe by the OAM/NCCAM despite its having spent hundreds of millions of dollars over the last decade.

With regard to "alternative medicine," about which there is no agreement as to what it actually is besides a marketing slogan and a cover for fraud, let me simply read into the record the observations of the editors of this country's two foremost medical journals. They spoke for all of us in writing:

> "There cannot be two kinds of medicine - conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted."[3] [*NEJM* 1998]

and

> "There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking. Whether a therapeutic practice is 'Eastern' or 'Western,' is unconventional or mainstream, or involves mind-body techniques or molecular genetics is largely irrelevant except for historical purposes and cultural interest. ... as believers in science and evidence, we must focus on fundamental issues-namely, the patient, the target disease or condition, the proposed or practiced treatment, and the need for convincing data on safety and therapeutic efficacy."[4] [*JAMA* 1998]

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[3] Angell M, Kassirer JP, "Alternative medicine--the risks of untested and unregulated remedies." *N Engl J Med* 1998;339:839.

[4] Fontanarosa P. B., and Lundberg G. D. "Alternative medicine meets science" *JAMA*. 1998; 280: 1618-1619.

These same principles ought to apply in the case of products claimed to have health and nutrition benefits. There cannot be two kinds of drugs: those with a known composition, quality, potency, effects, hazards, interactions, shelf life, and so on, and those about which all these things are little more than a guess. Neither can there be two standards in promotional advertising for such products: one that requires a competent scientific basis before it is disseminated and one in which, for all practical purposes, anything goes. To have it otherwise, ultimately, is to have two kinds of law: one ruled by facts and reason and one that is not subject to such "traditional," "orthodox" and "conventional" considerations.

It is not going to be easy to start picking up the pieces and setting things right. But further delay is not going to make it any easier. The National Council Against Health Fraud and other groups and individuals whose concerns are truly for consumers, science, compassion, and true freedom of choice in the medical marketplace can be relied on to assist in this task.

I thank you very much for your time and consideration and I hope I have given you something worthwhile to think about on this terribly important subject.