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## **Introduction**

Thank you Mr. Chairman.

Indeed it is an honor, and I am delighted, to have been asked to speak with you today about this most important topic. Having come from a very small town, which I would define as a place where my parents would know the make-up, dress, and decorum of a date with whom I went to the movies, before I got home, I never imagined either being here, or doing many of the things I have done. I have had many co-workers, colleagues, teachers, and assistants along the way, and any credit due me is credit due, much more, to them.

Yes, indeed, I did attend a bit of school. And even though I have done many things in my professional life, let me say that I am first and foremost a clinician. As is the case with most of my professional colleagues, my aim is always to place the interests of my patients first. Those interests, I emphasize, include the notion that what we say to patients and our clinical methods be backed by sound science. A correct diagnosis becomes the road towards a treatment or cure, and is always supported by a consistent history, physical findings, and objective tests. Conjecture, belief, and unproven hypotheses have little place in clinical practice. These rightly belong in the realm of research where adequate protection for the rights and interests of patients have been put in place, and are closely monitored.

Health care is one of the most important areas in anyone's life. With the complexity of the human organism, and with the specialized knowledge required to evaluate providers and methods, regulatory agencies have been developed to license professionals and the materials with which they work. Most practitioners are honest, caring providers. For those who are not, the public requires that its government provide protection from scams, con artists, and other abusive practices; especially the use of ineffective drugs, ineffective devices, dangerous materials, and dangerous devices. The public also requires protection from unscrupulous merchants who are driven by greed.

We enjoy one of the best medical care systems in the world. This has not happened by accident. More than a century of diligent work has made our system of evidence-based medical care, and I use the term "medical care" in a most general sense, the envy of most other countries. We have produced some truly amazing capabilities--from artificial body parts to kidney dialysis; from elimination of diseases by vaccination to organ transplants; from mapping the human genome to powerful medications to controlling severe mental illness; from curing some forms of cancer to making parents of otherwise infertile couples; and the list continues, and is quite long.

We have made lives longer, better and healthier. This has been done with substantial support for scientific research from both government and the private sector. While we may disagree on where and how to spend our resources, there has been little disagreement on what standards we should have. We demand objective, scientific, evidence-based data collected from carefully drawn experiments and clinical trials, which are then used to show that clinical care and medicines used are sound, scientific, effective, not harmful, and beneficial.

Our system is not perfect, by any means. Beyond our scientific base we exist in an open democracy that

has an economic system founded in capitalism. As we all know, these elements can occasionally conflict. Market, and political and societal forces can certainly affect behavior, control mechanisms and methods of covering costs, direct decision-making, and determine access to care. Resolving these conflicts is the very essence of our government, and one reason for our success is that we regularly review where we have been and where we are going.

The rise of modern medicine and the sale and use of medicines over witchcraft, shamanism, vitalism, folktales, anecdotes, wishful thinking, and snake oil has not been easy, but has also not been by accident. It has been the consequence of society's desire to want health care to be reproducible, safe, and efficacious. The only way to achieve these objectives has been to apply scientific method to what we do, and to constantly examine our practices against this standard.

While we are a people of many beliefs and understand the place of beliefs in our society and in our lives, we readily understand and accept that belief is not science. Modern medical care and medicines are based on science, and demand that evidence be the basis of our practices. There is still a place in medicine for the art of practice, a bedside manner, and practical skills, but the "foundation of the house" is, and will continue to be, scientifically gathered evidence. As we all know, there is absolutely a place for belief and religion as a complement to what we do.

In recent years there has been a movement to undo the requirement that evidence be the only standard by which medical care is judged and governed. This movement has been proposed and advanced principally by those who wish to profit from being freed from the requirements of evidence. It has also been promoted by others who claim that anything should be allowed, whether it has a rational basis or not, and that "freedom in health care" or "health freedom" is some kind of right, and an innate principle under which charlatans, quacks, and unscientific and unqualified practitioners can operate. These advocates want a system where "anything goes" without any safeguards for either safety or effectiveness, let alone the truth. To make things a bit worse, this movement has been joined by pseudoscientific zealots, and has been embraced by a growing number of profiteers.

Make no mistake, this apparently "innocent" movement, which appears to bring the "free market" to health care, is a major danger. The issue is **not**, as the promoters contend, protecting the so called "medicine-pharmaceutical company complex". The promoters and profiteers have put up this "smoke screen" to obscure their real agenda, which is to escape the reins of evidence and regulations so that they can enrich themselves. Through a program of disinformation and obfuscation these neo-snake-oil salespeople have begun to undermine the foundation of our excellent system of care. They have begun to succeed at substituting pseudoscience for science, anecdote for evidence, and nonsense for substance. Quality, scientifically-based health care is currently at risk. More than that, the reliability of the health care you yourselves receive is in severe jeopardy.

I come here today to speak with you about this problem.

The promoters and profiteers have been very effective so far. They have whittled away at regulatory mandates, they have blurred the lines between science and nonsense, and they have begun to advance legislation to further their goals. In their quest they have used every classical "trick" in the proverbial "book" to advance their agenda. They have used flawed logic, engaged in clever usage and misapplications of terms, and accused others of "conspiracy theories", and other bogeymen, to suggest that some pharmaceutical company-medical establishment cartel is trying to keep "them" from "saving money" for the public by withholding treatments and methods which allegedly "work", but can be done for very little money by medically unqualified individuals. Nothing is further from factual reality.

In the popular media we are barraged by stories about secret herbal folk remedies and tiny electrical devices which can cure all diseases for "a fraction" of what "conventional medical care" costs. We see ads and testimonials about how wearing refrigerator strength magnets in our clothing will somehow improve strength and endurance, or athletic performance. Despite our widespread knowledge of medicinal plants and pharmaceuticals, we are being asked to believe that vast bodies of knowledge have somehow been "suppressed for years", allegedly to keep profits high in the medical establishment and to restrict access to care. Further, we are being asked to accept as legitimate "primary care physicians", individuals who have unsupported theories of disease that have to do with "life forces being mis-aligned", imaginary parasites which inhabit our bodies, supposed derangements of our vertebral columns which cannot be demonstrated, and alleged unnamed "toxins" in our environment.

While it is one thing to discard something that is worn-out, ineffective, or damaged, it is something else to suggest that we discard science for conjecture and fanciful notions.

What kind of logic have we taught in our schools that would lead one to believe that a vial of water to which a spec of material had once been added and then diluted to the point where no trace of the material was there contains some kind of magic healing powers? What kind of logic would suggest that all the major diseases (cancer, heart disease, diabetes, viral infections including AIDS) are caused by imaginary parasites living in our bodies which harbor mutant bacteria, and that a simple electrical oscillator can destroy these organisms creating instant cures? What kind of logic would indicate that unseen and undetectable energy fields flow around our bodies and are somehow disrupted by what we eat, breathe, and imbibe causing disease and disability?

Many of you are probably chuckling to yourselves about these fanciful notions. However, recent legislation enacted in some states would permit all of these to be legitimate health practices. Supposedly these practitioners would have to obtain "informed consent" and instruct the patient about the lack of evidence that supports the proposed treatment or program. Can we safely assume that the promoters of these illogical theories would be completely and objectively honest with their patients? Can we also assume that they would not use their positions as levers to foist these on suggestible, naïve, or desperate patients, or their families? Can we also assume that one could apply regulation to something which, by its very definition, is undefinable? Even though I was born in a small town I am not so naïve, and no matter where you are from, I doubt you are as well.

While any of us may be the target of such purveying predators, those who are most likely to be approached and duped by these hucksters are more likely the elderly, the infirm, the chronically ill, the desperate, and the downtrodden. After a person is in their clutches, the promise of a simple cure often is unfulfilled, but is indeed linked to the acquisition of a substantial profit by the practitioner.

Let's now focus on some areas of concern where this Committee, the Senate as a whole, and your colleagues in the House should direct some scrutiny:

- Redefinitions of the New Age
- Experimentation disguised as patient care
- Problems with enforcement

In the brief time I have to speak today I cannot elaborate on all of these. I hope, with a few cogent examples, to give you some idea of what is out there, and why it may be problematic.

## **Redefinitions of the New Age--Calling Something By A Name Doesn't Make It So**

The world of science is not a closed club. One must merely put forward evidence of a claim and have it judged on the "open market" of ideas. The process is simple, open and available. The rules are fair and evenly applied. Make your hypothesis, put forward your evidence, publish your results, and let others judge your methods, results and conclusions. If your evidence is good, and your logic is sound, your hypothesis is accepted. If not, then it should be withdrawn.

Instead of this widely accepted practice that has gone on for thousands of years, we are seeing an increasing array of initiatives to legitimize otherwise illegitimate practices and disciplines. Legislatures are being asked to create licensing boards for practices that lack a scientific basis. Regulatory agencies are being told they cannot regulate drug substances if they are called something other than drugs. So-called "supplements" are being marketed and used as if they were drugs free of regulation. Words such as "Complementary and Alternative Medicine" are reinterpreted to cover any non-scientific idea and practice that has not met the criteria I outlined above. The public is separated only by clever language from effective regulation. And, worse than that, the public is not effectively protected from catastrophic problems. I doubt that is what Congress intended in the Dietary Supplement Health and Education Act of 1994 (DSHEA). Already we have seen numerous reports of deaths and severe disability due to some of these so-called "food and dietary supplements", ephedra and aristolochia just to name two that you may have heard about. There are many more. These, and other dangerous compounds, are widely sold in "health food" stores as "supplements", or are ingredients in "herbal" and other remedies sold under the same concept. Does simply calling something a "food or dietary supplement" make it a true food, or even a supplement? I don't think so. Somehow calling something a "traditional Chinese medicine" implies it has been in use for centuries and, because of that name alone, is somehow valid, safe, and effective. The truth lies elsewhere. Let us not mince words. These substances are being promoted as drugs, in the common everyday usage of that term, clever language, creative terminology and nosological acrobatics, not withstanding.

Let's turn to another example. To get to the National Institutes of Health in Bethesda from DuPont Circle I can take a cab or the Metro, I can walk or even ride a bicycle. These are true "alternative" methods of travel. However, no matter how hard I wish, or whatever I may choose to believe, I can't ride a magic carpet, or self-levitate and fly to Bethesda. The "alternative" to scientific, evidence-based medical practices is non-evidence based, non-scientific nonsense. It is grossly wrong and frankly ridiculous to place this collection of anecdotes, pseudo-science and conjecture called "alternative medicine" on the same stage with the real thing. Yet that is precisely what has been done by legislative fiat on both the federal and state levels. This cannot and should not continue.

For those who may not remember, perhaps a lesson in history may be useful. In the decade before the Mayflower landing at Plymouth, Massachusetts, a mathematician/astronomer named Galileo produced evidence that the Earth was not the center of the solar system. He validated the proposal of Copernicus that the planets moved in orbits around the sun. As you might recall this went against the prevailing "law" of his land and he was condemned as a heretic and exiled. In those days the "law" was from religious edict. It took many years, but the validity of his data was confirmed. Today we would consider the notions that the Earth is flat, or that the Sun revolves around the Earth as without foundation. Our colleagues at NASA have given us ample evidence that Galileo was correct.

The vindication of Galileo's ideas was **not** merely a triumph of science over belief. Rather, the clash of Galileo's theories and the existing "law" was evidence that belief alone did not belong at the helm of the ship of state. Indeed, our forefathers (and foremothers) fought to separate religious belief from the state, embodied it in our Constitution, and that has been one of our most important precepts and strengths.

Consider how the events of the early 1600's compare to the issues to those of today. They are almost a case study in role reversal.

Systems of health care based on "life forces", energy fields, and unseen parasites are not science at all, and, at best, are forms of "pseudo-religious" belief. Some of these are obviously cults. Others are the products of delusions and chicanery. No matter how they are packaged, these methods and ideas are **not science**. Those who are trying to legitimize this neo-vitalism through legislation are, in my opinion, trying to legitimize a religion. Mind you I have no quarrel with any religion. I only ask that a rose be labeled a member of the genus *Rosa*., and that we follow the precepts of our Constitution.

In a book entitled, "The Cure for All Diseases", a woman named Hulda Clark proclaimed that she had found by "research" that "all diseases have simple explanations and cures once their true cause (sic) is known." Clark claims a naturopathic degree and maintains that a rare Asian liver fluke inhabits our bodies and is triggered by "toxins" in the environment to harbor mutant bacteria which cause all of our illnesses--diabetes, high blood pressure, seizures, chronic fatigue syndrome, migraines, Alzheimer's Disease, Parkinson's Disease, multiple sclerosis, and AIDS. She further claims that inherited genetic diseases (e.g. retinitis pigmentosa, Muscular Dystrophy) can be "disinherited." All of this can be done with some simple electronic devices you can build yourself with some parts from a local electronics store, some remedies (including the dangerous material wormwood) which are sold as "supplements", and some "cleanses" by which you purge your gastrointestinal tract, liver and kidneys to rid yourself of imaginary "gallstones" and "toxins".

Clark's books and products have produced millions of dollars in revenue. A number of outlets, including ones that just happen to be run by her son and her brother, hawk her recommended items and sell the devices she claims cure "all diseases". Based on even a cursory look, many of these items appear to be illegal drugs and devices. Why then are they easy to find and readily available for sale? I submit that the current laws are difficult to adequately enforce, and that clever marketing and some deliberate layering and nesting of sales entities make it hard to find the true sellers and suppliers of these items.

While it might be argued that some of these items are "harmless" since they really don't "do anything", I would like to respectfully disagree, and illustrate this point by bringing to the Committee's attention the story of a young woman with cancer who followed the teachings of Hulda Clark "religiously":

**My friend, Hanne, a young woman of 42 years, was diagnosed with severe breast cancer. She got a full mastectomy and was treated with chemo and radiation.**

**She contacted an alternative practitioner, who besides magnetic treatments also deals with the Hulda Regehr Clark protocols. These protocols are based on the idea that all cancers are caused by a single internal parasite - the human fluke.**

**Clark claims that all cancers ...are caused by "parasites, toxins, and pollutants" and can be cured by killing the parasites and ridding the body of environmental chemicals. "All cancers are alike. They are all caused by a parasite. A single parasite! ...if you kill this parasite, the cancer stops immediately. The tissue becomes normal again. In order to get cancer, you must have this parasite ...."**

**My friend started to follow the prescriptions... for cleanses and zapping in order to rid herself of the flukes.**

**The practitioner told her, that her beloved pets maybe were the cause of her cancer by infecting her with the parasite! He urged her to get the animals (5 dogs, 4 cats and birds) out of the house.**

**She managed to place all the animals with others, except 2 dogs, which were also treated with the zapper! I must tell that she was single, and her pets were her whole life and heart. She had a limited circle of friends, whom all have dogs, cats and other animals. She therefore could not visit them, nor ask them to visit her, because she was afraid of being re-infected! Even her mother, who took care of her, could not bring her dogs, they had to be placed with others too. She and her mother ended up sitting very much alone - and THAT I find to be really cruel! Taking away a terminal person's last joy of life, and placing a false hope for full recovery.**

**She paid him at least \$800 for capsules, tinctures, zappers.... She followed the protocol by the letter, ate organic food, and changed her soap and hygiene articles to organic products.**

**After she had finished the chemo and radiation treatments, she started to work again, but shortly (½ year) after she was diagnosed with a recurrence of the cancer, which had now spread to her lungs and liver, in spite of what Hulda Clark claims!!**

**She again turned to the ...practitioner, who once again claimed he could cure her, and he would now use a real strong cure! (She received chemo at the same time.)  
.... She said that [following the recommendations of] HC was her only hope ....consuming all those herbs and capsules, of which some are known to be poisonous. They sure made her vomit a lot, and spoiled her appetite! And thereby stole the good which proper nutrition could have given her.**

**No matter what, she continued on the HC-protocol all by the letter.... She blindly trusted ... as "HC is a doctor and has written several books, she must be sincere!"**

**One Friday she was taken to the hospital suffering from severe lack of oxygen due to the cancer having spread to the lung tissue. Tuesday I visited her, and watched her zapping, both her and the dogs, and she swallowed a bunch of capsules...**

**Hanne died Monday night, Jan. 15, 2001.**

**God bless her soul.**

**[written by Pia Johansen, Hanne's friend]**

I would also pose a few simple questions to you. Do you honestly believe that this alleged treatment is harmless? Can you properly call this "Health Freedom" or is it Health Tyranny?

### **Pseudoscientific Experimentation Disguised as Patient Care**

In our society the public affords health practitioners an unusually high status compared with some other countries. Also, in our society, we have placed a high value on life. Consequently, people who save lives provide healing, and ameliorate disease engender gratitude. However, this status is not without a series of obligations. Knowing people's most personal secrets and the complexities of their lives carries with it the requirement of absolute confidentiality. Additionally, there is the matter of trust. Health professionals are not merely entrusted with the private information they come to know, but, more importantly, are trusted with the very lives of their patients. That is, one is expected to do what is proper, honest, safe, and in the patient's best interests. This trust means that a practitioner must be open, current, and careful, and is not allowed to deviate from professional standards. These standards include the notion that a practitioner neither experiments with his treatments nor with the lives of his patients, unless there is a high potential for a direct benefit to the patient, and the patient fully understands what is being done, including all risks. A practitioner is also entrusted to do no harm. The notion of doing no harm is

extended to include taking unknown risks without known benefit. Violation of this trust undermines the very foundation of the health professions, and, in my opinion is immoral.

It is problematic when practitioners advance their personal ideas, often disguised as legitimate treatments, upon unsuspecting patients for both real and fanciful illnesses. Beside the unsubstantiated claims and methods promulgated by Hulda Clark, we regularly hear about inappropriate use of hyperbaric oxygen, chelation therapy, and conventional drugs, used for unapproved purposes, for allegedly "treating" "poisonings", arteriosclerosis, and cancer. We also hear about alleged diagnoses made by a litany of pseudo scientific mumbo-jumbo including: applied kinesiology, hair analysis, whole blood analysis, live cell analysis, and other such nonsense. These alleged illnesses are "caused" by environmental "toxins", dental "cavitations", alleged mercury and heavy metal toxicity, NICO, and other made-up conditions. Commonly we also hear of unapproved electrical devices used in both the "diagnosis" and "treatment" of these conditions.

So called "chelation therapy" is a case in point. This concept has some appropriate uses in medicine, namely treatment of acute metal poisonings with arsenic and lead. However it has been contorted into something else by a number of practitioners. These practitioners claim that they can "treat" calcified atherosclerosis of the arteries of the heart and other organs with this technique. Others claim to lower cholesterol and to treat a number of serious illnesses such as rheumatoid arthritis. Millions of dollars in payments are collected for this procedure. The evidence would suggest it is a giant scam. In an attempt to make what they do appear legitimate, some practitioners have even suggested they are participating in a "study" and have the patients sign "consent forms" for this illegitimate treatment.

Among the most essential ions in our bodies is calcium. It is absolutely necessary for the clotting of blood and muscle contraction. Significant changes in serum calcium levels can be fatal. Thus, applying any chelating agent that is attracted to divalent cations must be done with great care and caution.

E.D.T.A.(EDTA) stands for ethylenediamine tetraacetic acid. There are legitimate medical uses for some forms of EDTA, notably the calcium (or magnesium) disodium salt, and the plain disodium salt. For example, acute lead poisoning can be managed with Calcium (or Magnesium) disodium EDTA. Acute calcium excess (often due to parathyroid tumors, or cancer) is a medical emergency and can be managed with judicious use of disodium EDTA. This latter agent is quite dangerous if misused, since the serum calcium can plummet and cause death.

Some practitioners believe that they can use Magnesium Disodium EDTA or Disodium EDTA for allegedly removing calcium from atheromatous plaques which line diseased arteries. Atheromata(pl. of atheroma) are pathological collections of cells deep in the walls of arteries which contain various forms of cholesterol. Occasionally, some of these atheromata calcify. The "chelation therapists" mistakenly believe that treatment with Magnesium Disodium EDTA will remove this calcium and remove the atheromata. This belief is unsupported by scientific theory, scientific fact, and practical experience. A number of reviews on the topic of chelation therapy for treating atherosclerosis (the presence of atheromata) in the lining of arteries of major importance (aorta, coronary arteries, and major arteries to the extremities) has shown that this therapy is not only ineffective, but may also cause damage to the walls of arteries and actually cause atheromata to appear. The use of any form of EDTA for treatment of atheromata or atherosclerosis is not approved by the U.S. FDA.

At the very best, even the proponents of chelation therapy for atherosclerosis therapy admit that this concept is experimental. So why is it widely advertised and promoted to the elderly?

The idea that EDTA chelation would remove calcium from atheromata is not supported by science.

First, most atheromata are not calcified. Second, even with theoretical "success" of the treatment for calcium removal from atheromata, biochemists have shown that the amounts that could be removed are miniscule and irrelevant to the disease process.

Where chelation therapy advocates have suggested any success it has been with the ability of people with severe peripheral vascular disease of the legs to improve their walking distances slightly after therapy. Even these claims are controversial, and there are data to suggest that these claims, largely supported by only subjective data, are specious.

Major medical organizations and publications, including the American Medical Association, multiple state licensing boards, the American Heart Association, Harvard Medical School Health Letter, and many medical scientists, have indicated that chelation therapy with EDTA is ineffective for treating, eliminating, or ameliorating vascular disease.

At the very best, chelation therapy with EDTA for treatment of atheromatous cardiovascular disease, is unproven and experimental. Yet, despite this fact, hundreds of unscrupulous practitioners foist this on the public through active promotion. It is claimed that 30-50 "treatments" must be done for "results" and these cost anywhere from \$100 to \$150 each, paid in cash. Virtually every health plan and Medicare do not pay for these treatments.

I am regularly sent advertising clippings from areas of the country with high proportions of elderly individuals which suggest that this therapy is "an alternative to bypass" or can "prevent" arteriosclerosis. One organization, the American College for the Advancement of Medicine (ACAM) has consented to stop false advertising after enforcement actions by the FTC, however, the FTC cannot possibly engage all of the individual practitioners who promote this idea.

Since their consent decree with the FTC, however, ACAM has apparently developed a scheme to make it appear that their members are participating in an "experiment" where EDTA therapy is "tested" "clinically". This alleged "study" has some of the trappings of a clinical trial, but none of the substance. It appears to be, in my opinion, a pseudoscientific babble of imprecise, unclear activities for its members to present to unsuspecting, often elderly patients who have real cardiovascular diseases. I have personally reviewed multiple cases of patients who were directed away from potentially life-saving, or life-prolonging, conventional, evidence-supported treatments for cardiovascular disease to chelation therapy which provided no benefit other than to enrich the practitioner who promoted and performed it. I have personally seen several patients maimed and several deaths by such careless practitioners.

Chelation therapy is only one of many such areas of illegitimate human experimentation. I have seen the elderly (and others) regularly victimized in schemes for "cancer cures", treating Amyotrophic Lateral Sclerosis, alleged heavy metal poisoning, heart disease, and neurodegenerative disorders. The since delicensed Colorado dentist, Hal Huggins, emptied the bank accounts of an elderly Kansas farm couple after convincing them that he could treat the wife's breast cancer and her husband's ALS. The husband nearly died during treatment when he aspirated unnecessary pills which were to allegedly "detoxify" him from his dental fillings. The wife wasted away after her teeth were removed inappropriately. Therapy which may have cured her was postponed. And I can give you more examples of the "dental amalgam scam" which are more egregious.

For a number of rather transparent reasons--largely greed, basic incompetence in "standard practices", and uncontrolled ego--some practitioners cross the line between proper and improper behavior. Some common excuses that are offered are: "I am a pioneer and way ahead of the rest of the profession.", "I discovered the "cure" and am the only one who has it.", " There is a plot by big medicine and others to

keep this simple therapy away from you since "they" would stand to lose millions if it got out that.....". All of these ring hollow to those who know their art/science, but can be appealing to those who place high trust on their practitioners and are also desperate, unsuspecting, or have impaired functioning. Catching and stopping these "thieves of the professions" is a task often left to the licensing boards at the state level. However, their crimes typically transcend the mandates of the boards and extend into areas of federal jurisdiction. These crimes cross state borders; use telephones, modems, the Internet, and the mails they also typically may involve money laundering and hiding assets via "off-shore accounts", and often violate rules of federal reimbursement and entitlement programs.

Prosecuting these "pariahs of the professions" takes years, large budgets, and persistence. Most regulatory boards and state prosecutors turn over at such rates that merely completing an investigation takes several generations. The misbehaving practitioners often have huge war chests, as they have enriched themselves on the public. These often dwarf the meager budgets of state prosecutors. Affording expert witnesses, collecting information, and successfully prosecuting a meritorious case are extremely difficult. Even then, the regulatory board can often not recover its costs of such a prosecution, fine the offender, or mandate restitution in most states. The smaller states can barely get to the investigation stage, since the entire budget of the board comes only from licensing fees, and must cover staff salaries, licensing activities, travel, rent, and even the telephones. There is often little left over for enforcement.

We need model legislation to tighten the laws against predatory practitioners. We also need to help the smaller states overcome the problems they face in being unable to afford to enforce the rules to protect the public. We also need to put "teeth" into the punishment for offenses. Too often the guilty get a slap on the wrist, write off the cost of their defense as a cost of doing business, and go right back to bilking the public.

### **Hype, More Problems with Enforcement, and Mass Marketing--the Uneven Playing Field**

Most doctors are very desirable advertising targets. We prescribe tens of thousands of dollars worth of laboratory tests, a similar value of radiographs, and hundreds of thousands of dollars worth of pharmaceuticals each year. Obviously we get a considerable amount of attention paid to attract where our eyeballs gaze. Some time ago I received, in the mail, what I would call a "throw-away" journal. Those of us in the medical field are quite familiar with these. They are unsolicited publications that look like magazines but are thinly disguised to appear as medical journals. Usually they are compilations of practical tidbits and a few unusual cases. Occasionally they contain a reasonable review. They are not cutting edge. What they do contain are lots of advertisements for those things we doctors prescribe.

But this "throw-away journal" was different. It was called the "Journal of Longevity" and it was targeted at the general public. The segment of the public it was targeted for was obviously "older".

You know what I mean by that expression. Those of us who find grey hairs, but would like to think they are something else, and then begin to count them. Those of us who get mailings from the AARP, soliciting membership. Those of us who look at the obituary pages in the newspaper each day to see if anyone we knew has departed our midst. Those of us who look ahead, do a little math, and wonder whether we have more days left ahead of us compared to the number we have experienced already.

The "Journal of Longevity" that I received did not come from a medical mailing list. It came from a mailing list targeted at people over 50. I use a distinctive coding system to track the origin of mail, and this one came from a source that I knew had access to my age and demographics.

The "Journal of Longevity" fits an image of what I would describe as very "slick" and very targeted. It

was not a "journal" at all, but a carefully constructed advertisement for products, made to look as if it were an authoritative medical journal. The "articles" were each only a few pages long, and had very smooth, colorful graphics, pleasant photographs, and very "interesting" titles.

Some recent articles were: "The Key to Keeping and Renewing the Body's Energy", "Are Stem Cells the Answer to Blood Sugar Problems?", "Why 60% of Men Over 40 Have Sexual Problems", "Blended' Sexual Cocktail--A Shield Against Aging?" and "Solution to Postmenopausal Difficulties Found." The authors of these articles all appeared to have professional degrees but had credentials such as: "has given numerous TV and radio interviews", "is a gastroenterologist with a successful private practice", and "is the author of several books...Blessed with an abundance of energy and expertise, he jockeys between his medical centers in Brooklyn and .....his radio show.....in Manhattan." The photographs in the articles appear to be obviously staged with colorful liquids in laboratory bottles, a brand new lab coat on the person gazing into a brand new microscope, or a hospital operating room. The "references" included a number of medical journal articles often from ten to twenty years ago from obscure sources, or which were impossible to source, for example, [www.reuters.com](http://www.reuters.com), without any specific date or heading.

Each article had a not-so-hidden message. There was some "food supplement" or "herb" sold as a food supplement that seemed to be "important" to the topic of the article, and, you guessed it, that material just happened to be sold by Gero Vita International.

The "Journal of Longevity" is produced by "Health Quest Publications of Reno, NV" which is owned by G.B. Data Systems, Inc. According to the Secretary of State of California, G.B. Data Systems has corporate offices at 521 Washington Blvd., Suite 420, in Marina Del Rey, CA 90292. G.B. Data Systems is listed as a part of Gero Vita International and is directed by A. Glenn Baswell (Florida Department of State, Division of Corporations).

A Web Site [www.dietfraud.com](http://www.dietfraud.com) has an article on Mr. Braswell and Gero Vita International entitled "Gero Vita International & Glenn Braswell Scam the World from Toronto Mailboxes Etc. Location." This posting states the "address" for Gero Vita International is really a Mail Boxes Etc. outlet at 4936 Yonge Street in Toronto. There were links at this site to articles about a dubious pardon for Mr. Braswell (U.S. News and World Report), an investigation in progress regarding tax evasion, and references to ties with major politicians, including activities during the last presidential campaign. The Post article indicated that the George W. Bush campaign and the Florida Republican Party returned \$250,000 of Braswell's contributions. One area of interest was a reportedly doctored letter of endorsement of alternative medicine under Florida Governor Jeb Bush's byline in the "Journal of Longevity". Mysteriously, this letter does not appear in the "Journal of Longevity" archives for the issue in which it appeared (July 2000) at [www.journaloflongevity.com](http://www.journaloflongevity.com).

The "Washington Post" (February 6, 2001) highlighted Mr. Braswell's 1983 felony convictions for fraud, perjury, and tax evasion while discussing the pardon granted him by former President Clinton. This same article quoted Stephen Barrett, M.D. of Quackwatch, Inc. who said about Braswell, he "has probably managed to sell more health-related products with misleading claims than anyone else in the history of the world. His gross intake has very likely been over a billion dollars." "Consumer Reports" was quoted in 1998 on Gero Vita, "We see a lot of misleading marketing, but what spews out of Gero Vita Industries rivals the worst". "Consumer Reports" referred to the publications of Gero Vita as "masquerading as science. [Their] booklets cite actual studies, but twist the findings to support the company's own unsubstantiated claims."

Recently highlighted on the website of Gero Vita International ([www.gvi.com](http://www.gvi.com)) were: Florimin--a prebiotic formula to strengthen body (sic) against superbugs, Heart Shield--safeguard your heart, Testex--Yohimbe and Muira Puama for sexual enhancement, and DentaZyme--powerful enzyme spray

for healthy gums. Of note is the fact that these products had accompanying "literature" from the "Journal of Longevity".

I regularly read the medical literature and have taught at three major medical schools. The article in the "Journal of Longevity" by "the gastroenterologist with the successful private practice" suggests that there is an "imbalance of bacteria in the intestines" and that "researchers" (who are, of course, unnamed), have formulated a "prebiotic supplement" rich in "biologically active friendly flora and a special plant fiber". This article calls a "prebiotic" a "colonic" nutrient. I can tell you as a cellular biologist and physician that this is pure nonsense. The human colon functions primarily as a place where water is absorbed from the material within. That material has already been digested and its nutrients have been absorbed in the upper portions of the gastrointestinal tract. Beyond water absorption, the colon is mostly a conduit for waste material. Nowhere on the Gero Vita website could I find a list of ingredients in the "prebiotic" Florimin. I went to its on-line direct assistance and the person who answered, "David", could not give me a list of ingredients. I even sent an e-mail to its customer support address without success.

I next went to explore "DentaZyme" a spray which purportedly is "potent enough to inhibit oral bacteria from forming" and will "protect" my gums and teeth, although it doesn't say from what. It is implied that "DentaZyme" is for stopping poor oral hygiene, and that "this problem is a primary cause of respiratory illness as well as heart and gastrointestinal problems". This is patently false. I quote directly from [www.gvi.com](http://www.gvi.com).

Poor oral hygiene leads to far more serious problems than cavities and gum disease. It's one of the primary causes behind such conditions as respiratory illnesses as well as heart and gastrointestinal problems. **DentaZyme** is one of the first oral sprays potent enough to inhibit oral bacteria from forming. It not only protects your gums and teeth, but it also helps deter harmful bacteria from invading your vital organs. And, it comes in a convenient, easy-to-use oral spray that fits in your purse or pocket.

It is extremely difficult for enforcement agencies to deal with "supplement chameleons" such as Gero Vita. New "products" appear in the blink of an eye. What little information is given to the public can change daily and appears in multiple forms--print, direct mailing, and the Internet. The company appears to be a series of companies but is really one business, akin to a set of nesting wooden dolls, where each can hide within another. It appears in multiple guises in multiple places, even in different countries.

I am neither an attorney nor a law officer. I am merely a doctor. What I have seen shows me apparently deliberate attempts to mislead the public into buying products with information that is factually incorrect, misleading, and deceptive. Gero Vita is only one of many such companies, but is among the largest.

Since DSHEA seems to allow virtually anything to be called a "supplement", claims of benefit to humans can be attached to materials which are anything but true foods or nutritional supplements. Even then, the "claims" are, in my opinion, far beyond what Congress ever intended or has permitted for these items.

How can regulatory and law enforcement agencies effectively deal with this onslaught of "supplements"? Do they have the tools to be able to stop false claims and protect the public? Are they playing on an even playing field? I would answer, no.

One might say that Gero-Vita/G.B. Data Systems/ "Journal of Longevity", etc. are not breaking any law, and are merely "in business". They sell to people who willingly buy their products. If their literature and

hype are, well, a little "aggressive", their main defense would be "let the buyer beware". The data would suggest that this is not merely a simple story of a simple company that is entirely within the law. Make no mistake, this is a well-oiled Goliath that has reached to the highest points of our government to keep the cash rolling in and the snake oil rolling out. Where are the data to show their claims are supported? Where are protections the public rightly expects? Are the regulators trying to wrestle with Goliath with one proverbial leg cut off and one proverbial hand tied behind their back?

For many reasons that are self-evident, enforcement actions against such a company as Gero Vita are difficult. To be effective, regulators must be able to act at speeds equal to the target regulatee. They must also have the muscle and manpower. They must also have the resources to devote to such a task and still carry on their other duties. It is obvious that multiple agencies must be involved in working on the problem: FDA, FTC, FBI, US Postal, just to name a few. The problem reaches into every state and multiple foreign countries. There are laws on the books to deal with these crimes, however, there appears to be a distinct lack of enforcement. As just once example, Congress needs to investigate why the US Postal Service has not been very active over the last decade in prosecuting false advertising that is promulgated via the mail.

To deal with problems such as this one, we need to have collaboration, cooperation and condensation of effort to match the targets. But we need even more. We need a strategy and a plan, not just to confront this problem, but to prevent it at its source. We need a serious reappraisal of DSHEA to allow us to stop the fleecing of the public and the promotion of nonsense that would suggest that simple "food supplements" will make us young, improve our sex lives, give us energy, and reverse biology.

I urge the Committee to also consider ways to improve the enforcement abilities of the FTC and FDA, which are the lead federal agencies responsible for monitoring promotion and use of therapies and drugs. Currently these agencies are understaffed in relation to the volume of illegitimate activity to the direct detriment of the public. Since practitioners are licensed by individual states, some mechanism must be found to assist the states in their enforcement activities. The abilities of state licensing boards to deal with illegitimate therapies and the practitioners who promote them are overwhelmed by the size of this problem. These agencies are typically funded only by licensing fees and have many other duties to perform. Practitioners can, and do, market services across state lines. A mechanism must be found to address this problem without interfering with powers left to the states by our Constitution.

I would further assert that there is a need for federal/state task forces to deal with these problems as they transcend the mandates of any one entity. Effective strategies need to be put in place to act at the preventive level. A good start would be the convening of meetings among state licensing boards, state investigating agencies, state prosecuting agencies, FTC, FDA, FBI, US Postal, and other interested parties to begin a discussion of how to attack this significant and growing problem. Millions if not billions of dollars are scammed each year from the public. As mentioned earlier, this form of health fraud also causes considerable death and disability, the burden of which often falls on the federal government through Medicare and other entitlement programs. These are crimes against all of us, since society-at-large is typically the resource that has to repair the damage that these criminals do. They truly steal from us all.

Some other areas where Congress can act easily with little cost and significant results are:

- To assist the Mexican Government in closing illegitimate cross-border clinics which offer illegal therapies and treatments, often by unlicensed providers. For example, recent raids in Baja, California closed several illegal clinics, including one run by Hulda Clark, who was mentioned earlier. However, only a small number of operations was included in this sweep. There are many, many more similar "clinics" which appear to have been set up to evade our laws.

By closing such operations which often operate on both sides of the border, with mail drops, "800" telephone numbers, and referral services, we have the opportunity to solve problems for us and our neighbor to the south. Similarly, improved collaboration with the Canadian authorities could help put an end to Toronto maildrops and other cross border activities which allow fraudsters to elude regulators and prey on the public of both nations.

- To require any company that engages in multiple level marketing (MLM) disclose performance results to any prospective agent before they "sign up". MLM schemes are common vehicles to purvey worthless "dietary", "nutritional" and "food" supplements.

Full disclosure of the lack of efficacy of the products and the meager chances of financial rewards may dispatch the MLM menace once and for all.

- To develop enabling legislation to allow States' attorneys general to get nationwide injunctions against sales and distribution of illegitimate and falsely advertised products. The States' attorneys general would act as deputies of, and in concert with, federal agencies such as the FTC, FDA and other agencies which have mandates for consumer protection.

Perpetrators of fraud and other schemes can easily shift operations from one state to another, disabling and/or confounding the ability of state authorities to act to protect the public. Enabling legislation would close these escape routes, and add depth and potency to the existing federal resources without added cost but with considerable benefit.

## **Summary**

I propose that Congress develop a plan to expeditiously deal with the problems I have outlined. We cannot regulate effectively when it takes from five to ten years to address a problem. Within a few years the problem has likely grown, moved, and metamorphosed itself confounding any attempts at administrative action. The landscape changes quickly and the thieves are highly mobile. Nutrition scams and the other abuses I outlined above have simply gone on for too long. This very Senate Committee determined in 1983 that "quackery and medical related frauds" are number One of the ten "most harmful frauds directed against the elderly." It would appear that we have come a long way since 1983, but in the wrong direction.

We need to convene an interagency task force to deal with these issues, and keep it active until the message is sent that we will not tolerate abuses such as I have reported above. We must streamline the process of prosecution, while still protecting the rights of the accused. More importantly, we must also protect the rights of the public to receive adequate, appropriate, and scientifically valid health care. We must level the playing field so that the perpetrators no longer have an unfair advantage over the regulatory agencies. We must provide resources for quick and effective action, make sure reparations are made, and make the penalties severe enough so these crimes will not pay.

More than anything we must marshal our resources to begin discussions on how to keep science and evidence as the framework of our medical system. We need a plan, a timetable, and designated leadership to make this happen. The cost of not acting is too great. We don't need more government to do this. We need to redirect what we have to accomplish these goals.

Consumer advocacy groups, such as the National Council Against Health Fraud, Inc., stand ready to work with all levels of government, and any other interested parties, to address the problems I have

outlined, and to help keep our health care system scientific, effective, and the best in the World.

I am delighted to have been asked to appear here today, and with that said, I will conclude my remarks, and would welcome any questions.