

**SWINDLERS, HUCKSTERS AND SNAKE OIL
SALESMAN: HYPE AND HOPE MARKETING ANTI-
AGING PRODUCTS TO SENIORS**

HEARING

BEFORE THE

**SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE**

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SALESMEN: HYPE AND HOPE OF MARKET-
ING ANTI-AGING PRODUCTS TO SENIORS**

MONDAY, SEPTEMBER 10, 2001

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m., in room SD-215, Dirksen Senate Office Building, Hon. John Breaux (Chairman of the Committee) presiding.

Present: Senators Breaux, Wyden, Lincoln, and Craig.

**OPENING STATEMENT OF SENATOR JOHN BREAU,
CHAIRMAN**

The CHAIRMAN. The Committee on Aging will please come to order. Good morning, everyone. I would like to thank all of our guests who are here this morning, and also my colleague, Senator Wyden. We expect other members of the Aging Committee to join us in a very short amount of time. This is a very important hearing of the Senate Aging Committee, and we will use this hearing as an opportunity to examine the marketing of dietary and specialty supplements that particularly target our Nation's elderly and senior citizens. I want to thank Senator Larry Craig, who will be with us momentarily as the ranking Republican member of the committee, for his cooperation and support throughout this investigation. I want to particularly thank our witnesses who will be testifying before us this morning for their testimony and their assistance and cooperation.

People have been searching for the fountain of youth ever since Ponce DeLeon, and they will probably continue to do so for decades and generations into the future. Our job in this hearing is not to kill that hope and desire to remain youthful and healthy as long as possible, but rather the role of the committee is to try and help protect American citizens, particularly our elderly, who are preyed upon by modern-day snake oil salesmen. I would like to say up front that this hearing will focus on companies that mislead consumers with regard to dietary and specialty supplements.

As with any industry, the vast majority of manufacturers and marketers of supplements are reputable and law-abiding. It is the bad actors in this industry that we are concerned about today. Supplements are becoming increasingly popular. I take them myself and I will continue to do so in the future. Individuals who are both healthy and ill take supplements for a variety of reasons. Some

take supplements to increase energy, to build muscles, or to lose weight. Others have begun taking supplements as alternatives to traditional medicine and escalating prescription drug cost. More and more, our Nation's seniors are turning to these supplements.

Today, it is estimated that \$27 billion annually or more is spent on supplements and that 60 percent of these consumers are older senior citizens. These products are marketed to our seniors in a variety of ways. Not long ago, my wife and I, at our home, received in the mail the *Journal of Longevity*. At first glance, it appeared to me, as the example on the chart shows, that this was a scientific journal, extolling the virtues of supplements, focusing on those that have alleged anti-aging effects. To me, it resembled the *New England Journal of Medicine*, and I was very impressed with the way it was structured and the way it was presented.

I actually wanted to start ordering everything in the magazine, and the more I read, the more I came to the conclusion that if it sounds too good to be true, it probably is. I was drawn in, until I finally concluded, after consulting with my staff, that the mailer was simply a very fancy advertisement for one company's products. The *Journal of Longevity* appears to me to simply be a series of articles that discuss health issues that seniors face, and then provides a very simple solution, the solution being the dietary supplements developed and distributed by the same parent company that publishes the magazine.

Some of the articles and advertisements simply prey on the fears of the elderly, while others counsel the reader to take a particular supplement in place of traditional medicine. It really made me start thinking about the marketing tactics of some of these companies and the products that they promote. The dietary supplement industry in this country is largely self-regulated. Unlike new prescription and over-the-counter drugs, the law does not require supplements to undergo pre-market approval for safety and effectiveness.

The current United States regulatory system provides little assurance that commercial supplements have predictable pharmacological effects or that the product labels provide accurate information; and furthermore, the manufacturers of the supplements are not required to register with any government agency. This is of great concern to me, and I know to this committee. Surveys have shown that the use of complementary and alternative medicine in the United States has increased an amazing 380 percent between the years 1990 and 1997, and this trend will almost certainly continue as the baby boom generation draws closer to retirement age and seeks out new and different ways to maintain and improve their health and retain their youth.

We need to know that the products our seniors and all of us are taking are safe and effective. I want to make it clear one more time that we are not here today to talk about the science of complementary and alternative medicine; rather, we are only looking at the bad apples in the supplement industry, those folks who market misleading and/or ineffective products.

In an effort to convey the nature of and the methods used by the companies that mislead the elderly, this morning we are going to examine the operation of one of the largest companies that sells the

so-called anti-aging and other dietary supplements. GB Data Systems, Inc. is the holding company for at least 10 businesses selling dietary supplements. A. Glen Braswell is the president and owner of GB Data Systems. Gero Vita International and Health Quest Publications, which publishes the *Journal of Longevity*, are both controlled by GB Data Systems.

As I stated earlier, the *Journal of Longevity* that my wife and I received at our home in the mail is simply, in my opinion, an elaborate, misleading advertising tool that markets several of the Gero Vita International products. I had the cover of the one issue of the journal enlarged, and you can see it to my right. Again, it looks to me to be a medical journal such as the *New England Journal of Medicine* when it is received in your home. I actually asked my staff to order some of the Gero Vita International products for me. After two attempts, we have still not received them. I do have enlargements for some of the advertisements of some of these products.

First of all, I have an ad for a product named ACF 223, that claims it is the healing breakthrough of the century. You can note from the cover that one of the assertions is, "Live 26 percent longer." Maybe the doctors here can tell us whether this is true. One of the amazing things is the bottom section of it that talks about it can work for people with—and it names a whole series of very serious illnesses: arthritis; heart disease; high cholesterol; prostate problems; high blood pressure; and also can work for people with wrinkles and with pain, with low sex drive, memory loss and age spots.

Next, I have a copy of the cover of the magazine that was actually sent to my home. Who would not want to be able to turn back the hands of time, as apparently this woman appears to have done on the cover? As I stated earlier, some of these ads, I think, simply try to scare people into buying the product.

The next chart describes the aging process, as, "being murdered from within, one cell at a time." It happens to also be for ACF223.

The next poster describes a "brown slime," developing on the brain neurons. The associated article in the magazine suggests that this brown slime is a precursor to Alzheimer's disease. My staff contacted the National Institute on Aging and were told by the National Institute on Aging that no such studies have ever, or are currently underway that support such a claim.

The next poster, No. 6—is an ad for Prostata, and it suggests that if you do not take the Prostata supplement, you could end up in a hospital bed.

Finally, we have posters of products that allegedly actually slow the aging process. Gero Vita, GH3, poster No. 7.

The longevity caps is poster No. 8.

The HGH activator, poster No. 9.

Teston 6, poster number 10.

I think the question before the committee and I think the question for many Americans are do these products actually do what these ads suggest that they do, or do they do anything at all, for that matter? I am hoping today's hearing can possibly give us some of the answers to these very important questions.

We have invited several witnesses to testify. We will hear first from Mr. Mike O'Neil, who is the former chief financial officer of GB Data Systems, Inc. He can explain to us the inner-workings of the company and its marketing tactics. Will also hear from Mr. E. Vernon Glenn, who is a private-practice attorney, who will tell us about some of his clients' dealings with GB Data Systems, Inc.

Our second panel, we will have Mr. A. Glen Braswell, who is president of GB Data Systems, Inc. and Gero Vita International, and Mr. Ron Tepper, who is editor of the *Journal of Longevity*. Both gentlemen are here with their attorneys in compliance with subpoenas issued by this committee.

The General Accounting Office is here today to release the findings of a report that I requested several months ago. The report is entitled, "Health Products for Seniors, Anti-Aging Products Pose Potential for Physical and Economic Harm." I am looking forward to hearing what GAO has to say. We have also invited some experts with extensive background in the areas of complementary and alternative medicine, and particularly dietary and nutritional supplements to testify as to the impact, both physically and financially, on our Nation's elderly citizens. We will also hear from Dr. Joyce Lashof of the University of California at Berkeley School of Public Health, Wellness Letter, along with Dr. Robert Baratz and Dr. Timothy Gorski.

Finally, we have asked the government agencies that are tasked with monitoring dietary and nutritional supplements and protecting consumers from fraud to be here today to tell us about their efforts and their concerns in this area. We have a representative from the Food and Drug Administration, the Federal Trade Commission, the Federal Bureau of Investigation, and the Attorney General of the State of Maryland.

Before we get to our witnesses, I would like to ask our colleagues if they have any comments they would like to make, and first we would like to recognize the ranking member of this Aging Committee, Senator Larry Craig.

Senator Craig.

STATEMENT OF SENATOR LARRY CRAIG

Senator CRAIG. Well, thank you very much, Mr. Chairman. Mr. Chairman, first of all let me thank you and your staff for putting today's hearing together. I agree that it is important to not only raise the awareness of the potential of scams and products in the market that are simply not what they are led to be by their advertisements. That is our job and our role, especially when the consumer that is preyed upon may be the most vulnerable of our population. Clearly, we must enforce the law, remove the threat of dangerous products from the market and bring to justice criminals who prey on the frightened and the hopeless.

I look forward to the hearing and to the government witnesses and their efforts in this area. But having said that, I will also say that it is important that we remain wary of calls for expensive regulation that may restrict an individual's freedom to make his or her own health decisions. It is a balance, and that balance should always be adhered to, and that is something that I think this committee has served well in its role over the last good number of

years. So it is with that that I approach this hearing with great interest. I have seen the *Journal of Longevity*. I have thumbed through it on many occasions, and having been fairly aware of what good health and nutrition is all about, I think, oh, my, if it were only true, because in most instances the claims argued I believe to be, at best, not true.

With that, let me turn this hearing back to you, Mr. Chairman, and I will be in and out intermittently. But I do want to attend some of it, and I thank you.

The CHAIRMAN. Thank you, Senator Craig.
Senator Wyden.

STATEMENT OF SENATOR RON WYDEN

Senator WYDEN. Thank you, Mr. Chairman. I want to commend you for your leadership in putting together an extremely important hearing. This is an issue that I have followed very closely since the days when I was director of the Oregon Gray Panthers. I think it is very important now to take a fresh look at this issue and how it has changed. The fact is that those who prey on seniors constantly seem to be getting sleazier and more creative, and what has really changed in the last few years is that they now have at their disposal tremendous new technologies, and as a result of worldwide mobility, can essentially set up offshore overnight.

One of the things that I want us to look at, and we have not looked at in the past, is international cooperation in this area, because it is very clear that some of these snake oil—these information-age snake oil merchants will just look to set up very close to the United States and then figure out how to run a worldwide operation, and there have been problems with the postal laws and other laws in terms of trying to get these individuals who are preying on seniors and stop their conduct.

I will tell you going into this discussion that I largely share Senator Craig's view that we do not need a whole lot of new laws and new programs. What we need is a way to make sure that the cops on the beat here in the United States and worldwide have the tools that they need, and we need to look at some new ways, for example, to try to draw some lines between what constitutes an authoritative medical article and what constitutes hype and essentially deception. I think that is why it has been so helpful that you have taken the committee through this exercise of looking at some of these articles that, clearly to those of us who focused on gerontology over the years, look over the line.

But what is important about this and why we ought to be taking a comprehensive look at this is that the rip-off artists, who were once people who would sell stuff door-to-door, for example, like questionable roofing deals and maybe they focused in the health field, like selling Medigap policies that were not worth the paper they were written on, have now moved into the areas that this committee is looking at; claims that people will naturally be attracted to, because we have seen such a health revolution in biology and genetics, that people will be drawn to these kinds of programs unless they get the facts. That is what is so important about this hearing, is your helping to get the facts out. It is putting a hot light on some of these new and very significant ways in which older

people, both in this country and around the world, are getting fleeced. I want to make it clear that I think this is just about the most important work this committee could be doing, and as usual I will look forward to working with you.

The CHAIRMAN. Thank you, Senator Wyden.

We want to welcome our first two witnesses, Mr. Mike O'Neil and Mr. Vernon Glenn, for their testimony. Because of the sensitive nature of the testimony and the subject matter that we are dealing with today, we are going to be asking all of our witnesses to please be sworn in and promise to tell the truth. I would just note to all the members that they should be aware that under Title 18, Section 1621 of the U.S. Code, that lying before Congress is certainly subject to being prosecuted by law, and I think that we understand that. So I would ask the witnesses to please stand and raise your right hand. Do you promise that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. O'Neil. I do.

Mr. Glenn. I do.

The CHAIRMAN. Please be seated, and we will be happy to receive the testimony first of Mr. Mike O'Neil.

**STATEMENT OF MIKE O'NEIL, FORMER CHIEF FINANCIAL
OFFICER, GB DATA SYSTEMS, O'NEALS, CA**

Mr. O'NEIL. Good morning. I would like to begin by giving you some personal background.

The CHAIRMAN. Get that mike, Mr. O'Neil. Get it a little bit closer to you, so we can all pick it up.

Mr. O'NEIL. Is that better? OK. Let me begin by giving you some personal background so you will have some perspective on how it is I happen to be appearing before you today. My education and working career has always been the financial arena. I spent 20 years in both commercial banking and worked for companies, but my primary focus has been on financial reporting and analysis. I have lived in California since 1983, but consider myself to have New England roots. I am married to a doctor, have two children.

As a rule, my career and life have been based in logic and fact. On the surface, this may make me appear to be a poor candidate to discuss advertising practices of any company. However, in my capacity as the chief financial officer for the Glen Braswell Company, I attended and had input in most meetings of senior staff; included in these were weekly advertising discussions of content, scheduling, production, along with senior management meetings to discuss product development and company direction.

A description of the associated companies of Glen Braswell, GB Data, et cetera, would list some 13 companies that are primarily involved in the sales and distribution of what have become known as nutraceuticals. Combined, these companies have annual revenues of approximately \$200 million. The targeted age market for these products is 45-to 60-plus-year-olds. As the CFO from August 1998 to January 1999, I was effectively third in command at the company, behind the chief operating officer and Glen Braswell. With the knowledge gained from that position, I have been asked to come before you to discuss the focus and intent of the company's

advertising practices and why they should demand any attention at all from this committee.

If the name Glen Braswell sounds somewhat familiar to you, it should. Mr. Braswell was the subject of a lot of attention back in January and February of this past year as a result of a last-minute Presidential pardon, which was arranged through the former First Lady's brother and which the press referred to as a pardon-for-money scandal. At the time, Glen Braswell was reported in the press to be, "a convicted felon who was under investigation by the Internal Revenue Service for a massive offshore tax evasion scheme."

Because of the pardon, he no longer has a felony conviction on his record. However, I can tell you that the IRS investigation is ongoing. As you might imagine, as the former CFO, I am involved in that investigation. As such, I have been asked and request from you that we do not place the ongoing investigation in harm's way by discussing it in this hearing.

The Braswell companies operate as direct-mail marketing companies; that is, they sell directly to the consumer without going through retail outlets. This is accomplished by sending marketing information to consumers through the mail. Consumer names and addresses are bought and sold by the millions via brokers who categorize names according to whatever demographic requirements are required. Gero Vita, Life Force, Therapeutics and other Braswell companies rent these lists and mail four-to 16-page solicitations to people on the list, touting the benefits of nutritional supplements.

Again, the target market is 40-to 60-year-olds—I'm sorry, 65-year-olds—who have good credit and have been willing to buy through the mail. These practices, in one form or another, are virtually identical to all direct mail businesses in the industry.

What makes the Braswell companies unique to a handful of marketers is the predatory nature of the advertising message. The primary vehicle for the sale of products is a 50-page advertisement that has been referred to here and noted as the *Journal of Longevity*, published monthly. The magazine claims to be a journal of medical research reviews in the preventive medicine fields. The fact is that it is neither a journal, nor does it present any reviews of any preventative medicine. Every word in the magazine is composed by Braswell staff, and furthermore every word is designed to do one thing, sell Braswell products.

The magazine is presented in such a manner so as to suggest that it is a legitimate medical journal with articles written by various medical professionals. In the articles, they described a variety of medical situations that are painful, debilitating or life-threatening. These articles run three to four pages with medical detail and facts. In these articles, they describe various nontraditional herbal supplements that can solve these medical situations and restore health to whatever you apparently are bothered by. Then, as luck would have it, there is an ad in the journal for nutritional supplements sold by a seemingly unrelated company that contains the ingredients just described in the previous article, and an 800-number where you can order that product.

It is a nice, clean process, except that nowhere in the journal does it tell anyone that this is an advertisement. Further, the articles are not written by medical professionals, but rather by Braswell staff. They are reviewed by medical professionals, but written in-house. Finally, the ads contain outright false statements. The ads and articles routinely toss phrases around such as, “Thousands of doctors have praised,” whatever product, and, “Millions of men use whatever product,” which is blatantly false. One product claims to improve memory, sex drive, and reduces the chance of a heart attack by 83 percent.

The article routinely described medical problems as life-threatening, potentially deadly, causing severe illness or death. They are described to scare or threaten the reader into purchasing the antidote, or at least try the product for \$29.95. The products sold by the Braswell companies are rotated through the journals, with new product names and articles concocted as necessary; that is, if a product does not do well, it is renewed and given life in treating some other malady. New products were introduced at marketing meetings, with Mr. Braswell retaining the right to override any conclusions from any meetings.

On more than one occasion, products were deemed to be ineffective and ads too outspoken or provocative for publication in marketing meetings, only to be overwritten by Mr. Braswell, many times to the disbelief of the staff involved. What makes this inappropriate is the nature of the articles and the advertisement. What makes the activity inexcusable is it takes advantage of people with legitimate medical needs who are susceptible to a message of miracle remedies and cures. What needs to be considered here, in my opinion, is not what the person who is in pain is thinking when they read the ads, because they want to believe—they almost need to believe what is in the story.

But, rather what needs to be considered is what the person writing the ad knows to be true, and to the extent that there is a difference, there is fraud. I cannot say that all the products do not work or the people who take them do not feel better. I am not a doctor, I am not a research scientist, and I have no basis to have an opinion on that portion of the product. What I am saying is that the process that is used to recruit customers is flawed, laden with lies and deception, and that the product could not possibly deliver what is promised in the advertising.

I am not the first person to come to this conclusion. A Washington Post story of the companies quote the editors of Consumer Reports as saying in 1988, “We see a lot of misleading marketing, but what spews out of Gero Vita Industry rivals the worst.”

“Consumer Reports,” continues the Post, “characterize the company’s literature as masquerading as science.” The booklets cite actual studies, but twist the findings to support the company’s own unsubstantiated claims. In South Carolina, three sports figures, Richard Petty, Stan Musial, and Len Dawson, filed suit in Federal court against Braswell and Gero Vita for misusing their names in advertisements for Prostata, a claimed prostate cancer-preventing supplement. The lawsuits, filed in 1997 by Mr. Glenn here and Gedmiem Howe III involved a series of advertisements that iden-

tify the three sports figures among a group of men who, “waited too long and are suffering from prostate problems.”

Finally if you look at the company itself, there is an underlying commitment to deception. All the advertisements by the company contain a return in Canada, thus suggesting the company is either located or headquartered in Canada. I recently placed a call to customer service at the company that I used to work for and was told that the company chiefs were in Canada, but that she was in Maryland.

Braswell companies have no employees of an executive or any other kind in Canada, but have what amounts to a Mailboxes, Etc. address in Toronto. The reason is simple: The United States Postal Service cannot easily interrupt mail going outside the company—outside the country, I am sorry. If you look at the *Journal of Longevity*, the return address is Reno, NV. There are no employees in Reno.

These are two of the list of attempts to confuse both the general public and the government agencies. When I was there, and I do not believe things have changed, Braswell companies had employees in Marina Del Ray, CA, a shipping warehouse in Las Vegas, NV. The reasons the companies wish to have the appearance of foreign ownership and ghost locations is to create a delay for any individual or government agency seeking to locate the company. To the best of my knowledge, all of these employees are legal if you pay the appropriate taxes and file appropriate documentation. However, the elaborate tactical maneuvering of the company suggests it is aware of its own deception and has taken preventive measures to delay and confuse what it must have known would be eventual government investigation.

One of the reasons I was brought to the company was to help clean up the company for potential sale. Financial reporting and operational procedures were improving, but still compartmentalized and fragmented. During my time with the company, we had discussions with a number of buyers, and every one of them had concerns with Braswell advertising practices. While the potential buyers did not like his style, they wanted to know the financial effects of reducing the fabrications in advertising practices, clearly realizing the two are interdependent.

When I came to work for the company, Mr. Braswell had been described to me as an advertising genius who had the ability to build a company to \$200 million in annual revenues. As I came to know the insides of the companies, a different story became very clear. He is not an advertising genius. He is simply willing to advertise outside conventional industrial boundaries. To me, this is not a genius. It is a liar.

In my position as a chief financial officer, I was able to obtain answers to questions on advertising and work with the chief operating officer, Mr. Ted Ponich, to determine the hows and whys of the company's operating principles and practices. When he was hired in 1996 and I was hired in August 1998, we were advertised by senior outside consultants that the company wanted to improve its image and to convert from a clandestine operation to a traditional company. By November 1998, it was clear there was no desire to improve the company, but rather the desire to appear to be

making changes at the company by hiring persons such as Ted and myself and other department heads with traditional business backgrounds, while Mr. Braswell and senior advisors continued to manipulate the advertising and financial performance of the company.

The goal was to sell the company to an unsuspecting investor or competitor. Just after Thanksgiving of that year, Mr. Ponich and I met, where he informed me he was convinced Mr. Braswell recognized he could not change the company without senior staff, and he intended to use this leverage to approach him with his concerns as to the direction of the company.

Things did not go the way Ted had planned. The meeting ended with Mr. Braswell telling Mr. Ponich he wanted the company to go back to the old way of doing business. Mr. Ponich was a man of great integrity, and he told Mr. Braswell either the company gets cleaned up or I will personally turn you into every government authority I can find. In January 1999, four department heads, including Mr. Ponich and I, were terminated for the stated reason that the company was going in a different direction. True to his word, shortly after we were terminated, Mr. Ponich met with myself to discuss going to the appropriate governmental agencies.

While part of me just wanted to get on with my life, two things occurred which would not let me. No. 1, I would not let my friend take this process on by himself. More importantly and fundamentally, people should not be allowed to get away with what was going on. We had been insiders. We knew the strategy. We knew the practices of the company. We knew its professional advisors and could best ensure that the efforts of the various agencies were beneficial and productive, and, in fact, contacted the IRS, Federal Trade Commission, State Franchise Tax Boards, the Post Office, Food and Drug Administration, various other government agencies, including the offices of the two Senators from California.

We expected retaliation from Mr. Braswell. We were not disappointed. I was sued for a number of issues, as was Mr. Ponich. The suit against me was ultimately withdrawn. Ponich's suit has been pending the outcome of a continuing IRS investigation against the company. However, I am certain that it is fraudulent and it will be settled in his favor at the appropriate time. The lawsuits were a not-so-thinly veiled message of power and money by the Braswell companies against those who would dare to help us. Suits were no surprise to us, as it was consistent with the Braswell strategy of overwhelming any opponent with expensive and extensive litigation brought by very reputable law firms.

Besides the expensive defense, the strategy is to ruin the reputation and credibility of individuals and to ensure that it is near-impossible for them to be employable in the future. As you may imagine, working in the financial field and having been sued by your last employer for financial transgressions is not helpful to a career. Mr. Ponich was tragically killed in an automobile accident last October. I will tell you I gave up his cause of trying to expose the Braswell companies, and the companies continue to publish the *Journal of Longevity*, mail out weekly advertisements to millions, and continue to thrive.

However, at the beginning of this year, after the Presidential pardon debacle, people began to notice the Braswell companies

again. I read a number of articles on Braswell companies by leading newspapers and periodicals which describe Braswell as scam artists, convicted felons, supplement fraudster, huckster, swindler, con artist, and as a man convicted of mail fraud and perjury. Even with all of this notoriety, the company still continued to be allowed to go on. The fundamental reason I am here today is to discuss why a company headed by a man as described above can remain in business and continue to prey on the elderly and infirm.

We all know there are Federal and State agencies designed to protect the public from these activities and there are a suitcase-full of laws already in place to make sure that what I have just described does not occur. In my opinion, we do not need any laws or agencies in addition to what we already have. What we do need is to have the laws already in place enforced, and the agencies charged with monitoring these types of companies do their job.

The challenge is Mr. Braswell's senior advisers are not going to make it easy for anyone or any agency to impact their ongoing business. I have had many discussions with Mr. Braswell. The thing he fears most of all is going back to jail. He has a substantial amount of money and he will use it. The first thing he will do is out-lawyer whomever he goes against, even if that is the government. His current legal team is a Who's Who of the law profession. They have a client list which starts at the former President and Vice President and moves to major companies and influential people. His financial and technical advisers are the best money can buy. They know the law and they know what is massable within the law.

The second thing you face when dealing with companies such as these are both simple and yet difficult to overcome. They play fast and very loose with the truth. The company has elevated deception to an art form. He already knows the advertising and return policies within the company are fraudulent. Why should we believe that they are all of a sudden honest when it comes to dealing with government investigators or, for that matter, anyone who is a perceived threat to the ongoing operation? The United States Postal Service, which was responsible for shutting down the 1983 Braswell operation by stopping its mail, cannot easily interrupt mail destined to Canada. So they go get a Canadian address.

The FDA, after reviewing some of Gero Vita and other Braswell products, issued an import alert for product coming from Canada. The agency believes it did its job. However, the fact is there is product coming from Canada because the company is headquartered in Marina Del Rye, CA. The products are encapsulated at various labs on the West Coast and product is shipped from a company warehouse in Las Vegas. The company maintains its primary banking relationships—the Royal Bank of Canada. All funds are wired there on a daily basis. While the money in Canada is not beyond the reach of U.S. officials, it will delay by 2 or 3 days any seizing process and allow the company to move funds offshore.

Over the past 2 years, almost all of the agencies that were contacted by us have come back to say that their initial investigation revealed the Braswell companies to be foreign-based, beyond their jurisdiction, even after we advised them of who Mr. Ponich and I were and what we knew, the best we would receive was a promise

from a few agencies to look into the matter. For the record, over half-a-dozen calls to each of our State's Senators yielded zero response.

The Braswell strategy has been effective, and to stop the predatory nature of the advertising and fraud, in my opinion, you have to defeat the strategy. In a nutshell, this strategy is simple—first, remain anonymous. No one knows who you are or where you are—compartmentalize the company so even employees do not know exactly what goes on. Contract out much of the company's activities. Stay off government radar screens and stay out of the limelight. Mr. Braswell believes that government agencies love to go after big fish. A legitimate concern of Braswell is that his company was getting too big, one of the reasons for sale is that it would begin to attract attention.

The second strategy is to hire the best attorneys and accountants that are available, feed them a tale of misery, accented with deception. These people know the government, they know the people within the government and they know the attending weaknesses within any agency. The reputations and credentials of the professionals representing Mr. Braswell are known and respected by most agencies and various government attorneys. This is intimidation, but it works.

Third, delay the process; provide no information or overwhelm an agency with useless information; ask for extensions; plead ignorance; mistakes of intent. Most agencies are very forgiving. Use the bureaucratic nature of government investigating agencies against them; that is, most bureaucrats do not want to draw attention to themselves or other agencies by investing government resources in a losing effort. These people who work for government agencies do not want attention any more than Mr. Braswell does, but for different reasons. If they know that going against Mr. Braswell will be long, expensive and may yield nothing, they are inclined to look for a reason to avoid confrontation.

Last, strategic settlement; if there is a chance that the loss is unavoidable, settle the issue, seal the results, maintain your anonymity. That is the basis of the company and provides the freedom from which they operate. The company, policies and procedures that I have just described exist. It is real, operates in California, but how do you know that? This committee has the opportunity to view what I have just told you as either the truth or the ramblings of a disgruntled former employee. I would suggest to you that there are consequences to either avenue. If you ignore me, you take the chance I was telling the truth and that the company preys on the elderly and people who are infirm and in need of hope. These people need a collective voice, and this committee can be that voice. If you take me at my word, you are going to be taking on a man who has money, therefore can buy power and influence, both of which are the non-negotiable currency of many governmental endeavors. Let's not forget, he just received a Presidential pardon.

Ultimately, if we are successful in changing or eliminating Gero Vita, GB Data and the Braswell companies, another will step up and fill the void, as long as there are people in pain and getting older, when older brings pain and illness, there will be people who believe that there is an herb in India or a plant in China that holds

the secret to pain-free existence that our government does not want them to know about it. The fact is most Chinese and Indians do not live near as long as Americans, but packaged and presented in the proper format, there are millions of people, perhaps tens of millions in this country, that are willing to ignore this fact and buy into the fraud sponsored by companies such as Gero Vita, Theraceutical, and other Braswell-type companies and enrich the owners in the process.

The job of this government and this committee, as I see it, is to simply make sure there is a level playing field, that citizens have all the information they need to make an informed decision, and the information is founded in fact. Fraud and deceit, wherever it exists, unlevels the playing field and clouds the facts.

Thank you.

[The prepared statement of Mr. O'Neil follows:]

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TESTIMONY OF

Mike O'Neil

before the

SPECIAL COMMITTEE ON AGING

SEPTEMBER 10, 2001

I would like to begin by giving you some personal background so that you will have some perspective on how it is that I am appearing here today. My educational and working career has always been in the financial arena. I spent twenty plus years in both commercial banking and working for companies where my primary focus has always been on financial reporting and analysis. I have lived in California since 1983, but consider myself to have New England roots. I am married to a doctor, and have two children. As a rule, my career and life have been based in logic and fact. On the surface, this appears to make me a poor candidate to discuss advertising practices of any company, however in my capacity as the Chief Financial Officer for the Glen Braswell companies, I attended and had input in most meetings of senior staff. Included in these were the weekly advertising discussions of content, scheduling and production along with senior management meetings to discuss product development and company direction. A description of the associated companies of Glenn Braswell would list some 13 companies that are primarily involved in the sales and distribution of what have become know as neutraceuticals. Combined, these companies have annual revenues of approximately \$200 million. The targeted age market for these products is 45- 60 year olds. As the CFO from August of 1998 to January of 1999, I was effectively the third in command at the companies, behind the COO and Glenn Braswell. With the knowledge gained from that position, I have been asked to come before you to discuss the focus and intent of the company's advertising practices and why they should demand any attention from this committee.

If the name Glenn Braswell sounds somewhat familiar to you, it should. Mr. Braswell was the subject of a lot of attention back in January and February of this year as the result of a last minute Presidential pardon which was arranged through the former first lady's brother in what the press referred to as a pardon for money scandal. At the time, Glenn Braswell was reported in the press to be "a convicted felon, who was under investigation by the Internal Revenue Service for a 'Massive off shore tax evasion scheme". Because of that pardon, he no longer has the felony conviction on his record however I can tell you that the IRS investigation is ongoing. As the former CFO, I am involved in that investigation. As such, I have been asked and request from you that we do not place that ongoing investigation in harm's way by discussing it at all in this venue.

The Braswell companies operate as Direct Mail Marketing companies. That is, they sell directly to the consumer without going through retail outlets. This is accomplished by sending marketing information to consumers through the mail. Consumer names and addresses are bought and sold by the millions via brokers who categorize names according to whatever demographic requirements are needed. Gero Vita, Lifeforce, TheraCeuticals International and other Braswell companies rent these lists and mail 4 to 16 page solicitations to the people on the

list touting the benefits of the nutritional supplements. Again the target market is 40-60 year olds who have good credit and have been willing to buy through the mail. These practices, in one form or another, are virtually identical to all of the Direct mail businesses in the country.

What makes the Braswell companies unique to a handful of Marketers, is the predatory nature of the advertising message. The primary vehicle for the sale of products is a 50 page advertisement that is published monthly as the "Journal of Longevity". This magazine claims to be "a journal of medical research reviews in the preventive medicine fields". The fact is that it is neither a journal nor does it present any reviews of any preventive medicine. Every word in the magazine is composed by Braswell staff and furthermore every word is designed to do one thing sell Braswell product. The magazine is presented in such a manner so as to suggest that it is a legitimate medical journal with articles written by various medical professionals. In the articles they describe a variety of medical situations that are painful, debilitating or life threatening. These articles run three to four pages with medical detail and facts. In these articles they describe various non-traditional herbal supplements that can solve these medical situations and restore health to whatever you are bothered by. Then, as luck would have it, there is an ad in the journal for a nutritional supplement sold by a seemingly unrelated company that contains the ingredients just described in the previous article and an 800 number where you can order the product. It is a nice clean process except that nowhere in the journal does it tell anyone that it is an advertisement. Further, the articles are not written by medical professionals but rather by Braswell staff. Finally, the articles and ads contain outright false statements. The articles and ads routinely toss phrases such as "thousands of doctors have praised whatever product" and "millions of men use whatever product" which are blatantly false. One product claims to improve memory, sex drive and reduces a chance of heart attacks by 83%. The articles routinely describe medical problems as life threatening, potentially deadly, causing severe illness or death. They are designed to scare and threaten the reader into purchasing the "antidote" or at the very least trying the product for \$29.95. The products sold by the Braswell companies are rotated through the Journal with new product names and articles concocted as necessary. That is, if a product does not do well, it is renamed and given life in treating some other malady. New products were introduced at marketing meetings with Braswell retaining the right to override any conclusions from meetings. On more than one occasion, products were deemed to be ineffective and ads too outspoken and provocative for publication in marketing meetings, only to be overridden by Glenn Braswell many times to the disbelief of staff. What makes this inappropriate is the nature of the articles and advertisements. What makes this activity inexcusable is that it takes advantage of people with legitimate medical needs who are susceptible to a message of miracle remedies and cures. What needs to be considered is not what the person, who is in pain, is thinking when they read the add, because they

want to believe, almost need to believe, but rather what does the person writing the ad know to be true. To the extent that there is a difference, there is fraud.

I cannot say that all the products do not work or that people who take them don't feel better. I am neither a doctor, nor a research scientist and have no basis to have an opinion on the product. What I am saying is that the process that is used to recruit customers is flawed and laden with lies and deception and that the products could not possibly deliver what is promised in the advertising. I am not the first person to come to this conclusion. A Washington Post story on the companies quotes the editors of Consumer Reports as saying in 1998 "We see a lot of misleading marketing but what spews out of Gero Vita Industries rivals the worst." Consumer Reports, continued the Post, characterized the company's literature as "masquerading as science. The booklets cite actual studies but twist the findings to support the company's own unsubstantiated claim." In South Carolina, three sports figures, Richard Petty, Stan Musial and Len Dawson, filed suit in federal court against Braswell and Gero Vita for misusing their names in advertisements for Prostata, a claimed prostate cancer-preventing supplement. The lawsuits, filed in 1997 by Charleston lawyers E. Vernon Glenn and Gedney M. Howe III, involve a series of advertisements that identify the three sports figures among a group of men who "waited too long and are suffering" from prostate problems. Finally, if you look at the company itself, there is and underlying commitment to deception. All advertisements by the company contain a return address in Canada thus suggesting that the company is either located or headquartered in Canada. I recently placed a call to customer service at the company and was told that the "company chiefs were in Canada but that she was in Maryland". The Braswell companies have no employees of an executive or any other kind in Canada but rather have what amounts to a "Mail Boxes, Etc." address in Toronto. The reason, simple, the US Postal Service cannot easily interrupt mail going outside the country. If you look at the "Journal of Longevity", the return address is in Reno, NV. There are no employees in Reno either. Those are two of a list of attempts to confuse both the general public and government agencies. When I was there, and I don't believe things have changed, the Braswell companies had employees in Marina del Rey, CA and at a shipping warehouse in Las Vegas, NV. The reasons that the companies wish to have the appearance of foreign ownership and ghost locations is to create a delay for any individual or agency seeking to locate the company. To the best of my knowledge, all of these ploys are legal if you pay the appropriate taxes and file the appropriate documentation, however the elaborate tactical maneuvering of the company suggests that it is aware of it's own deception and has taken preventative measures to delay and confuse what it must have known would be eventual government investigations.

One of the reasons I was brought to the company was to help clean up the company for a potential sale. Financial reporting and operational procedures were

improving but still compartmentalized and fragmented. During my time with the company we had discussions with a number of buyers and every one of them had concerns with the Braswell advertising practices. While the potential buyers did not like his style, they wanted to know the financial effect of reducing the fabrications and advertising practices clearly realizing that the two were interdependent. When I came to work for the company, Braswell had been described to me as an advertising genius with his ability to build a company to \$200 million in annual sales. As I came to know the insides of the company, a different story became very clear. He was not an "advertising genius", but rather he was simply willing to advertise outside of the conventional industry boundaries. To me, this isn't a genius... it is a liar. In my position as the Chief Financial Officer, I was able to obtain answers to questions on advertising and worked with the Chief Operating Officer, Ted Ponich, to determine the how's and why's of the company's operating principles and practices. When he was hired in 1996 and I was hired in August of 1998, we were advised by senior outside consultants that the company wanted to improve its image and convert from a clandestine operation to a traditional company. By November of 1998 it was clear that there was no desire to improve the company but rather the desire to "appear" to be making changes at the company by hiring persons such as Ted, me and other department heads with traditional business backgrounds while Mr. Braswell and seniors advisors continued to manipulate the advertising and financial components of the company. Then the goal was to sell it to an unsuspecting investor or competitor. Just after Thanksgiving, Mr. Ponich and I met where he informed me that he was convinced that Braswell recognized that he couldn't change the company without senior staff and he intended to use this leverage to approach him with his concerns as to the direction of the company. Things did not go the way Ted had planned and the meeting ended with Mr. Braswell telling Mr. Ponich that he wanted the company to go back to the "old way of doing business" and Mr. Ponich telling Mr. Braswell that "either this company gets cleaned up or I will personally turn you into the government authorities". In January of 1999, four department heads including Mr. Ponich and I were terminated for the stated reason "the company was going in a different direction". True to his word, shortly after we were terminated, Mr. Ponich met with me to discuss going to the appropriate governmental agencies. While a part of me just wanted to get on with my life, two things occurred to me. I would not let my friend take this process on by himself and more importantly, people should not be allowed to get away with what Gero Vita, GB Data and other Braswell companies were planning. We had been insiders, knew the strategy and practices of the company and its professional advisers and could best insure that the efforts of the various agencies were beneficial.

We in fact contacted the IRS, Federal Trade Commission. State Franchise tax Boards, Post Office, Food and Drug Administration and various other government agencies including the offices of the two Senators from California. We expected

retaliation from Braswell and were not disappointed. I was sued for a number of blatantly false issues, as was Mr. Ponich. The suit against me was ultimately withdrawn. The Ponich suit has been held pending the outcome of a continuing IRS investigation against the company however I am equally certain his will be settled in his favor at the appropriate time. These lawsuits were a not so thinly veiled message of power and money by the Braswell companies to those who would dare to help us. The suits were no surprise to us as it was consistent with the Braswell strategy of overwhelming any opponent with expensive and extensive litigation brought by very reputable law firms. Besides the expense of defense, the strategy is to ruin the reputation and credibility of individuals and to insure that it is near impossible for them to be employable. As you may imagine, working in the financial field and having been sued by your last employer for financial transgressions is not helpful to a career.

Mr. Ponich was tragically killed in an automobile accident last November. I will tell you that I gave up his cause of trying to expose the Braswell companies and that the companies continue to publish the Journal of Longevity, mail out weekly advertisements to millions of people and continue to thrive.

After the Presidential pardon debacle, people began to notice the Braswell companies. I read a number of articles on the Braswell companies by leading newspaper and periodicals which describe Braswell as scam artist, convicted felon, supplement fraudster, huckster, swindler, con artist and as man convicted of mail fraud and perjury. Even with all of this notoriety, the companies still continue to be allowed to go on.

The fundamental reason that I am here today is to discuss why a company, headed by a man as described above can remain in business and continue to prey on the elderly and infirmed. We all know that there are federal and state agencies designed to protect the public from these activities and there are a suitcase full of laws already in place to make sure that what I have just described does not occur. In my opinion, we do not need any more laws or agencies to come to the party. What we do need is to have the laws, already in place, enforced and the agencies charged with monitoring these types of companies, do their job. The challenge is that Mr. Braswell and his senior advisors am not going to make it easy for anyone or any agency to impact the ongoing business.

I have had discussions with Glenn Braswell. The thing he fears most of all is going back to jail. He has a substantial amount of money and will use it. The first thing he will do is out lawyer whomever goes against him, even if that is the government. His current legal team is a who's who of the law profession. They have a client list which starts and the former President and Vice President and moves to major companies and influential people. His financial and technical advisors are also the

best that money can buy. They know the law and they know what is massageable within the law.

The second thing you face when dealing with the companies is both simple and yet difficult to overcome. They play very fast and loose with the truth. The company has elevated deception to an art form. If you already know that the advertising and return policies are fraudulent, why should you believe that they are all of a sudden honest when it comes to dealing with the investigators and for that matter, anyone who poses a perceived threat to the ongoing operation. The US Postal Service, which was responsible for shutting down the 1983 Braswell operation by stopping the mail, cannot interrupt mail destined for Canada so go get a Canadian address. The FDA, after reviewing some of the Gero Vita and other Braswell products, issued an import alert for product coming in from Canada. The agency believes that it did its job however; the facts are that there is no product coming in from Canada because the company has its headquarters in Marina del Rey, California. The products are encapsulated at various labs on the west coast and the product is shipped from a company warehouse in Las Vegas. The company maintains its primary banking relationship at the Royal Bank of Canada. All funds are wired to the bank on a daily basis. While the money in Canada is not beyond the reach of US officials, it will delay by two to three days to any seizing process and allow the company to move the funds offshore if necessary.

Over the past two years, almost all of the agencies that were contacted have come back to say that their initial investigation revealed the Braswell companies to be foreign based and beyond jurisdiction, even after we advised them of who Mr. Ponich and I were and what we knew, the best we received was a promise from a few agencies to "look into the matter". And for the record, over a half a dozen calls to each of our state senators offices yielded zero response.

The Braswell strategy has been effective and to stop the predatory nature of the advertising and fraud you have to defeat the strategy. In a nutshell, the strategy is:

1. Remain anonymous: no one knows where you are or who you are. Compartmentalize the company so even employees don't know exactly what goes on. Contract out as much of the company's activities as possible. Stay off government radar screens and out of the limelight. Braswell believes that government agencies love to go after the big fish. A legitimate concern of Braswell was that his company was getting to big and would begin to attract attention.
2. Hire the best attorneys and accountants that are available and feed them a tale of misery accented with deception. These people know the government and the attending weaknesses within any agency. The reputations and

credentials of the professionals representing Braswell are known and respected by the agencies and various government attorneys. The intimidation factor works.

3. Delay the process, provide no information or overwhelm an agency with useless information. Ask for extensions, plead ignorance or mistakes in intent. Most agencies are forgiving. Use the bureaucratic nature of government investigating agencies against them i.e. most bureaucrats do not want to draw attention to themselves by investing government resources in a losing effort. These people working for governmental agencies don't want attention any more than Braswell does but for different reasons. If they know that going against Braswell will be long and expensive and may yield nothing, they are inclined to look for a reason to avoid a confrontation.
4. Strategic settlement: that is if there is a chance of loss that is unavoidable, settle the issue and seal the results. Maintain the anonymity that is the basis of the company and provides for freedom of operation.

The company, policies and procedures that I have just described exists. It is real and operates in California but how do you know that? This committee has the opportunity to view what I have just told you as the truth or the ramblings of a disgruntled former employee. I would suggest to you that there are consequences to either avenue. Ignore me and you take a chance that I was telling the truth and there is a company that preys on the elderly and people who are in need of hope. These people need a collective voice and this committee can be that voice. Take me at my word and you will be taking on a man who has money, and therefore can buy power and influence, both of which are the non-negotiable currency of most governmental endeavors. Let us not forget that he just received a presidential pardon.

Ultimately, if we are successful in changing or eliminating the Braswell companies, another will step up and fill the void. As long as there are people in pain and getting older brings pain and illness, there will be people who believe that there is an herb in India or a plant in China that holds the secret to a pain free existence and that our government doesn't want them to know. The fact is that most Chinese and Indians don't live near as long as most Americans, but packaged and presented in the proper format, there are millions of people, perhaps tens of millions, in this country that are ready to ignore this fact and buy into the fraud sponsored by companies such as Gero Vita, Theraceutical and other Braswell type companies and enrich the owners in the process. The job of the government, as I see it, is to make sure that there is a level playing field, citizens have all the information to make an informed decision and the information is founded in fact. Fraud and deceit, wherever it exists, unlevels the field and clouds the facts.

The CHAIRMAN. Well, Mr. O'Neil, thank you very, very much for a very detailed and very elaborate tale. I think the information that you provided in your testimony is extremely important to this committee. We thank you for being with us. I know it has not been particularly easy for you to do so.

We will next hear from Mr. Vernon Glenn, who is an attorney from Mt. Pleasant, SC. Mr. Glenn, we welcome you to the Aging Committee.

**STATEMENT OF E. VERNON R. GLENN, ESQ., LAW OFFICES OF
E. VERNON F. GLENN, MT. PLEASANT, SC**

Mr. GLENN. Thank you, Senator Breaux. I appreciate the committee's invitation to testify and I hope what I have to say is helpful. My biography has already been provided to the committee. I am a trial lawyer and I live across the river from Charleston, SC. I would be remiss if I did not extend the salutations and good greetings from Mrs. Virginia Kyle Hine and Mr. Edwin Kyle. Ms. Hine's son, Johnny, is my best friend from college, and they sent their best to Senator Breaux.

I was taught as a child that if it quacks like a duck, walks like a duck, waddles like a duck and has white feathers like a duck and has got an orange bill like a duck, then in all likelihood it is a duck. I am here to tell you now that what Mr. O'Neil has told you is not only a story of some significant tragedy for our seniors in this country, but it is a duck. This fellow, Braswell, whose deposition I took this time last year down in Miami, I would submit to this committee is a recidivist of the highest and most chronic nature.

Let us not forget that Mr. Braswell was sent to jail, to Federal prison, by Federal Judge Marvin Shoob back in the early 1980's. Now, why was he sent to prison? Let us review: Mr. Braswell was sent to prison for lying about breast-enhancing and hair-growth products, and false marketing, and lying before a grand jury, and income tax fraud. All of it was related to his marketing. I have with me an excerpt from the Atlanta Journal Constitution, 1983: "Glen Braswell, once a reputed multimillionaire who lived in an Atlanta mansion and ruled a mail-order empire was sentenced to prison Monday in Federal court here. 'He can't even pay his phone bill now, they say,' said Assistant U.S. Attorney Robert Stubbs, who handled the Braswell prosecution. The picture painted in court testimony was that Braswell has little left to show for his years of business and will be lucky to keep one of the three homes that he owned in better days. He received a 3-year sentence for filing false tax returns and a perjury conviction, and when he is released he has 5 years on probation, and he is also to have Federal alcohol and drug rehabilitation while he is in the Federal pen in Kentucky."

Ladies and gentleman, I am here to tell you the more things change, the more they stay the same, and we are now at another moment of critical mass. Mr. Braswell is absolutely making money hand-over-fist on the backs of aging and scared and fearful Americans. There are two ways to stop this, I would submit, and I bet somebody else up there has got another idea, but my two ways are this: One, we have got to educate our seniors, and that seems to

be an ongoing process, because hope and hopefulness always triumphs education. It just does. We want to believe. I am 51 now. I have gotten very creaky, and old, and grumpy about it, and I would love it if somebody would give me something to make me feel better every morning.

Having said that, I also am old enough and experienced enough and educated enough to understand that there is no magic cure in a bottle. I wish that there was, but there is not. So the ongoing educational process, a little bit, is not going to be that effective. The other part of it is somebody has got to start swinging a great big bat at these people. I know about Braswell because I represented a bunch of people that ended up—and we ended up suing him, and we sued him in a very unlikely place. We sued him in Federal court in South Carolina, and Mr. Braswell did not want to come down to the low country of South Carolina and sit and face a jury of his peers.

Mr. O'Neil and I were chatting earlier and he told us we were just a flea on a dog's back. They paid us some money—we are not allowed to disclose how much and it was a goodly sum, but I am not going to tell you how much—but it did not mean anything to Glen Braswell, and his insurance company paid some of it and Mr. Braswell paid some of it. Isn't that about right? And Mr. Braswell went on, and that is the reason, when I sent my remarks up to this committee, "Sin in haste and repent at leisure." That is something my mother always said to me and I now say it to my children.

Mr. Braswell has a great time sinning and it takes him a long time to repent, and until you all get your big stick out and all these nice law-enforcement agencies sitting back here, Mr. Braswell is going to continue to get a free pass. He wants to sell these companies, ladies and gentlemen. He has got a passport. He is going to leave the building. He is going to come in here with a phalanx of lawyers. He is going to leave with a phalanx of lawyers, and we will all throw our hands up in the air. I submit we can do better than that.

John Cheever, one of the great American authors, once said that, "America is a Nation haunted by a dream of excellence." I always loved that. He said that at the Bicentennial. Walter Cronkite interviewed him. What he was saying was we are always stumbling and staggering and trying to figure out what is the right thing to do, and we mess it up all the time and we get it wrong a lot, but we keep trying. So our plea to this committee is please keep trying, please let's sort of put on our armor now. Let's tell the big-dog, white-collar law firms no, no more, we are not going to let you stand in the way here. We are going to do our job for our senior citizens and for our people who are sick and scared. It is the right thing to do.

Last, I would draw your attention to three quick things, and then I will be quiet. My children would look at me when I say that and say, "Daddy is lying again," so I want to make full disclosure. There is a poster over here that we pulled up off the Gero Vita web site, and I would commend this to you. I know the Braswell people will love it because it is free advertising. You know that old thing, "I don't care what you say about me, as long as you get my name right." But it is www.gvi.com. You can go there and I mean you can

buy it all, and I wish you would look at the bottom. This is the Prostata. This was the company, the product that GVI sells, that we got into these lawsuits with, with Jim Ferree and these other sports celebrities. They have a disclaimer on the bottom, and I want to read it to you real quickly: "Gero Vita products are dietary supplements—that is it—and as such are not intended to treat, cure or prevent any disease. Those seeking treatment for specific disease should consult a physician or other qualified health care professional prior to take a Gero Vita product or any dietary supplement." The message is: Buy our stuff, but before you put it in your mouth, go on and see your doctor.

Well, your doctor is going to tell you that it is not worth a tinker's damn, none of it is. It is junk. It is all junk. I consulted with one of the finest gerontologists in the country, Dr. Walter Ettinger, then of Wake Forest University Medical School. Walter Ettinger knows more about dealing with the aging issues with elderly Americans than just about anybody I know. Walter Ettinger said this stuff is not medically efficacious.

My time is up. I have one last comment. In the web site they have a special section, and I do not mean for this to be salacious. This is sad. Sexual enhancers, they sell—they list 10 of them, with such fascinating names as Sexativa Plus, Teston cream and Intamax. I conclude my formal comments to this committee by giving you a brief description of the so-called claimed medical efficacy of Teston cream and Intamax, which they sell, by the way, in a combo-pack. Teston cream—now, you all tell me if the Federal Trade Commission does not believe this is false advertising: "Teston cream is a hormonal supplement," which, by the way, nobody knows how much hormone is in it or if any is in it because it is not vetted by anybody. It is only distributed by GB Data Systems through their operations in Canada, Reno, and all parts of the globe.

But what you do with Teston cream—and this is fabulous—you rub it on your clean, dry abdomen, and then your sex life is going to take off. Now, I am going to tell you now if I can rub some cream on my clean, dry abdomen—I guess if you had a sweaty or dirty abdomen, you are out of business. The other part of it is the Intamax. Now, this is even better. Here is the double-barrel. If you get both—if you can get both, first, I guess, you put the Teston cream on your clean, dry abdomen, but then you spray Intamax with its six prosexual nutrients into your mouth. I do not know when you do this, because they are not telling us, but I am sure that would really kind of lighten the mood. "Can elevate your sexual vigor to new heights of passionate lovemaking."

Folks, this is garbage. This is junk. These people walking in here today, they can dress it up any way they want, but the truth of the matter is this is real wrong, and you all—and you all have the power to put the brakes on these people. I have always felt that during the course of my life, that from time to time things achieve a critical mass, things evolve. They kind of come to a point where things are going to happen. Well, golly, the country is getting older. I am getting older. We are all getting older, and these people are out there just preying on us. Stop them.

Thank you.

[The prepared statement of Mr. Glenn follows:]

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Sin in Haste; Repent at Leisure

Gero Vita's Duping of Seniors

I appreciate the committee's invitation to speak. I hope my remarks will be helpful. I can only specifically discuss GV Data Systems, GeroVita International, Glenn Braswell and some of their offspring because they are the parties I have sued. However, in my investigations and work-ups, I gathered considerable information about this entire burgeoning industry and its products.

Sales of dietary and nutritional supplements have grown into a multi-billion dollar industry. With overstated, inaccurate and misleading claims directed at an aging and fearful population, manufacturers and distributors of these supplements generate substantial sales. As our population ages, this market will become even more lucrative.

Under present day requirements, dietary and nutritional supplements are not regulated. Subsequently, they are not inspected or quality controlled by the FDA. These products, which contain vitamins, minerals, herbs and other ingredients, have purported health benefits for allergies, prostate cancer, arthritis, digestive disorders, bone and joint health, obesity, immune system failure, anti-aging, sexual disorder and diminished memory, among many others. These ingredients come from all over the world. Many claims made about the benefits of these supplements are anecdotal, unsubstantiated, gross exaggerations and downright bogus.

One of the largest direct marketers of health products, if not the largest is Gero Vita, International. In 1998, as a result of direct mailing of 20 million elaborate mailers EVERY month (totaling 240 million mailers that year). Gero Vita grossed about \$170 million in sales. An ad for a sales director last year boasted that the company had grossed \$250 million. Obviously, this is an enormous market!

While it is agreed that an adequate supply of vitamins and minerals are essential to good health, curative and preventative properties of these multitudinous substances have yet to be proven. With only some exceptions, the great majority of people will receive proper and adequate amounts in a balanced daily diet. Nevertheless, this industry in general and Gero Vita in particular, rapaciously markets its potions and elixirs.

My involvement with Gero Vita came about when a client, an old family friend and professional athlete, came to me after he was alerted by a golfing partner that his likeness adorned a sales brochure for a prostate cancer product which boldly claimed both preventative and curative results. Our lengthy investigation and lawsuit followed. In the process, I came to know much about Gero Vita International, Gero Vita Laboratories, G.B. Data Systems, Life Force Laboratories, S & G Laboratories, Health Quest Publications and their chief executive and owner A. Glenn Braswell. Eventually I came to represent three other high-profile sports celebrities who also were featured on these same brochures.

My clients, who all have substantial endorsement contracts and arrangements with various legitimate products and have likewise worked hard to be legitimate spokesmen for valid products, accused Glenn Braswell, G.B. Data Systems, et al, saying he had defamed their character through the unauthorized use of their likenesses in direct mail advertising. In peddling their herbal remedy *Prostata*, Braswell and G.B. Data Systems inappropriately and inaccurately reported on my clients' health and medical conditions. In 1997, Braswell and G.B. Data Systems mailed two different fliers featuring my clients' photographs and implying a bogus endorsement to over 17 million addresses. Subsequent sales of *Prostata* associated with those two brochures alone were over \$5 million.

Earlier, in 1995, the FDA sought to limit Gero Vita's claims by banning the importation of the company's products that claimed they could prevent or treat disease. In 1997, the ban was extended to cover Life Force Laboratories, another company related to Gero Vita. *Prostata* itself is the object of FDA Import Alert #66-41 wherein officials are directed to automatically seize any *Prostata* **imported into** the country. (Ironically the FDA has no authority over *Prostata* manufactured or otherwise assembled in the United States.) Aside from the unauthorized endorsements, my clients were offended and angered to be linked to an inferior, medically-spurious product and a deceptive marketing scheme that was under the scrutiny of government investigation and penalty.

Braswell's business life has been marred by numerous questionable practices. During the process of discovery, I quickly became aware that Braswell and his companies were no strangers to litigation. In 1983 Braswell and companies settled FTC charges that they did not have adequate scientific evidence that the hair loss products worked and had not issued refunds upon request to customers as guaranteed. They were ordered to pay \$610,000 in penalties and further barred from making performance or efficacy claims for any product or service without reliable scientific evidence to substantiate them.

In the mid 1980's, the U.S. Postal service in Atlanta had 138 false representation complaints which were filed against 50 different medical/cosmetic business entities owned by Braswell. The cases concluded with 32 false representation orders and 15 consent agreements.

Also, Mr. Braswell pleaded guilty to mail fraud involving faking of "before and after" results of bust developers, hair growth, and cosmetic products. He was sentenced to five years' probation. He was also sentenced to a three-year prison term for Federal income tax evasion and perjury charges stemming from the Postal Services' mail fraud investigation. During his incarceration, the sentencing judge ordered Braswell to undergo counseling and treatment for alcohol and drug problems.

Also in 1984 while he served his federal prison term, Braswell entered a no-contest pleas to grand theft charges related to a burglary arrest at the home of a former employee. He was sentenced to two years' probation to run concurrently with his federal sentence.

Braswell and companies are currently under investigation by the U.S. Attorneys Office in Los Angeles for criminal tax fraud and money laundering charges involving tax avoidance in the tens of million dollars. Their accounting practices are under fire for costing of products sold and subsequent reductions of profits made on various corporate tax returns. The investigation is focusing on allegations that Braswell, Gero Vita and G.B. Data Systems used an off-shore company, Deleon Global Trading, to falsely mark-up reported costs of products that Gero Vita purchased from vendors. This enabled Gero Vita to evade corporate income taxes and to provide Gero Vita with purported justification for transferring millions of dollars to off-shore accounts in an effort to conceal funds from the IRS.

President Clinton's last minute pardon of Braswell has clouded these current investigations and probes. Remarkably, the larger story was assembled and published by *National Inquirer* reporters who were able to piece together the connection of Braswell to attorney Hugh Rodham who was responsible for getting the pardon request to Clinton. (The status of the federal investigation in Los Angeles is unknown to me and I presumed not yet resolved. In candor, I have never seen a copy of the pardon granted and do not know whether it covers the current investigation or Mr. Braswell's earlier felony convictions.)

Nevertheless, Mr. Braswell's business appears to remain profitable. Aside from the profusion of lawsuits and investigations surrounding Braswell and his business ventures, he recently went through a very public divorce in Miami. In a mediated, voluntary settlement agreement, he agreed to pay his wife \$42 million dollars over eight years.

In Prostata mailers, Gero Vita predicts veritable prostate Armageddon for those remiss in purchasing its products. Certainly no one should make light of the very real problems associated with prostate health, but Gero Vita cites a gloomy outlook for everyone who neglects to buy Prostata. Using scare tactics and appealing to vanity and virility, Prostata is implied to prevent and treat prostate enlargement, impotence, and incontinence. Intentionally ambiguous ad copy says Prostata offers nutritional support for prostate health by "soothing and strengthening" the gland and "reversing prostate growth". Murky marketing touts zinc, lycopene and hydrangea

extracts that will inhibit growth and keep the prostate's size in check. According to the brochure, one of the most common benefits of Prostata is the revitalization of one's sex life. The slick and salacious ads ominously warn of possible side effects of mainstream surgical and medical prostate treatments that will leave men impotent and with enlarged breasts.

After all the benefits of Prostata are extolled, promises are made and satisfaction warranted, a discreetly placed disclaimer is tucked away at the bottom of their web page "Gero Vita products are dietary supplements and as such are *not intended to treat, cure or prevent any disease*. Those seeking treatment for a specific disease should consult a physician or other qualified health care professional prior to taking Gero Vita products or any other dietary supplement. I submit this disclaimer is there solely as lawsuit/liability repellent. If a discerning consumer were to adhere to the admonishment, no sales of Prostata would ever occur.

In addition to investigating the litigation history of Mr. Braswell and his companies' marketing strategies for the preparation of my clients' lawsuits, I also sought expert medical opinions on the efficacy of Prostata. I had the Prostata, its ingredients and other information provided by Gero Vita supporting its health claims scrutinized by Walter Ettinger, M.D., Head of the Department of Gerontology at the Paul Sticht Center for Aging associated with the Wake Forest University School of Medicine. Dr. Ettinger is renowned and respected in the field of gerontology. Dr. Ettinger notes that the ingredients in "Prostata may have some biological effects on the prostate, but any claims that it may prevent the development of prostate cancer are without **any** scientific foundation." (Emphasis added.) He goes further in saying "the advertising material and articles are misleading. The material implies that the use of this product will lower the risk of prostate cancer, but the evidence cited speaks only to prostatitis (swollen prostate) and benign prostatic hypertrophy." When required during the discovery phase of the cases' development to substantiate the cancer fighting claims of Prostata, the defendants could do nothing more than provide a few medical journal articles that dealt with swelling of the prostate and not prostate cancer. *Swelling* and *cancer* are never to be mistaken as the same condition.

Gero Vita uses vanity, fear of death and aging along with inability to perform sexually to sell millions of dollars of Prostata and many other supplements each year. Glossy four-color brochures featuring celebrity "endorsers", testimonials, purported scientific study and evidence by "expert" persuade hopeful seniors to part with their hard-earned money for a daily dose of hope. Gero Vita creates consumer confusion by using physicians and scientists of dubious background to lend legitimacy to their supplements' assertions. Several members of their advisory boards are themselves subjects of investigations and professional restrictions.

Gero Vita has also been accused of taking medical research and misrepresenting results to appear to support the effectiveness of their products. Currently, in Albany NY, reputable arthritis specialist Joel Kremer, M.D., has sued Gero Vita and GB Data Systems for producing advertising in which Dr. Kremer's name was used without permission to create the appearance of endorsing the company's anti-arthritis supplement. Mary Prudden, M.D., of Columbia University alleges that Gero Vita has misrepresented the independent research of her late father-

in-law Dr. John Prudden to support claims that the product Arthro-7 supposedly rebuilds joints and stops arthritis. Both suits are pending.

In summary, Prostata and other Gero Vita supplements are questionable products and compounds. They do not perform as they are advertised and there is no proof or medical evidence that they should. However, through misleading marketing to an unsuspecting consumer, sales of these concoctions generate tremendous sums of monies for Mr. Braswell. In light of the volume of charges, complaints, lawsuits, and the subsequent jail terms, sanctions, fines and settlements, one would assume Glenn Braswell would learn a lesson and understand the wrongs he has committed. Despite all, his companies thrive and multiply. The price he has had to pay to conduct business and bend and break laws, is insignificant compared to the immense profits he has made at the expense of gullible, trusting seniors..

Caveat Emptor: Let the Buyer Beware! Unfortunately until seniors are made aware of these scams, and there are two decades' worth to disclose, they will never be able to become more judicious consumers. The best advice is to see a doctor first. Eat a balanced diet. Exercise. Be skeptical!



E. Vernon F. Glenn
Testimony to the U.S. Senate
Special Committee on Aging
September 10, 2001

EVFG/ahg
enclosure

A Few Of The Millions Who Waited Too Long And Died From Prostate Problems!



Don Ameche, Actor



Bill Bixby, Actor



Steven Ross, CEO of Time Warner



Telly Savalas, Actor



Dick Sargent, Actor

These Five Are Winning The Battle



Jim Ferree, Senior PGA Tour Player



Jerry Lewis, Actor

Don't Join The First Group; Take Care Of Your Prostate Today!

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3

CHARLESTON SC 29402-0835



The CHAIRMAN. Mr. Glenn, thank you very much, and Mr. O'Neil, thank you very much. A couple of questions, Mr. Glenn has just indicated, in his opinion, that the products are garbage and junk. But, Mr. O'Neil, can you give us an idea of how much the company was making selling the products that Mr. Glenn just described as garbage and junk?

Mr. O'NEIL. Sure. The company has a profit—pure profit percentage of between 18 and 20 percent. As he so effectively described the product, which I would not even try to do again, they sell typically for \$29.95. Of that \$29.95, the majority of the expense going into that \$29.95 is advertising. The product itself is probably bottled and put in a box for \$4, \$5 dollars. So advertising is clearly the No. 1 expense of the company.

The CHAIRMAN. Do you have any idea what the gross revenues were?

Mr. O'NEIL. I have no idea what it was for the last couple of years, but I know they were on target for \$200-plus million.

The CHAIRMAN. I am sorry. How much?

Mr. O'NEIL. They were on target for \$200-plus million when I left the company.

The CHAIRMAN. \$200-plus million? Was that—over what period of time?

Mr. O'NEIL. A year.

The CHAIRMAN. A year?

Mr. O'NEIL. Yes.

Mr. GLENN. Let me put it in further perspective. When Mr. Braswell went to prison in 1983, 1984, he was broke. So in about 17 years, he has gotten way past back to even. They advertised last year, after Mr. O'Neil and Mr. Ponich and the others were summarily kicked out the door for trying to tell the truth, they advertised in a number of trade journals that they wanted a director of marketing for a \$250 million-a-year gross sales company. We know that in the cases that we were involved in, that they mailed out almost 12 million brochures, and these are expensive brochures. They used one of the biggest and finest printing outfits in the world, Quebecor, Magog out of Canada, and they mailed out about 12 million of these glossy, slick brochures. They were just four-fold, but they made about \$7, \$8 million in sales off those brochures.

They track by zipcode a personal note—and I have seen the document. Mr. Braswell owns all this stuff lock, stock and barrel. If there is any minority ownership, it is very, very minority. Just to put it in perspective, this was a man who was broke 17, 16 years ago, when he got out of prison. He just settled with one of his wives for \$42 million, and he is paying her. That is a lot of cash.

The CHAIRMAN. Mr. O'Neil, we got one of the copies of the *Journal of Longevity* at my house. How did I get on the mailing list?

Mr. O'NEIL. Mailing lists are an industry unto themselves. There are brokers out there who, if you buy something, you order something, ask for information on something, any time you give your name and address out somebody is capturing it. It is a very elaborate industry, because obviously you do not want to pay for names that are already your customers. But essentially somebody in your family made a request, ordered something, got a Visa card, got a TRW report. There are 1,000 different ways of getting on a list, and

these lists are traded, these lists are sold. They are rented—essentially, you rent them for four cents a name or thereabout.

The CHAIRMAN. Was there a conscious effort to get names of people who are seniors?

Mr. O'NEIL. Absolutely. As Mr. Glenn pointed out, you want to sell your product to the target market, and the more you can refine that, the advertising is very expensive. If you look at the quality of the advertising, not what is contained within the issue, but just at the quality of the journal itself, the reason it looks like, as you referred to, the American Journal of Medicine or the *New England Journal of Medicine* is because it is equally well-prepared, probably better prepared, if you truly wanted to go into the details of it. It is very well done, it looks legitimate, and that is very expensive to do. So you do not wish to put that advertising piece, as it truly should be referred to, in the hands of a 20-year-old who would not know their prostate if they had to.

The CHAIRMAN. Do you have any information or knowledge as to how—I was impressed with the pictures of the doctors and all their little initials behind their names, M.D.s, Ph.D.s, et al., behind each one of their pictures and their names. I am just wondering, do you have any idea of how the company got doctors to associate with the articles and did, in fact, the doctors write the articles, to your information?

Mr. O'NEIL. The articles were written at the *Journal of Longevity*, which are—the offices of the Journal of Longevity, the offices of GB Data, the offices of Gero Vita, are all on one floor, in one building, literally across from each other. So to presume that there is a distance between them would be an overexaggeration. What happens with the doctors—and as you know, I am not a doctor—but there are many doctors that believe that this stuff is valuable to you, as some would say it is not valuable to you. So they seek out doctors who are willing to have their names associated, they write the article, they ship it to the doctor for their review.

The CHAIRMAN. Who would write the article?

Mr. O'NEIL. Writers. If you flip to the front of that book, you will see a bunch of budget writers. The people will write the article, do the research—and they include a bibliography in there, and the research is from wherever—and then ship the article off to the doctor to be reviewed for—you know, to see if they were willing to come on board with it. There is a list of doctors, and from within the company, I can tell you that there are certain doctors that you can ship whatever to and they will sign off on it, and other doctors are more critical.

The CHAIRMAN. My final question—thank you. Was there any discussion at any time as to whether the word “advertisement” should appear in this journal at any time, and if so, what was the conclusion?

Mr. O'NEIL. That would defeat the purpose, simply put. That is a short answer to a long question, but that would defeat the purpose. The purpose is not to have that considered as an advertisement. The purpose is presenting that whole process—if you look through that journal, there is virtually no other product, other than the Braswell products, advertised in there, and yet it presents itself to be a journal, and if you read under the title, of medical review.

So to call that an advertisement is to put a stake in the heart of it.

The CHAIRMAN. Thank you both, gentlemen, very much.

Senator Wyden

Senator WYDEN. Thank you, Mr. Chairman.

Mr. O'Neil, a special thanks to you. It takes tremendous guts to do what you are doing, and not just walking through that door and talking casually. There is real exposure for somebody like yourself who does this, and I appreciate it. I think you heard me say that what I think really has changed over the years, in terms of how you fleece seniors, is that you use these new technologies, No. 1, and with modern transportation you have got worldwide mobility, and I think what you have documented in your testimony, particularly at the top of page four, is especially troubling, in terms of the relationship between California and Las Vegas and Canada.

I want to ask you just a couple of questions about that. You mentioned that the company's money is sent to Canada so that if anybody goes after it, there is a delay so it can be transferred again quickly. Do you have a sense of where the money ultimately ends up?

Mr. O'NEIL. Yes, I do. I imagine you will probably want me to elaborate on that. As one might imagine, this is a \$200-plus million operation and there are expenses that need to be paid. The money is collected either through credit card receipts or through the actual through-the-mail receipts, and starts in the Royal Bank of Canada. From there, it goes to—or at least it formerly went to, when I was there—Bermuda, to accounts controlled by Mr. Braswell directly, and then from then on I have my suspicions, but I cannot quote exactly where it goes. But it does not end up back here, and the purpose behind that is very simple. In 1983, it was the United States Post Office that shut him down simply by interrupting his stream of cash. If you take the mail, you take the receipts. Now, credit cards were not as prevalent back then, but you interrupt his mail, you interrupt his receipts, you interrupt his cash-flow.

Senator WYDEN. Does the money move through multiple jurisdictions overseas, in your opinion?

Mr. O'NEIL. Define multiple jurisdictions.

Senator WYDEN. I am trying to be helpful to you. As I say, I think what you are doing is extraordinarily gutsy, and I obviously want you to tell me where it is going to end up, but I realize this is a very sensitive point. As I say, this is a field I have worked in for 20 years now, since I was director of the Gray Panthers, and I think there is clearly a new approach that allows this money to be moved literately all over the globe virtually overnight, and I want, consistent with what you feel comfortable saying, for you to tell me a little more about that.

Mr. O'NEIL. Sure. The money flows, as you said, quickly. The money flows effortlessly, as simply as wire transfers and the money is in California this morning, this afternoon it is in Canada, and tomorrow morning it is wherever it needs to be. As to whether it takes guts to come up here and say something, I would just like to say one thing on that, and that is that my friend, Ted Ponich, who passed away, made a promise to this man of what he was

going to do if he did not clean up his act. I am just fulfilling a promise. I am not—this is not—trust me, I got other places I would rather be.

Senator WYDEN. I got that drift.

Mr. O'NEIL. I am not the best person to do this. He was a gregarious person that would be better served here, but he said what he was going to do. I agreed with it, so I am here. So whatever you want to know, less what is going on with the IRS, I am more than willing to tell you.

Senator WYDEN. You also mentioned that you had gone to several agencies to ask them to work with you on this. Can you tell us a little bit more about how you were treated by those agencies?

Mr. O'NEIL. Are you sure you want to know? Yeah, all right. Not well—courteously, but not well. There is a sense among the agencies of do you really want to take on this man? Do you really want to face the lawyers that you are going to be facing in a couple of seconds and go head-to-head with them, and potentially lose? When you go to the FTC or you go to the FDA, there is no Mr. FDA or Mr. FTC. It is not one person. You are talking to a person who works for the agency—I am sure very well-intentioned—but they work for an agency. They do not represent the agency. They do not have ownership in the agency. They want to make their job appear as easy as possible.

Included in that was our two Senators from California, and they were very courteous—I mean, their staff. You do not talk to them, naturally. But the staffs of every agency we went to were very courteous. Some did some investigations and came back and said Canadian company. And we flat told them—Mr. Ponich was with me at the time, “Look, you are looking at the chief financial officer and the chief operating officer of the company. We know they are in Marina Del Ray. We know there are no—” And then they would say, “Well, let us look into it further,” and it just rolls on down the road.

So it was a frustrating experience at best, and functionally, as I said, I gave it up. It just was not—it was not worthy my time to just be told there is nothing here or there is nothing worth it, in the agency, to go after him, or there is nothing we can latch our hands on to, or there is some agency and we are going to subordinate our investigation to the IRS and wait till it—and they do not have to be—they can mutually exclusive, I guess is what I am saying.

Senator WYDEN. If you could get to me the names of the people in some of these agencies that you met with, I would very much like to go over that with them, and I share your view. I do not think they get up in the morning and say, “Look, I want to let some people off the book.” I think that clearly these are issues that take a whole lot of effort and whole lot of commitment, and my sense is sometimes that is not forthcoming, and I want to follow this up.

Mr. O'NEIL. Senator Wyden, you are right. Essentially, there is an investment that they have to make in their own credibility, their own time, and agency resources, and I am sure they kind of do a return on investment at their own level, and say, “This is what we are going to go up against,” and frankly there are not five

people in this room that could tell where O'Neals, CA really is. I am one man from O'Neals, CA. Who am I going to talk to? Who am I?

Senator WYDEN. That really leads to the last question I want to ask for you, Mr. Glenn, because your testimony was very good, and I obviously share your concerns. The point about the agencies and the investment goes right to the heart of what you need to do in this area.

I am not convinced, for example, you need to bring hundreds and hundreds of cases. What you need to do is send a very strong message in instances where it is clear that the conduct is over the line, because if you send a really strong message, that has real deterrence value, and then all of a sudden those who prey on seniors are going to have to be a little more cautious. That goes to the point that you made with respect to swinging the bat and swinging the bat hard, which is again something I have been very committed to in my years, working with older people.

What is being missed as of now when people swing the bat? Let's say you are at the plate, you hold the election certificate, you sit where Chairman Breaux is and a couple of other members of U.S. Senate, and so you have got an opportunity now to make sure that when the bat is swung, you are not just flailing around out there, but you are really swinging it so has to have the maximum effect when you really need to send a deterrent, which is what I was trying to elicit from Mr. O'Neil. So tell us, if you would, how you swing that bat.

Mr. GLENN. I would have a real brief meeting with the following people in attendance, and I would ask them for their full and total corporation. I would invite the head of the Federal Trade Commission, the head of the Food and Drug Administration, the United States Postal Inspector, the Canadian ambassador, the Ambassador from the Grand Cayman Islands, where one of the big offshore holding companies is DeLeon Holdings, I believe it is. I am saying it, he ain't. And I would also have the U.S. Attorney from California, who is in charge of the ongoing, pending criminal tax fraud investigation. I would say, "Gentlemen, ladies, we are going to get on the same page, we are going to get on the same page now, and in 10 days I want you back in my office telling me exactly what we are going to do, and we are going to shut this scam artist down and we are going to shut down now," And I believe that is probably already in the works. This is part of my critical mass theory.

But I think that is the easiest way. You get everybody that has an opportunity to take a shot at this guy, legitimately, and get them all on the same page at one time, and then run it.

Senator WYDEN. We are going to try to—and under Chairman Breaux's leadership—we are going to try to bring that kind of meeting about.

Mr. GLENN. I do not think there is any question there is.

Senator WYDEN. Thank you.

The CHAIRMAN. Thank you, Senator Wyden. We have been joined by Senator Lincoln.

Any questions at this time, Blanche?

Senator LINCOLN. No questions. I may have a few opening remarks.

[The prepared statement of Senator Blanche Lincoln follows:]

PREPARED STATEMENT OF SENATOR BLANCHE LINCOLN

Good Morning Mr. Chairman and thank you for holding this timely and important hearing.

A recent Newsweek article said that, "...in England, old age is imminent, in Canada inevitable and in California optional." In their day and age in America, are able to replace practically anything that we want from hair to hips. So it's no wonder that our expectations for health "fix-er-uppers" are high.

As the Newsweek article that I'm referring to made clear, most of us want to live as long as possible, but we also want that life to be healthy.

We are blessed in our society to have access to some of the most exhilarating types of activities; and just because we are "a certain age" doesn't mean we want to stop doing those things. Americans want to remain as active and involved in every aspect of our lives as possible. We don't even want to retire until it is absolutely necessary. So, we all run the risk of being "victimized" when it comes to products that help hold at bay those aches and pains and essentially "slow-down" the process of aging.

Our senior population is growing and Baby Boomers more than anyone will be seeking the most effective health sustaining products. This problem is of national concern, considering that it is estimated that this is a \$27 billion dollar a year industry and 60 percent of those consumers in this industry are senior citizens.

Given this set of circumstances I believe it is our responsibility to be aware of companies that wish to prey upon our vulnerabilities. We must arm our caregivers with yet one more weapon with which to fight for and protect our seniors from these abuses-knowledge.

I'm glad to be here today and look forward to the testimonies of our witnesses. Thank you Mr. Chairman.

The CHAIRMAN. OK. Good deal.

Gentlemen, we thank you very much. You all have been very helpful to this committee. Perhaps we may have some future discussions with you, and the best of luck to both of you. Thank you very much.

We would like to now welcome up our next panel, the second panel, which will consist of Mr. Glen Braswell, who is president of Gero Vita International, and Mr. Ron Tepper, who is editor of the *Journal of Longevity*. The gentlemen, I understand, will be accompanied by their attorneys, and we would be pleased to have them come before the committee. We will, of course, ask them to take the same oath testifying to their truthfulness as the first panel did, and would ask them to please take their positions at the witness table.

Mr. Braswell and Mr. Tepper, I was saying while you were entering the room that we would ask you to please stand and swear to the truthfulness of your testimony, as we have had the first panel do, and all the other panels, as well. Gentlemen, would you please stand and raise your right hand? Do you solemnly swear that the testimony you are about to give to the Committee on Aging be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. TEPPER. I do.

Mr. BRASWELL. I do.

STATEMENT OF GLEN BRASWELL, PRESIDENT, GERO VITA INTERNATIONAL, MARINA DEL RAY, CA; AND RON TEPPER, EDITOR, "JOURNAL OF LONGEVITY," HEALTH QUEST PUBLICATIONS, MARINA DEL RAY, CA

The CHAIRMAN. Please be seated. Gentlemen, we are glad that you are here. I understand that you do not have any testimony to present as a statement to the committee. Is that correct?

Mr. TEPPER. That is correct.

Mr. BRASWELL. That is correct.

The CHAIRMAN. Well, then in that case, I think that it would be appropriate if we would just, since you do not have a printed statement to the committee, just to proceed to asking you some questions about the subject matter of the hearing today.

I would like to start by first asking Mr. Braswell if you are the sole owner or stockholder for the GB Data Systems and their subsidiary companies?

Mr. Braswell.

Mr. BRASWELL. On advice of counsel, I respectfully decline to answer the question, based on my rights under the Fifth Amendment.

The CHAIRMAN. Mr. Braswell, I know the answer, but if you would make sure you have your mike as close to you as you possibly can.

Mr. Tepper, you are identified as the editor of the *Journal of Longevity*. My question is isn't it true that the publication, *Journal of Longevity*, which you have seen displayed here, is owned by GB Data and is not, by any definition, an independent medical journal? Is that correct or not correct?

Mr. TEPPER. On advice of counsel, I respectfully decline to answer the question, based on my rights under the Fifth Amendment to the U.S. Constitution. On advice of counsel, I assert the privilege.

The CHAIRMAN. Mr. Braswell, the address that we have noted in the Journal of Longevity to order the products that are advertised for distribution and sale is in Canada. Do you have, in fact, any employees or offices or facilities or products based anywhere in the country of Canada?

Mr. BRASWELL. On advice of counsel, I assert the privilege.

The CHAIRMAN. Mr. Tepper, the previous panel of witnesses, one of the attorneys, talked in terms of litigation, that he has proceeded to represent people who are allegedly endorsing products in the Journal of Longevity without their permission. The question is has the Journal of Longevity and you as the editor ever utilized statements or likenesses of any individuals without their permission to do so, that appeared subsequently in the journal?

Mr. TEPPER. On advice of counsel, I respectfully decline to answer the question, based on my rights under the Fifth Amendment to the U.S. Constitution. On advice of counsel, I assert the privilege.

The CHAIRMAN. Mr. Tepper and Mr. Braswell, I think there is a trend here. Mr. Braswell, I have just got to ask you, do you really use any of these products that are advertised in that Journal of Longevity yourself?

Mr. BRASWELL. On advice of counsel, I assert the privilege.

The CHAIRMAN. Gentlemen, certainly you have the constitutional and legal right to do that. The assertion of the Fifth Amendment right to not testify is a right that has been long-recognized in this country, and we respect that right. It is not an indication of guilt or innocence or anything of that nature. You have that right and we respect your exercise of that right, and obviously to continue a long line of questioning with the same answers is not going to get us anywhere, nor provide any additional information, and the committee really needs to move on to other people who will be testifying about this and other matters dealing with the marketing of products, particularly to seniors.

With that, and your assertion of your rights, which again you have the right to do, both Mr. Braswell and Mr. Tepper would be excused at this time.

We now, as this panel is departing, have a third panel which we will anxiously bring to the forefront. Ladies and gentlemen of the third panel, we are pleased that you are here. We would like to invite your testimony. I think it is a distinguished panel, and we would like to introduce them. The first member of our panel is Dr. Janet Heinrich, who is the Associate Director of Health, Education and Human services at the GAO. Welcome back. Next we have Dr. Joyce Lashof, of the University of California at Berkeley, author of the Wellness Letter, which we have looked at; Dr. Robert Baratz, pleased to have you with us; and also Dr. Timothy Gorski. Dr. Gorski, we are delighted to have you, as well. We will begin with Dr. Heinrich and with the General Accounting Office.

Dr. HEINRICH. Mr. Chairman and members—

The CHAIRMAN. Pull those mikes real close. Let me ask—because of everybody's time constraints, we are going to ask that you attempt to summarize your statements. Dr. Heinrich, you have done this many times before, and all of our witnesses. We are going to be fair. We have three Democratic Senators here, and I expect others to be in attendance in the near future. But I have read everything you have written, and I think our colleagues have. I have read it, I have underlined it, and I have re-underlined it. So I have already heard it. So I would like very much for you to attempt, to the extent that you can, summarize it for the record. It will appear in its entirety in the official public record, and I want to get to the questions and hopefully the dialog that would be most helpful.

Dr. Heinrich.

STATEMENT OF JANET HEINRICH, D.Ph., R.N., ASSOCIATE DIRECTOR, HEALTH, EDUCATION, AND HUMAN SERVICES DIVISION, GENERAL ACCOUNTING OFFICE, WASHINGTON, DC

Dr. HEINRICH. Mr. Chairman and members of the committee, we are pleased to be here today as the committee considers risks associated with anti-aging and alternative medicine products marketed to senior citizens. These products are popular among consumers, with as many as 40 percent of senior citizens reporting some use. As you have stated, they include dietary supplements, such as ginkgo biloba, used to improve memory, and ginseng, used to relieve stress. Some products are promoted with anti-aging and cure-all claims for which there is little scientific evidence of either safety or effectiveness.

Because of your concerns about these anti-aging product claims, you asked us to do a report on some of the potential harms that are physical and economic, and to examine Federal and State oversight.

The CHAIRMAN. Do you know when we asked for that request, because I was trying to figure out when we asked for it? Do you have that in your file?

Dr. HEINRICH. Oh, yes, we do.

The CHAIRMAN. When would that be?

Dr. HEINRICH. It was probably July—March, March.

The CHAIRMAN. March?

Dr. HEINRICH. Yes.

The CHAIRMAN. Thank you. Please continue.

Dr. HEINRICH. Although documented adverse effects for most products are generally mild, potential harmful complications from supplements can occur due to several factors. Research shows that some supplements can have serious health consequences for seniors, such as respiratory failure, kidney damage. FDA has issued warnings that the herbal product, comfrey, for example, used for colds and coughs, represent a serious safety risk to consumers from liver toxicity. I was able to purchase some comfrey this weekend that had a warning that said should not be taken internally because there may be some harmful alkaloids if taken over a long period of time.

Individuals with certain underlying medical conditions should avoid some dietary supplements. For example, ginseng is not recommended for persons with hypoglycemia, and kava kava, thought to promote relaxation, may worsen symptoms from Parkinson's disease. A variety of frequently used dietary supplements can have dangerous interactions with prescription and over-the-counter drugs. Several supplements, such as, again, ginseng and ginkgo biloba, alter bleeding times and should not be used with blood-thinning products like warfarin or coumadin, and should not be used prior to surgery.

Other risks are associated with poor manufacturing practices. Supplements have been found that were contaminated by pesticides and heavy metals, some of which can be toxic. Finally, dietary supplements may contain more active ingredients than indicated on the product label. In a study of DHEA, a dietary supplement that may increase hormone levels, one product was shown to have as much as 150 percent of what was indicated on the label, while other samples had none.

We do not have exact figures, but millions of dollars may be spent on unproven products. For example, rife machines, which emit electrical frequencies that manufacturers claim kills viruses and parasites can cost up to \$5,000. FTC estimated that for 20 companies the subject of law-enforcement activities, the average economic harm to consumers was about \$1.8 million per company. The potential for harm to seniors is a concern of public health and law-enforcement officials, and Federal and State agencies have some activities underway.

FDA has taken enforcement actions against firms selling anti-aging products alleged to be dangerous or illegally marketed. It has taken actions to remove from the market products that the agency

found were actually unproven new drugs or medical devices, and it has taken some actions against firms that promoted their dietary supplements for the cure or treatment of disease. FDA has not prohibited the marketing of any specific substances using its administrative authority under the Dietary Supplement Health and Education Act.

The agency has issued warnings for ingredients it deems to be unsafe and unlawful. However, many products remain on the market despite the agency's warnings. An example of this is the case of colloidal silver products. Some manufactures have claimed efficacy in treating HIV and other diseases with these products. Even though FDA banned colloidal silver products as an over-the-counter drug in 1999, these products may still be marketed as dietary supplements, as long as they are not promoted with specific disease claims.

Despite FDA oversight activities, colloidal silver products claiming natural antibiotic properties to address numerous health conditions remain available. FDA can also monitor dietary supplements by conducting inspections of manufacturing facilities. However, the agency inspects less than 5 percent of facilities annually. Publication of good manufacturing practice regulations would improve FDA's enforcement capabilities, and a proposal rule is awaiting approval. In conclusion, the risk of harm to seniors from anti-aging and alternative health products has not been identified as a top public health priority or leading enforcement target. However, evidence demonstrates that many senior citizens use anti-aging products, and that consumers who suffer chronic conditions may be at risk of physical and economic harm from some of these products.

Mr. Chairman, that concludes my remarks. I will be happy to answer questions.

[The prepared statement of Ms. Heinrich follows:]

United States General Accounting Office

GAO

Testimony

Before the Special Committee on Aging, U.S. Senate

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HEALTH PRODUCTS FOR SENIORS

Potential Harm From “Anti-Aging” Products

Statement of Janet Heinrich
Director, Health Care—Public Health Issues



Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to testify as the Committee considers "anti-aging" and alternative medicine products marketed to America's senior citizens. Today we are releasing a report that summarizes the risks associated with such products and reviews federal and state oversight activities in this area.¹

Anti-aging and alternative medicine products are popular among consumers. Surveys have found that as many as 40 percent of senior citizens have used dietary supplements in the past year and that approximately 10 percent of seniors use them regularly. These supplements include herbal or botanical dietary supplements, such as ginkgo biloba, ginseng, and St. John's wort, as well as specialty supplements, such as glucosamine, fish oil, and melatonin. Some of these products show potential health benefits. For example, some studies have suggested that St. John's wort may counteract feelings of mild to moderate depression and that ginkgo biloba may improve cognitive performance in dementia. However, regulators and medical experts are concerned that some products have health risks and some are marketed to seniors with anti-aging and "cure-all" claims for which there is little scientific evidence of either safety or effectiveness. There is also concern that seniors may be wasting money on products that have little or no therapeutic value.

Because of these concerns, you asked us to look at dietary supplements and devices that are marketed for health conditions that affect older adults. I will summarize the key findings of our report, in which we (1) describe the potential physical harm associated with some anti-aging and alternative medicine products, (2) describe the economic harm associated with questionable anti-aging and alternative medicine products, and (3) examine federal and state oversight efforts designed to protect consumers from questionable anti-aging and alternative medicine products.

In summary, dietary supplements marketed as anti-aging therapies may pose a potential for physical harm to senior citizens. Evidence from the medical literature shows that a variety of frequently used dietary supplements can have serious health consequences for seniors. Particularly risky are products that may be used by seniors who have

¹Health Products for Seniors: "Anti-Aging" Products Pose Potential for Physical and Economic Harm (GAO-01-1129, Sept. 7, 2001).

underlying diseases or health conditions that make the use of the product medically inadvisable or supplements that interact with medications that are being taken concurrently. Further, studies have found that products sometimes contain harmful contaminants or much more of an active ingredient than is indicated on the label. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have received reports of adverse events experienced by seniors taking dietary supplements in recent years. FDA has issued warnings to consumers and industry about the health risks of several dietary supplement products.

Unproven anti-aging and alternative medicine products also pose a risk of economic harm to seniors. Although we were unable to find any recent, reliable estimates of the overall economic harm to seniors from these products, we did uncover several examples that illustrate the risk of economic harm. FDA and the Federal Trade Commission (FTC) have identified a number of products that make advertising or labeling claims with insufficient substantiation, some costing consumers hundreds or thousands of dollars apiece. A recent review of cases prepared for us by FTC estimated that, for 20 companies marketing products to seniors that have been the subject of law enforcement activities, the average economic harm to consumers as a whole was about \$1.8 million per company. In addition, tests of selected dietary supplements have found that some contain little or none of the active ingredient claimed on the label, rendering these products virtually worthless.

The potential for harm to senior citizens from health products making questionable claims has been a concern for public health and law enforcement officials, and federal and state agencies have activities under way to protect consumers of these products. FDA and FTC sponsor programs and provide educational materials for senior citizens to help them avoid health fraud. The National Institutes of Health (NIH) has an expanding research agenda to evaluate popular alternative therapies. FDA has taken various enforcement actions against firms that have violated laws regarding the marketing and sales of anti-aging and alternative products, including products that were being marketed as dietary supplements but which are drugs. However, FDA has not prohibited the marketing of any specific substances using its rulemaking authority. Further, FDA's voluntary adverse event reporting system for dietary supplements has shortcomings, and proposed regulations to establish standards for good manufacturing practices, which could provide FDA with additional authority to regulate facilities that manufacture, distribute, and store dietary supplement products, have not yet been issued. Recently,

FTC and FDA have combined efforts in an ongoing Internet-based initiative known as "Operation Cure.All," which targets companies that make unsubstantiated advertising and labeling claims for dietary supplements and other health products. At the state level, agencies are working to protect consumers of health products by enforcing state consumer protection and public health laws, although anti-aging and alternative products are receiving limited attention.

Background

Since 1994, when the Dietary Supplement Health and Education Act (DSHEA) was enacted, sales of dietary supplements have soared. In 2000, total U.S. sales for herbal and specialty supplements reached \$5.8 billion. Surveys have found that many older Americans use these supplements to maintain overall health, increase energy, improve memory, and prevent and treat serious illness, as well as to slow the aging process, among other purposes. Products frequently used by seniors to address aging concerns include herbal supplements such as evening primrose, ginkgo biloba, ginseng, kava kava, saw palmetto, St. John's wort, and valerian, and specialty supplements such as chondroitin, coenzyme Q10, dehydroepiandrosterone (DHEA), glucosamine, melatonin, omega-3 fatty acids (fish oil), shark cartilage, and soy proteins. (See the appendix for details regarding these substances.)

FDA, FTC, and state government agencies all have oversight responsibility for products marketed as anti-aging therapies. In general, the law permits FDA to remove from the market products under its regulatory authority that are deemed dangerous or illegally marketed. FDA's regulation of dietary supplements is governed by the Federal Food, Drug, and Cosmetic Act as amended by DSHEA in 1994. DSHEA does not require manufacturers of dietary supplements to demonstrate either safety or efficacy to FDA prior to marketing them. However, if FDA subsequently determines that a dietary supplement is unsafe, the agency can ask a court to halt its sale. For dietary supplements, the Secretary of the Department of Health and Human Services may declare the existence of an imminent hazard from a dietary supplement, after which the Secretary must initiate an administrative hearing to determine the matter, which may then be reviewed in court. DSHEA does not require dietary supplement manufacturers to register with FDA, or to identify to FDA the products they manufacture, and dietary supplement manufacturers are not required to provide the adverse event reports they receive to FDA. However, FDA does regulate nutritional and health claims made in conjunction with dietary supplements.

FTC has responsibility for ensuring that advertising for anti-aging health products and dietary supplements is truthful and can be substantiated. FTC can ask companies to remove misleading or unsubstantiated claims from their advertising, and it can seek monetary redress for conduct injurious to consumers in appropriate cases. FTC published an advertising guide for the dietary supplements industry in November 1998, which reminded the industry that advertising must be truthful and that objective product claims must be substantiated. State agencies can take action against firms that fraudulently market anti-aging and other health products.

Some Dietary Supplements May Be Risky for Senior Citizens

Health risks associated with dietary supplements come in a number of forms. First, some dietary supplements have been associated with adverse effects, some of which can be serious. Second, individuals with certain underlying medical conditions should avoid some dietary supplements. Third, some frequently used dietary supplements can have dangerous interactions with prescription or over-the-counter drugs that are being taken concurrently. Fourth, dietary supplements may contain harmful contaminants. Finally, dietary supplements may contain more active ingredient than indicated on the product label.

Research suggests that among healthy adults, most dietary supplements, when taken alone, have been associated with only rare and minor adverse effects. Other supplements are associated with more serious adverse effects. For example, research suggests that DHEA may increase the risk of breast, prostate, and endometrial cancer, and shark cartilage has been associated with thyroid hormone toxicity. Adverse event reports can also signal possible risks from dietary supplements. FDA publishes lists of dietary supplements for which evidence of harm exists.³ In 1998, the agency published a guide to dietary supplements, which included a list of supplements associated with illnesses and injuries.⁴ FDA has also issued warnings and alerts for dietary supplements and posted them to its Web site.⁵ For example, the most recent alert reiterated the agency's concern,

³<http://www.cfsan.fda.gov/~dms/ds-ill.html>.

⁴P. Kurtzweil, "An FDA Guide to Dietary Supplements," *FDA Consumer* (Sept.-Oct. 1998, FDA 99-2323).

⁵<http://www.cfsan.fda.gov/~dms/ds-warn.html> and <http://www.cfsan.fda.gov/~dms/ds-osupp.html>.

first noted in 1993, that the herbal product comfrey represents a serious safety risk to consumers from liver toxicity.

Consumption of some substances has been shown to be inadvisable, or contraindicated, for persons with some preexisting medical conditions. For example, ginseng is not recommended for persons with hypoglycemia. Kava kava may worsen symptoms of Parkinson's disease. Saw palmetto is contraindicated for patients with breast cancer, and valerian should not be used by those with liver or kidney disease without first consulting a physician. A recent study also suggested that echinacea (promoted to help fight colds and flu), ephedra (promoted as an energy booster and diet aid), garlic, ginkgo biloba, ginseng, kava kava, St. John's wort, and valerian may pose particular risks to people during surgery, with complications including bleeding, cardiovascular instability, and hypoglycemia.⁵

According to a recent survey,⁶ about half of seniors who use a dietary supplement do not inform their doctor. Another survey found that seniors often used dietary supplements with a prescription medication. Since seniors take more prescription medicines on average than do younger adults, the risk of drug-supplement interactions may be higher. For example, evening primrose, ginkgo biloba, ginseng, glucosamine, and St. John's wort magnify the effect of blood-thinning drugs such as warfarin or coumadin. We also identified reports suggesting that ginkgo biloba may reduce the effects of seizure medications and glucosamine may have a harmful effect on insulin resistance.

Contaminated products can also pose significant health risks to consumers. For example, supplements have been found to be contaminated with pesticides or heavy metals, some of which are probable carcinogens and may be toxic to the liver and kidney or impair oxygen transport in the blood. One commercial laboratory found contamination in samples from echinacea, ginseng, and St. John's wort products. As much as 20 times the level of pesticides allowable by the U.S. Pharmacopeia was found in two samples of ginseng. Overall, 11 percent of the herbal products and 3 percent of the specialty supplements tested were contaminated in some way.

⁵M.K. Ang-Lee and others, "Herbal Medicines and Preoperative Care," *Journal of the American Medical Association*, Vol. 286, No. 2 (2001), pp. 208-16.

⁶D.M. Eisenberg and others, "Trends in Alternative Medicine Use in the United States, 1990-1997," *Journal of the American Medical Association*, Vol. 280, No. 18 (1998), pp. 1569-74.

Amounts of active ingredients that exceed what is indicated on a product label may increase the risk of overdose for some patients. Some scientific studies have found that there may be significantly more active ingredient in some herbal and specialty supplement products than is indicated on the label. Studies of DHEA, ephedra, feverfew (promoted as a migraine prophylaxis), ginseng, SAM-e (promoted as an antidepressant and in the treatment of symptoms associated with osteoarthritis), and St. John's wort have found that a number of products have substantially more active ingredient than indicated on the label. One study of DHEA found one brand contained 150 percent of the amount of active ingredient indicated on the label.⁷ In a study of ephedra, one product was shown to have as much as 154 percent of the active ingredient indicated on the label.⁸ Studies of ginseng have found some products contained more than twice as much active ingredient as indicated on the product label.

Recognizing that there are some safety risks, trade associations that represent manufacturers, suppliers, and distributors of dietary supplements have created and adopted voluntary programs to reduce the risks of potentially harmful products by standardizing manufacturing practices.

Seniors May Spend Millions of Dollars On Unproven or Poorly Manufactured Products

Some unproven anti-aging products can cost hundreds or thousands of dollars apiece. For example, rife machines, which emit light or electrical frequencies and claim to kill viruses and parasites, are frequently advertised on the Internet and can cost up to \$5,000. Some herbal product packages for cancer cures can cost nearly \$1,000. FTC provided us with a partial estimate of economic harm based on 20 cases involving companies that fraudulently marketed unproven health care products commonly used by seniors and for which national sales data were available. FTC estimated the average annual sales for those products at nearly \$1.8 million per company.

Consumers may be purchasing products that contain much less active ingredient than indicated on the label. Results of commercial laboratory

⁷J. Parasrampura and others, "Quality Control of Dehydroepiandrosterone Dietary Supplement Products," *Journal of the American Medical Association*, Vol. 280, No. 18 (1998), p. 1565.

⁸B.J. Gurley and others, "Content Versus Label Claims in Ephedra-Containing Dietary Supplements," *American Journal of Health-System Pharmacists*, Vol. 57 (2000), pp. 963-69.

tests and scientific studies that analyzed product contents for active ingredient levels have shown that some dietary supplement products contain far less active ingredient than labeled. For some products, analyses have found no active ingredient. Academic studies have shown similar results. In an analysis of DHEA products, nearly one-fifth contained only trace amounts or no active ingredient.⁹ In analyses of garlic products, most were found to release less than 20 percent of their active ingredient.¹⁰ One study of ginseng found that 35 percent of the products tested contained no detectable levels of an active ingredient,¹¹ and another found no detectable levels in 12 percent of the tested products.¹² Studies of SAM-e and St. John's wort products also found that tested samples often contained less active ingredient than indicated on the label.

Federal and State Activities Aim to Protect Seniors

Federal efforts to protect seniors from health fraud include providing educational materials on avoiding health fraud, funding research to evaluate popular anti-aging therapies, and carrying out enforcement activities against companies that have violated regulations. At the state level, agencies are working to protect consumers of health products by enforcing state consumer protection and public health laws, although anti-aging and alternative products have received limited attention.

Both FDA and FTC sponsor educational activities that focus on health fraud and seniors. For example, public affairs specialists in several FDA district offices had exhibits at senior health fairs and health conferences where they distributed educational materials on how to avoid health fraud, as well as cautionary guidance on purchasing medicines and medical products online. To help seniors discriminate between legitimate and fraudulent claims, FTC publishes a range of consumer education materials on certain frequently promoted products and services, including hearing aids and varicose vein treatments. The agency also publishes guidelines on

⁹J. Parasrampurna, "Quality Control of Dehydroepiandrosterone Dietary Supplement Products."

¹⁰L.D. Lawson and others, "Identification and HPLC Quantification of the Sulfides and Dialk(en)yl Thioureas in Commercial Garlic Products," *Planta Medica*, Vol. 57 (1991), pp. 363-70.

¹¹L.E. Liberti and A.D. Marderosian, "Evaluation of Commercial Ginseng Products," *Journal of Pharmaceutical Sciences*, Vol. 67, No. 10 (1978), pp. 1487-89.

¹²J. Cui, "What Do Commercial Ginseng Preparations Contain?" *Lancet*, Vol. 344 (1994), p. 134.

how to spot false claims and how to differentiate television shows from "infomercials."

Federal support of research on alternative therapies is provided by NIH's National Center for Complementary and Alternative Medicine (NCCAM). It has developed research programs to fund clinical trials to evaluate the safety and efficacy of some popular products and therapies for conditions such as arthritis, cardiovascular diseases, and neurological disorders. There are studies, either ongoing or planned, to examine the effects of glucosamine/chondroitin, melatonin, St. John's wort, ginkgo biloba, and others. In addition, the agency funds specialized, multidisciplinary research centers on alternative medicine in such areas as cardiovascular disease, neurological disorders, aging, and arthritis.

FDA enforcement actions taken against products that it judged to be unapproved drugs or medical devices include court cases filed to halt the distribution of laetrile products that claimed to cure cancer and to halt the sale of "Cholestin," a red yeast rice product with lovastatin that was marketed with cholesterol-lowering claims. FDA also took action to halt the marketing of the "Stimulator," a device that the manufacturer claimed would relieve pain from sciatica, swollen joints, carpal tunnel syndrome, and other chronic conditions. According to FDA officials, an estimated 800,000 of these devices were sold between 1994 and 1997, with many purchased by senior citizens.

FDA has notified some dietary supplement manufacturers that their promotional materials illegally claimed that their products cure disease. For example, some manufacturers of colloidal silver products have claimed efficacy in treating HIV and other diseases and conditions. Even though FDA banned colloidal silver products as a U.S. over-the-counter drug in September 1999, after concluding that it was not aware of any substantial scientific evidence that supported the advertised disease claims, colloidal silver products may still be marketed as dietary supplements as long as they are not promoted with claims that they treat or cure disease. FDA notified several dozen Internet-based companies making such claims that their therapeutic claims may be illegal. Despite these oversight activities, colloidal silver products claiming "natural antibiotic" properties to address numerous health conditions remain available.

FDA has not initiated any administrative rulemaking activities to remove from the market certain substances that its analysis suggests pose health risks, but has sought voluntary restrictions and attempted to warn

consumers. For example, aristolochic acid, a known potent carcinogen and nephrotoxin, is believed to be present in certain traditional herbal remedies as well as a number of dietary supplement products. Following reports of aristolochic-acid-associated renal failure cases in Europe, FDA has recently taken several steps. In May 2000, FDA issued a "letter to industry" urging leading dietary supplement trade associations to alert member companies that aristolochic acid had been reported to cause "severe nephropathy in consumers consuming dietary supplements containing aristolochic acid." In this letter, FDA concluded that any dietary supplement that contained aristolochic acids was adulterated under the law and that it was unlawful to market such a product. FDA has also announced that herbal comfrey products containing pyrrolizidine alkaloids may cause liver damage. The agency's letter to eight leading dietary supplement trade associations urged them to advise their members to stop distributing comfrey products containing pyrrolizidine alkaloids. However, even though FDA has told firms that market dietary supplements that products containing comfrey are adulterated and unlawful, some firms continue to market them, and the agency is left to identify and take action to remove them on a case-by-case basis as it becomes aware of them.

FDA can also monitor dietary supplements by conducting inspections of manufacturing facilities,¹³ during which its inspectors look at sanitation, buildings and facilities, equipment, production, and process controls. However, the agency inspects less than 5 percent of facilities annually. Publication of good manufacturing practice (GMP) regulations would improve FDA's enforcement capabilities, since DSHEA provides that dietary supplements not manufactured under conditions that meet GMPs would be considered adulterated and unlawful. A proposed GMP rule has been developed and is under review by the Office of Management and Budget.

In 1997, FTC launched an effort to find companies making questionable claims for health products on the Internet, as well as in other media. This initiative, "Operation Cure.All," primarily involved conducting Web-based searches on specified dates to identify Web sites making unsubstantiated claims that use of their products would prevent, treat, or cure serious diseases and conditions. The searches were conducted with the

¹³ Inspections are authorized under 21 U.S.C. 374.

participation of FDA, CDC, and some state attorneys general and other organizations.

Evaluations of "Operation Cure.All" have found that some companies have made changes in their Web advertising as a result of receiving e-mail alerts from FTC about potentially unsupported advertising claims. In 1997, an estimated 13 percent of notified companies withdrew their claims or Web site, while 10 percent made some changes. In 1998, an estimated 23 percent of companies withdrew their claims or Web site, while 10 percent made some changes. By comparison, the percentage of companies that made no changes in both years exceeded 60 percent. FTC has brought over 30 dietary supplement cases, including those from "Operation Cure.All," against companies making unsupported claims since the agency released guidelines on its approach to substantiation of advertised claims in 1998.

The states we contacted varied in their efforts to protect consumers from fraudulent or harmful health products, but in general focused little attention on anti-aging and alternative medicine products. State agencies reported that they receive relatively few complaints regarding these products. However, many officials said that consumers are being harmed in ways that are unlikely to be reported to state agencies and that misleading advertising and questionable health products are serious problems. States have identified a number of questionable health care products, services, and advertising claims that may affect older consumers.

States can protect consumers from fraudulent or harmful health products through two approaches. The first is enforcement of state consumer protection laws against false or misleading advertising. The second is through their public health authority to ensure food, drug, and medical device safety. With some exceptions, the states we contacted take action only if there is a pattern of complaints or an acute health problem associated with a particular substance or device. Seven of the fourteen states we contacted were involved to some degree in monitoring or enforcement activity, and three have ongoing efforts to review advertising, labels, or products to enforce their health and consumer protection laws.

Conclusions

The risk of harm to seniors from anti-aging and alternative health products has not been specifically identified as a top public health priority or a leading enforcement target for federal and state regulators. However, evidence demonstrates that many senior citizens use anti-aging products

and that consumers who suffer from aging-related health conditions may be at risk of physical and economic harm from some anti-aging and alternative health products, including dietary supplements, that make misleading advertising and labeling claims. The medical literature has identified products that are safe under most conditions, but can be harmful for consumers with certain health conditions. Other products, such as St. John's wort, are promising for some conditions, but are also associated with adverse interactions with some prescription medications. Senior citizens may have a higher risk of physical harm from the use of anti-aging alternative medicine products because they have a high prevalence of chronic health conditions and consume a disproportionate share of prescription medications compared to younger adults.

This concludes my prepared statement, Mr. Chairman. I will be happy to respond to any questions that you or Members of the Committee may have.

**GAO Contact and
Acknowledgments**

For more information regarding this testimony, please call me at (202) 512-7119. Key contributors include Martin T. Gahart, Carolyn Feis Korman, Anne Montgomery, Mark Patterson, Roseanne Price, and Suzanne Rubins.

Appendix: Known Claims, Adverse Effects, Contraindications, and Interactions of Herbal and Specialty Supplements

We focused our review on those herbal and specialty supplements that a recent survey by Prevention Magazine found were most frequently used by senior citizens for conditions associated with aging. For each supplement, we have listed in table 1 the health claims frequently associated with the products, although we have not attempted to validate the merits of any of the claims. We also list adverse effects that have been associated with the supplements, conditions for which the supplements might be contraindicated, and prescription medications with which the supplements might have dangerous interactions.

Table 1: Principal Claims and Principal Known Adverse Effects, Contraindications, and Interactions of Leading Dietary Supplements Used by Seniors to Address Issues of Aging

Product	Principal claims*	Principal known adverse effects	Principal known contraindications*	Principal known interactions
Chondroitin sulfate	Alleviates joint pain associated with osteoarthritis and reduces inflammation.	Mild gastrointestinal complaints such as heartburn and nausea.		
Coenzyme Q10	Slows aging; increases energy; enhances endurance and aerobic performance; strengthens heart; lowers blood pressure; improves immune function; promotes weight loss; treats cancer, stroke, and gum diseases.	Rare, but include heartburn, nausea, stomachache, diarrhea, headache, fatigue, and skin reactions.		May interact with blood thinners.
Dehydroepiandrosterone (DHEA)	Slows aging; improves memory; stimulates libido and increases sex drive; eases symptoms of depression; boosts energy; promotes weight loss; builds muscle mass and increases strength; prevents growth and recurrence of some cancers; protects against heart disease; reduces the risk of osteoporosis; prevents diseases such as diabetes, Parkinson's, and Alzheimers.	Increased facial hair; acne; scalp hair loss; oily skin; mood swings; aggressiveness; altered hormone profiles; liver abnormalities; menstrual cycle irregularities; increased risk of heart disease, diabetes, stroke, prostate cancer in men, and breast and endometrial cancer in women; insomnia; fatigue; low energy; headache; nervousness; deepening of the voice; irritability; decreased levels of high-density lipoprotein (HDL) cholesterol; heart rhythm disturbances; hepatitis.	People with a hormone-related cancer (prostate, ovarian, endometrial, breast) should consult physician. Should be avoided by men with enlarged prostate.	

Product	Principal claims ^a	Principal known adverse effects	Principal known contraindications ^b	Principal known interactions
Evening primrose oil	Beneficial for victims of coronary artery disease; improves rheumatoid arthritis and other inflammatory conditions; alleviates hot flashes, premenstrual syndrome, and breast pain associated with the menstrual cycle; improves eczema and dermatitis; aids in weight loss; prevents diabetic neuropathy; eases symptoms of schizophrenia and attention deficit/hyperactivity disorder; benefits chronic viral infections such as chronic fatigue syndrome; reduces effects of multiple sclerosis; aids high cholesterol, asthmatic cough, and upset stomach; has anticancer properties.	Gastrointestinal upset, nausea, loose stools, headache, seizure.		May increase the anticoagulant effect of drugs such as warfarin. Should not be used with anticonvulsant medication.
Garlic	Reduces serum cholesterol; thins blood; lowers blood pressure; may prevent heart disease, atherosclerosis, stroke, and hypertension; acts as antimicrobial for mild respiratory and digestive tract infections; relieves nausea.	Rare, but include mild gastrointestinal symptoms such as heartburn and nausea, body and breath odor, headache, and vertigo.	May decrease blood glucose.	May potentiate the blood-thinning effects of anti-inflammatory medications such as aspirin and supplements such as vitamin E and fish oil; may interact with the blood-thinning drug warfarin (Coumadin); may potentiate antihypertensives.
Ginkgo biloba	Improves memory and mental sharpness; alleviates symptoms of Alzheimer's disease; eases symptoms of depression; improves circulation; thins blood; improves cardiovascular health; acts as antioxidant; improves vertigo, headache, and tinnitus; relieves intermittent lower leg cramps, diabetic retinopathy, wheezing, dizziness, motion sickness, and Raynaud's.	Very rarely associated with gastrointestinal upset, allergic skin reaction, and headache.	Not for people with seizure disorders because it may reduce the effects of seizure medication. Not to be taken by people hypersensitive to poison ivy, cashews, or mangoes.	Could pose a concern to people with blood clotting problems or those taking anticoagulant medications. Not recommended for people using aspirin, or nonsteroidal antiinflammatory drugs.

Product	Principal claims*	Principal known adverse effects	Principal known contraindications*	Principal known interactions
Ginseng	Relieves stress, eases symptoms of anxiety, delays or reduces the effects of aging used as a tonic for well-being, enhances immune function, reduces blood sugar, improves cognitive function, relieves menopausal symptoms, acts as an antioxidant, hypocholesterolemia, enhances athletic performance, boosts energy, increases sexual stamina, helps with impotence and infertility, prevents and fights diseases such as cancer, increases energy, protects the heart, strengthens stomach functions, prevents arteriosclerosis, stabilizes blood pressure and insulin levels.	Generally considered quite safe although it is recommended that a course of treatment not exceed 3 months; may cause breast tenderness, swollen breasts, vaginal bleeding in women, nervousness, excitation, hypertension, headaches, insomnia, restlessness, vomiting, and may cause breast cancer to reoccur in women who have had the disease previously.	Caution recommended for individuals with hypertension and those prone to hypoglycemia. High doses may inhibit immune function in early stages of infection. People with cancer should consult their physician. People with cardiovascular disease or diabetes exercise caution.	May interfere with digoxin activity or monitoring. If used with warfarin or other anticoagulant, can alter bleeding times. If used with phenazine sulfate (an antidepressant) or a monoamine oxidase inhibitor (MAOI), can cause headaches, tremors, and manic episodes. Caution with insulin.
Glucosamine	Reverses osteoarthritis, protects joints and tendons from injury, decreases inflammation.	Occasional symptoms of gastrointestinal discomfort; reduced insulin secretion noted in animal studies.		Concern about interactions for people on blood-thinning medications and about harmful effects on insulin resistance.
Kava kava	Eases symptoms of anxiety, restlessness and nervous tension; promotes relaxation; aids sleep; balances mood; restores vigor; eases symptoms of depression and menopause (hot flashes); acts as an analgesic, headache remedy, and mild sedative; eases uterine inflammation, colds, rheumatism; promotes urination; soothes upset stomachs; eases symptoms of asthma and tuberculosis; cures fungal infections; inhibits gonorrhea; soothes stings and skin inflammations.	Can result in temporary skin and liver problems, allergic reactions, gastrointestinal discomfort, absence of urination, numbness of the mouth, painful twisting movements of the trunk, disturbances of the oculomotor equilibrium, and can disturb motor reflexes and judgment when driving.	Not appropriate for individuals with major anxiety conditions. Should not be used while driving. May worsen symptoms of Parkinson's. Use in endogenous depression should be avoided. Should not be used for more than 3 months. Should not be used if gall bladder or liver problems, including cirrhosis and hepatitis.	Should not be taken with alcohol or anti-anxiety drugs such as valium. May have additive effects with other muscle relaxants, sedatives, anti-anxiety agents, and antidepressants. Should not be taken with antidepressants or antipsychotics.

Product	Principal claims ^a	Principal known adverse effects	Principal known contraindications ^b	Principal known interactions
Melatonin	Promotes sleep, reduces symptoms of jet-lag, slows aging process, increases sex hormone secretion, acts as antioxidant, relieves tinnitus, may inhibit growth of breast cancer cells.	May cause infertility, hypothermia, and retinal damage; reduces sex drive in males; leads to high blood pressure, diabetes, and cancer.	Can induce or deepen depression in susceptible individuals. May be dangerous for people with cardiovascular risk factors. Should not be taken by people with immune-system disorders (including severe allergies), autoimmune diseases (such as rheumatoid arthritis), immune-system cancers (e.g., lymphoma), severe mental illness, or those taking steroids.	May interfere with hormone replacement therapy. May enhance the effectiveness of certain chemotherapy drugs.
Omega-3 fatty acids (fish oil)	Provides heart protection; dilates blood vessels; reduces blood pressure; reduces blood clotting; suppresses inflammation; relieves pain of rheumatoid arthritis; eases symptoms of depression and attention deficit/hyperactivity disorder; increases growth hormone levels; relieves symptoms of allergies, asthma, and skin disorders; can help prevent breast, prostate, and colon cancers; inhibits growth of pancreatic cancer, protects against kidney failure.	Encourages bleeding and hemorrhage, causes fishy breath odor, belching, abdominal bloating, increases total blood cholesterol.		
Saw palmetto	Aids in the treatment of benign prostate hyperplasia (BPH), increases libido, increases sperm production, increases breast size of women, useful as a urinary antiseptic and diuretic, prevents hair loss (men only), treats low thyroid function and irritable bladder.	Rare but include headaches, gastrointestinal disturbances, diarrhea, vomiting, upset stomach, constipation, nausea, dizziness, erectile dysfunction, difficulty sleeping, fatigue, and heart pain.	People with enlarged prostate should consult physician on a regular basis. Use should be avoided in patients with breast cancer.	

Product	Principal claims*	Principal known adverse effects	Principal known contraindications*	Principal known interactions
Shark cartilage	Cures or prevents cancer, promotes wound healing, relieves arthritis pain and stiffness.	Could lead to thyroid hormone toxicity, may cause nausea, indigestion, fatigue, fever, and dizziness.	May slow down the healing process for people recovering from surgery. Shark cartilage enemas should be avoided by people with a low white blood cell count. Relying on this type of treatment alone and avoiding conventional medical care may have serious health consequences.	
Soy proteins and isoflavones	Reduces cholesterol and triglyceride levels, reduces risk of heart disease, suppresses menopausal symptoms (hot flashes), reduces bone breakdown (osteoporosis), prevents cancer.	Mild gastrointestinal complaints such as bloating and flatulence.		May interfere with the absorption of supplemental thyroid hormones. May interact with ipriflavone, a synthetic isoflavone.
St. John's wort	Eases symptoms of mild to moderate depression; stabilizes mood; improves tolerance to stress; improves sleep patterns in older people; eases symptoms of anxiety; increases energy levels; controls appetite and promotes weight loss; eases bronchial inflammation, stomach problems, hemorrhoids, hypothyroidism, migraines, kidney disorders; aches insect bites and stings, skin diseases, scabies, skin inflammation, burns and wounds, and blunt injuries bedwetting; aids in wound healing and in resistance to viral infection when applied topically.	Mild gastrointestinal upset, skin rashes, tiredness, insomnia, restlessness, dizziness, confusion, photosensitivity, (especially in fair-skinned individuals) serotonin syndrome, dry mouth, fast or irregular breathing.	Can be toxic to sperm; not for the treatment of severe depression.	No longer believed that it magnifies effect of MAOI, but users should consult physician. May decrease effectiveness of HIV drugs, immunosuppressants, digoxin, blood thinners, chemotherapy drugs, and asthma medications. Abrupt withdrawal can increase blood levels of various medications. Should not be used with alcohol, narcotics, amphetamines, anticoagulants, antibiotics, or cold and flu medicines such as pseudo-ephedrine. Should not be used with other antidepressants or with certain cheeses. May interfere with action of certain oral contraceptives.

Product	Principal claims*	Principal known adverse effects	Principal known contraindications*	Principal known interactions
Valerian	Promotes relaxation, induces sleep, ease symptoms of anxiety, calms nerves, helps people quit smoking, eases congestion, and relieves muscle spasms.	Headaches, mild nausea, upset stomach, heart palpitations, restlessness, excitability, hypersensitivity reactions, insomnia, blurred vision, and very high doses may weaken the heartbeat and cause paralysis.	People taking sedatives or antidepressants should consult physician. Should not be consumed for more than 2 weeks. People with liver or kidney disease should consult physician.	Should not be taken with alcohol, certain antihistamines, muscle relaxants, psychotropic drugs, sedatives, barbiturates, or narcotics. Should not be taken with alcohol or other tranquilizers.

*Principal claims are manufacturing claims and uses that have been reported. However, we have not substantiated any of these claims.

*We do not include any contraindications for children or pregnant or nursing women.

Sources: *Physicians' Desk Reference for Herbal Medicines*, 2nd ed. (Montvale, N.J.: Medical Economics, 2000); Blumental, M. (ed.) *The Complete German Commission E monographs: Therapeutic Guide to Herbal Medicines*. (Boston, Mass.: American Botanical Council, 1998); J. H. McDermott, "Herbal Chart for Health Care Professionals" (chart) (Washington, DC: American Pharmaceutical Association, 1999); Bruss, Katherine (ed.), *American Cancer Society's Guide to Complementary and Alternative Cancer Methods* (Atlanta, Ga.: American Cancer Society, 2000); M. McGuffin and others (eds.), *American Herbal Products Association's Botanical Safety Handbook*, (Boca Raton, Fla.: CRC Press, 1997); Center for Science in the Public Interest, "Supplements: Latest research on vitamins, minerals and herbs" (reprinted selections from *Nutrition Action Healthletter*) (Washington, D.C.: Center for Science in the Public Interest, 1999); www.supplementwatch.com; and www.supplementinfo.org.

The CHAIRMAN. Thank you. We will have questions. That is some good information.

Dr. Lashof, thank you for being with us from California. We really appreciate it.

STATEMENT OF JOYCE C. LASHOF, M.D., ASSOCIATE CHAIR, EDITORIAL BOARD, "WELLNESS LETTER," UNIVERSITY OF CALIFORNIA SCHOOL OF PUBLIC HEALTH, BERKELEY, CA

Dr. LASHOF. Thank you very much, Senator. I appreciate this committee holding this hearing and looking into the marketing of nutritional supplements to the elderly. We at the University of California-Berkeley Wellness Letter seek to provide the public with an independent, reliable summary of available scientific information regarding all aspects of health promotion and disease prevention. Our criteria for evaluating such information include clinical trials with adequate numbers, double-blind controls, and good statistical techniques for analyzing the data, followed by publication in an independent, peer-reviewed scientific journal.

Following the passage of DSHEA, there was a burgeoning of products purporting to prolong life, improve the immune system, improve memory and relieve innumerable symptoms. Thus, over the past years, a significant portion of our efforts and print space has been devoted to carefully examining the claims, debunking the ones that could not be substantiated, and helping our readers navigate through the slick and mostly misleading advertising for dietary supplements.

One of the very first that we tackled in 1992 was Gero Vita. At that time, they were only marketing GH3 as an anti-aging formula, and we were extremely forceful in recommending that our readers disregard all claims for this product. Later, we went on to warn our readers not to believe any of the claims made in Gero Vita's Journal of Longevity. Today, Gero Vita's web site features no less than 12 products which claim to have anti-aging products. Those are displayed there. They include a number—and I will not go through them, for the sake of brevity.

I should point out that although the ingredients in dietary supplements are required to be listed on the label, the amounts of individual ingredients in so-called, "proprietary blends," is not required. The lack of a system of good manufacturing practices and more-stringent ingredient labeling regulations make it impossible to know how much, if any, of the purported active ingredient is actually in the products, and perhaps more importantly, whether it is uncontaminated. The Wellness Letter has now reviewed more than 70 dietary supplements, including conventional vitamins and minerals. Our complete supplement review is available on our web site, www.wellnessletter.com, and a print of this material has been made available to the committee, and I have our book with descriptions of 70 products here.

While we have acknowledged that some of these supplements appear to be useful in certain situations, such as St. John's Wort and glucosamine, the only supplements we currently recommend to our readers are Vitamin C, if dietary sources are insufficient, Vitamin E, folic acid, and a multivitamin for older adults whose diet may not be adequate. Our reasoning for this is that whereas vitamin

preparations are standardized and regulated, other dietary supplements reside in a murky netherworld, somewhere between drugs and food, exempt from all but the most minor of labeling regulations, yet again thanks to DSHEA, which we consider unfortunate legislation.

The manufacturers of these products have nonetheless been allowed to make claims in their advertisements that are almost completely unsupportable by scientific review. They are not required to prove efficacy or safety before they bring them to market. DSHEA has put the burden of proof on the FDA to show that something is not safe, and the FDA must rely on the reporting of adverse events, which in this case turns out to be a voluntary, inefficient and unwieldy system, and one that GAO has reported on.

The end result is a juggernaut industry that now approaches—I think your figure was \$26 billion, gone up quite a bit from my figure of \$17 billion. While dietary supplements are legally precluded from making health claims on their label—they cannot say they cure cancer, heart disease or even acne—they are nonetheless being marketed as medical miracles. But, in fact, these products have drug-like properties. They are a drug and they should be regulated and controlled like drugs. The common perception that so-called natural products used in dietary supplements are always safe is completely unfounded and dangerously misguided.

The rigorous scientific research that needs to be done in this area is certainly doable, but it is expensive. The manufacturers have very little incentive to carry it out. The industry has grown exponentially without this kind of testing and without standardization of ingredients, so it continues to rely on practically nothing but anecdotal information to support its claims. By and large, most young, healthy people who take dietary supplements do so without adverse consequences, except on their pocketbook. But the ill and the elderly are a different issue.

Perhaps the most insidious aspect of marketing dietary supplements to the elderly under the terms of DSHEA is that companies like Gero Vita can knowingly exploit the hopes and fears of a population for whom safety is extremely complicated and which, by and large, has more reasons to be concerned about the economic impact of useless substances.

One of the likely outcomes of aging is the slowing down of the renal and hepatic systems, which means that drugs of any kind, whether prescription or botanical, are not cleared as quickly through the kidneys and not metabolized as efficiently by the liver. This makes the elderly more susceptible to the effects and side-effects of any drug. Because older people typically take many forms of medication for chronic conditions, the likelihood of adverse interaction is greatly heightened, and I have listed on the next table some examples, and Dr. Heinrich has given other examples, and I will not go through them for the sake of the fact that the yellow light is on.

Let me put up another poster on DHEA—again, Dr. Heinrich mentioned. DHEA is a hormone manufactured in the human adrenal gland. This substance is being marketed as an anti-aging formula that enhances mood, energy, memory, boosts sex drive, reduces osteoporosis, improves fat loss, increases muscle mass and

improves the immune system, et cetera. It is not a natural medicine and most certainly not a dietary supplement, and should never have been classified as such. We do not understand how FDA did that.

You can go on and talk about the expense to the pocketbook of the elderly, whose income is limited, to see them spend money on these kinds of dietary supplements when they do not have enough money to spend for their prescription drugs, and we know that is a real concern of yours. It is really disturbing. Let me get specifically then to our recommendations. On the last poster, I have listed them. We believe that DSHEA should be repealed or at least amended to give FDA the power to regulate nutritional supplements as they now do over-the-counter drugs, and thus require scientific proof of efficacy and safety. We recognize that that is not going to happen soon. The forces against it are great. But until then, first we need to make adequate resources available to FDA and the FTC to enforce existing rules covering the claims made on labels and claims made in other advertising. FTC requirements for what can be used as an advertising claim, what it should be based on, are really quite good. But they do not have the resources to begin to enforce it, considering the size of the industry.

Finally, we believe that FDA should be required to finalize the current good manufacturing practices rule, which I gather has been put forward and is bottled up somewhere in the bureaucracy, and finally require that the labels of dietary supplements instruct consumers to report adverse events directly to the FDA, provide toll-free numbers for them and web site by which they can do that.

Thank you very much.

[The prepared statement of Dr. Lashof follows:]

Senate Select Committee on Aging
Testimony
September 10, 2001

Joyce C. Lashof, M.D., Professor Emerita and former Dean, School of Public Health, University of California, Berkeley, Associate Chair, Editorial Board University of California, Berkeley Wellness Letter

I would like to thank the members of this Committee for inviting me to participate in this investigation into the marketing of nutritional supplements to the elderly. This is a topic which is extremely important to us at the University of California, Berkeley Wellness Letter as we seek to provide the public with an independent, reliable summary of available scientific information regarding all aspects of health promotion and disease prevention. Our criteria for evaluating such information include clinical trials with adequate numbers, double-blind controls and good statistical techniques for analyzing the data, followed by publication in an independent peer-reviewed scientific journal.

When we began the Wellness Letter in 1984, our focus was largely on standard nutrition, fitness and stress management. Ten years later, in 1994 when what we consider to be the ill-conceived DSHEA legislation was passed (after unprecedented lobbying by the supplement industry) the floodgates opened to allow anyone to market almost anything as a dietary supplement. By that time our readers had already begun turning to us for clarification of the seemingly unbelievable claims being made for these products. If the claims were true, dietary supplements were surely the magic bullet everybody was seeking. If they weren't true – as many of our readers already suspected – and the supplements were just a waste of money, were the products at least safe?

As the years passed, a significant portion of our efforts and print space has been devoted to carefully examining the claims, debunking the ones that could not be substantiated and helping our readers navigate through the slick and mostly misleading advertising for dietary supplements. One of the very first that we tackled (in 1992) was Gero Vita. At that time they were only marketing GH3 as an anti-aging formula and we were extremely forceful in recommending that our readers disregard all the claims made for this product. Later we went on to warn our readers not to believe any of the claims made in Gero Vita's Journal of Longevity. Today Gero Vita's website features no less than 12 products which claim to have anti-aging properties. (Figure 1) They have names like TMG Force: An Anti Aging Breakthrough and ACF 223: A Patented Anti-Aging Formula. Not one of these 12 so-called anti-aging preparations has ever been tested and proven to be effective.

Although the ingredients in dietary supplements are required to be listed on the label, the amounts of individual ingredients in so-called "proprietary blends" is not required. The lack of a system of Good Manufacturing Practices and more stringent ingredient labeling regulations makes it impossible to know how much, if any of the purported active ingredient is actually in the products and perhaps more importantly, whether it is uncontaminated. The Wellness Letter has now carefully reviewed more than 70 dietary supplements, including conventional vitamins and minerals. Our complete supplement review is available on our website (www.wellnessletter.com) and a print out of this material has been made available to the Committee.

While we have acknowledged that some of these supplements appear to be useful in certain situations (e.g. St. John's Wort, Glucosamine), the only

supplements we currently recommend to our readers are Vitamin C (if dietary sources are insufficient), Vitamin E, Folic Acid and a multivitamin for older adults. Our reasoning for this is that whereas vitamin preparations are standardized and regulated, other dietary supplements reside in a murky netherworld somewhere between drugs and food. Exempt from all but the most minor of labeling regulations (yet again thanks to DSHEA) the manufacturers of these products have nonetheless been allowed to make claims in their advertisements that are almost completely unsupportable by scientific review. They are not required to prove efficacy or safety before they bring a product to market. DSHEA has put the burden of proof on the FDA to show that something is not safe and the FDA must rely on the reporting of adverse events, which in this case turns out to be a voluntary, inefficient and unwieldy system. The end result is a juggernaut industry that now approaches 17 billion dollars a year in sales.

While dietary supplements are legally precluded from making health claims on their labels – they cannot say they cure cancer, heart disease or even acne – they are nonetheless being marketed as cure-all “drugs” and medical miracles. It is a historical fact that many of today’s most important drugs have botanical origins. It is not unreasonable to assume that some of the herbal and other botanical preparations now being sold as dietary supplements may one day be shown to have predictable therapeutic outcomes. If, in fact these products have drug like properties, they are drugs and they should be regulated and controlled like drugs. However, the common perception that the so-called natural products used in dietary supplements are always safe, is completely unfounded and dangerously misguided.

The rigorous scientific research that needs to be done in this area is certainly doable, but it is expensive. The manufacturers have very little incentive to carry it out. The government cannot allocate enough money to NIH to evaluate the multitude of ingredients currently on the market. The industry has grown exponentially without this kind of testing and without any standardization of ingredients, so it continues to rely on practically nothing but anecdotal information to support its claims. By and large, most young, healthy people who take dietary supplements do so without adverse consequences, except to their pocketbook. But the ill and the elderly are a different issue.

Perhaps the most insidious aspect of marketing dietary supplements to the elderly under the terms of DSHEA is that companies like Gero Vita can knowingly exploit the hopes and fears of a population for whom safety issues are extremely complicated and which, by and large, has more reasons to be concerned about the economic impact of useless substances. When you promise older people (either explicitly or implicitly) that by taking your product they will slow down the aging process, live longer, have more energy, have fewer wrinkles, remember more and perform better sexually, you have touched a raw nerve.

According to the latest statistics compiled by AARP, over one-third of older persons reported they were limited by chronic ailments and most had multiple conditions. One of the likely outcomes of aging is a slowing down of the renal and hepatic systems, which means that drugs of any kind, whether prescription or botanical, are not cleared as quickly through the kidneys and not metabolized as efficiently by the liver. This makes the elderly more susceptible to the effects and side effects of any drugs. Because older people typically take

many forms of medication for chronic conditions, the likelihood of adverse interaction is also greatly heightened.

As you can see from Figure 2, some of the most common dietary supplements have known adverse effects in the presence of certain conditions, many of which are common in the elderly. One example of this is ginkgo biloba which is heavily marketed to improve memory and has a potent inhibitory effect on the platelet activating factor. This could lead to excessive bleeding and is especially troublesome for anybody already taking blood thinning medications or aspirin.

Another troubling example is a dietary supplement which claims to be DHEA, a powerful hormone manufactured in the human adrenal gland. This substance is being marketed as an anti-aging formula that enhances mood, energy and memory, boosts sex drive, reduces osteoporosis, improves fat loss, increases muscle mass, improves the immune system, reduces autoimmune disorders and reduces heart disease. (Figure 3) In its natural state the effects of this hormone on the body are not well understood and as a supplement it is potentially very dangerous. DHEA is not a "natural medicine" and most certainly not a dietary supplement and should never have been classified as such.

But even for those supplements which do not have adverse effects, the amount of money spent on worthless products is of great concern. Again, according to AARP, of the 31.7 million older persons reporting income in 1998, 36% reported less than \$10,000. The median income reported was \$13,768. About 3.4 million elderly persons were below the poverty level in 1998. It is particularly disturbing to think that older people might choose to spend money

on dietary supplements instead of prescription drugs which are known to be efficacious and safe.

Obviously the subject of dietary supplements could be discussed and debated almost indefinitely. The existence of a law like DSHEA makes it nearly impossible to change a situation which is complex and confusing and with issues that range from medical to economic to ethical. As long as the FDA and FTC are precluded from doing for dietary supplements what they have been able to do for food, prescription and over the counter drugs, we will never bring reason to this unreasonable and untenable situation. To this end we make the following recommendation. (Figure 4)

- **Repeal or amend DSHEA to give the FDA the power to regulate nutritional supplements as they now do OTC drugs and thus require scientific proof of efficacy and safety.**

While we recognize that this is the most important step forward that could be taken, we also acknowledge that it is unlikely to happen any time soon. In the meantime, we recommend the following:

- **Make adequate resources available to the FDA and the FTC to enforce existing rules covering claims made on labels and claims made in other advertising.**
- **Require the FDA to finalize the Current Good Manufacturing Practices which should include quality control, standardization and accurate labeling.**

- **Require that the labels of dietary supplements instruct consumers to report adverse events directly to the FDA and provide a toll free phone number and website.**

Thank you for your time.

EXHIBITS

FIGURE 1: From Gero Vita website (www.gvi.com/GVIWeb/antiaging.html)

FIGURE 2: Examples of Adverse Reactions From Common Dietary
Supplements Marketed to the Elderly

FIGURE 3: From DHEA website (www.1dhea.com)

FIGURE 4: Recommendations for Congressional Action

Figure 1



Anti-Aging

 Woman's Health Essential Health Formulations for the Mature Woman's Needs	 Femine Comfort Restores Moisture to the Mature Woman's Body
 Himalayan Life Formula 48 Herbs for Reproaction	 Lecella Fisherman's Alternative for the Mature Woman
 Stress Eliminator AMPHI Stress Relievers	 HIGH Activator Increase Vital Growth Hormone
 Gero-Vita G113 Nourish, Promote Rejuvenation Formula	 Neocel Ultimate Anti-Aging Formula
 Longevity Caps Life Extender and Newest Anti-Aging Approach	 SOD Plus Anti-Aging Enzymes in New Liposome Spray
 ACE 273 Patented Anti-Aging Formula	 TMO Force Anti-Aging Breakthrough

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Disclaimer:

Gero Vita products are dietary supplements and as such are not intended to treat, cure, or prevent any disease. Those seeking treatment for a specific disease should consult a physician or other qualified health-care professional prior to taking Gero Vita products or any other dietary supplements.

Figure 2
**EXAMPLES OF ADVERSE REACTIONS FROM COMMON DIETARY SUPPLEMENTS
 MARKETED TO THE ELDERLY**

Dietary Supplement	Claims, Benefits	Adverse Reactions, Contraindications
Ginkgo Biloba	Improves blood flow and circulatory disorders, prevents or cures absentmindedness, memory loss and dementia, treats eye disease and tinnitus.	No actual evidence of effectiveness except as a blood thinner. May interact with other blood thinners, including aspirin. Dangerous for individuals undergoing surgery.
St. John's Wort	Alleviates mild to moderate depression	May affect the way the liver metabolizes certain other drugs, resulting in blood levels that are too high or too low. Interacts with blood thinners and digoxin, among others. May intensify or prolong effect of anesthesia. May produce photosensitivity
Ephedra	Contained in many weight loss supplements and stimulants	Can elevate blood pressure and pulse rate and increase the likelihood of coronary problems. Deaths have been reported.
Yohimbe	Used as an aphrodesiac	There is no evidence that this serves to increase sexual desire. Dilates blood vessels. Specifically contraindicated in anyone with liver or kidney disease.

Figure 3

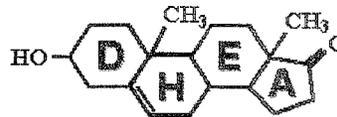
DHEA

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- Reduced Autoimmune disorders.
- Less Heart Disease.

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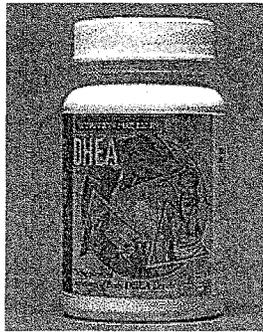
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 Nutrition for Life International. A 15 Year
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Discount**

Figure 4

RECOMMENDATIONS FOR CONGRESSIONAL ACTION

University of California, Berkeley Wellness Letter
September 10, 2001

- **REPEAL OR AMEND DSHEA TO GIVE THE FDA THE POWER TO REGULATE NUTRITIONAL SUPPLEMENTS AS THEY NOW DO OTC DRUGS AND THUS REQUIRE SCIENTIFIC PROOF OF EFFICACY AND SAFETY.**
- **Make adequate resources available to the FDA and the FTC to enforce existing rules covering claims made on labels and claims made in other advertising.**
- **Require the FDA to finalize the Current Good Manufacturing Practices which should include quality control, standardization and accurate labeling.**
- **Require that the labels of dietary supplements instruct consumers to report adverse events directly to the FDA and provide a toll free phone number and website.**

The CHAIRMAN. Dr. Lashof, thank you for your testimony and thank you for the good work that you do out at the university. It is very informative and very helpful.

Next, we will hear from Dr. Robert Baratz. Dr. Baratz, glad to have you before the committee.

**STATEMENT OF ROBERT S. BARATZ, M.D., Ph.D., DDS,
NEWTON, MA**

Dr. BARATZ. Thank you, Senator Breaux. Health care is one of the most important aspects of anyone's life. While we may disagree on where and how to spend our resources, there has been little disagreement on what standards we should have. The rise of modern medicine over witchcraft, shamanism, vitalism, folk tales, anecdotes, wishful thinking and snake oil has not been by accident. While there is still a place for the art of practice, a bedside manner and practical skills, the foundation of the house is and should continue to be scientifically gathered evidence.

In recent years there has been a movement to undo this standard, advanced by those who wish to profit from being freed from the requirements of evidence, and promoted by others who claim that anything should be allowed, whether it has a rational basis or not. So-called health freedom is claimed as some kind of right under which charlatans, quacks, and unscientific and unqualified practitioners can operate. Its advocates want a system where anything goes, without any standards for either safety or effectiveness, let alone the truth.

Neo-snake-oil salespeople, pseudoscientific zealots and profiteers have blurred the lines between science and nonsense, and have begun to undermine the foundation of our excellent system of care. They substitute pseudo science for science, anecdote for evidence, and nonsense for substance. Quality, scientifically based health care is currently at risk. I come here today to speak with you about this problem. In the popular media we are barraged by stories about secret herbal folk remedies and tiny electrical devices which can cure all diseases, and I brought one with me. If anyone needs to be cured, I can do it. [Laughter.]

Accompanied by testimonials of how wearing refrigerator-strength magnets will improve strength and endurance, we are asked to believe that vast bodies of knowledge have somehow been suppressed for years, allegedly to keep profits high in the medical establishment. We even are being asked to accept as legitimate primary care health practitioners, individuals who have unsupported theories of disease based on life forces being misaligned, imaginary parasites inhabiting our bodies, derangements of our spines which cannot be demonstrated, and unnamed toxins in our environment. We are being asked to discard science for conjecture and fanciful notions.

Those who are most likely to be targeted and duped by these purveying predators are the elderly. Given the limited amount of time we have to speak together here, I urge you to read my written remarks, which carry much more detail than I can present here now.

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. Instead, we are seeing an increasing array of initiatives to legitimize otherwise illegitimate practices. Lawmakers are being asked to license practices that lack a scientific basis. Agencies are being told they cannot regulate drug substances, such as we have heard about today, if they are called something else.

So-called supplements are being marketed and used as if they were drugs, free of regulation. Words such as complementary and alternative medicine have been reinterpreted to cover any nonscientific idea and practice. The public is separated from protection only by clever language, something Congress never intended in DSHEA. We have seen numerous reports of death and severe disability due to so-called supplements, including Ephedra, Aristolochia, just to name two, and there are many more. I noted, as the prior speakers were speaking, dead people cannot report adverse events.

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.

To get to the National Institutes of Health from DuPont Circle, I can take a cab or the metro. These are true alternative methods of travel. No matter what I believe, I cannot 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 wrong and frankly ridiculous to place this collection of anecdotes, pseudoscience and conjecture, called alternative medicine, on the same stage as the real thing, but this is precisely what is being done.

A woman named Hulda Clark, who wrote this book, *"The Cure for All Diseases,"* and who promotes these zappers, says that she has found that all diseases have simple explanations. Clark has a mail-order naturopathic degree and claims that a rare Asian liver fluke, triggered by toxins in the environment and harboring mutant bacteria, cause all of our illnesses: diabetes, Parkinson's, multiple sclerosis, and even AIDS. Inherited genetic disorders such as muscular dystrophy, she says, can be disinherited. She can cure you with a simple electronic device such as this one, built with some parts from an electronic store and some supplements, including the dangerous substance, wormwood.

Outlets, including ones that just happen to be run by her son and her brother, hawk her dangerous items and sell her illegal devices. They are easy to find and readily available. I ask you, why? Let me relate the story of a young woman who followed the teachings of this Hulda Clark. This was written by her friend, Pia Johansson: "Hanna was diagnosed with severe breast cancer. She got a full mastectomy and was treated with chemo and radiation. An alternative practitioner who promotes Hulda Clark's protocols, prescribed cleanses and zapping. The practitioner told her that her pets carried parasites and were the cause of her cancer. She placed all the animals with others, except two dogs, which were also treated with the zapper. Her pets were with her her whole life and they were her heart."

“She has a limited circle of friends, but she couldn’t visit them, nor ask them to visit her, because she was afraid of being reinfected, which is what she was told. She paid him more than \$800 for these capsules, tinctures, and zappers, and followed the protocol to the letter. She had a recurrence of the cancer, now spread to her lungs and liver, and the practitioner once again claimed he could cure her. He was her only hope. Consuming those herbs and capsules—some are known poisons—they made her vomit and spoiled her appetite. She was taken to the hospital. I visited her and watched her zapping both her and her dog as she wasted away, barely able to swallow the Clark capsules. She died Monday night, January 15 of this year.”

Do you honestly believe that this is harmless? Can you properly call this health freedom? I call it healthy tyranny. These supplements are being used as drugs. There are other scans where other unapproved electrodiagnostical devices are commonly used for diagnosis and treatment. In so-called chelation therapy, illegitimate practitioners prey on the elderly, claiming they can treat atherosclerosis. Millions of dollars are collected for this bogus procedure. You can find the ads in virtually every South Florida newspaper. Advertising targets elderly individuals, suggesting this therapy is an alternative to bypass and can prevent arteriosclerosis.

The elderly and others are also regularly victimized in schemes for cancer cures, alleged heavy metal poisoning, heart disease, and neurodegenerative disorders. Colorado dentist Hal Huggins emptied the bank accounts of an elderly Kansas farm couple, 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 allegedly to detoxify him from his dental fillings. The wife wasted away after all her teeth were removed inappropriately. Therapy which could have cured her was postponed. These are examples of the dental amalgam scam. Stopping these thieves of the professions is a task of licensing boards at the State level. However, these crimes cannot typically transcend the mandates of the boards—they typically do transcend the mandates of the boards, excuse me. These crimes cross State borders, use telephones, modems, the Internet and the mails involving money laundering and hiding assets in offshore accounts. After enriching themselves on the public, misbehaving practitioners often have huge war chests, dwarfing the meager budgets of State prosecutors, where a licensing board often cannot recover the cost of prosecution, find the offender, or mandate restitution.

The CHAIRMAN. Dr. Baratz, excuse me. We are going to have to ask you to try and summarize.

Dr. BARATZ. OK. I am just closer to the end, Senator. Thank you.

We need model legislation to tighten the laws against predatory practitioners. The smaller States need help in being able to afford to enforce the rules. 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.

Let me come to the summary—toward the end, please. The problems I report transcend the mandates of any one entity. We need

Federal and State task forces to deal with these problems. Millions, if not billions, of dollars are scammed each year. Health fraud also causes considerably disability and death. 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.

Let me quickly name some areas where Congress can act at little cost with high impact: First, to assist the Mexican government in closing illegitimate cross-border clinics. Recent raids in Baja, CA, closed several illegal clinics, including one by Hulda Clark. We need improved collaboration with the Canadian authorities to help put an end to Toronto mail drops, which we heard about earlier; 800 telephone numbers, referral services and other cross-border scams which allow fraudsters to elude regulators.

Multilevel marketing schemes are common vehicles for promoting supplements and other dubious products. Full disclosure of product efficacy and meager chances of financial reward to any prospect, before they sign up, should be required for any company that engages in multi-level marketing. These simple steps may help dispatch the multi-level menace that we have now in the health arena. Enabling legislation should be enacted to deputize State attorneys general to get nationwide injunctions against sale and distribution of illegitimately and falsely advertised products. This would extend the reach of Federal agencies markedly at very little cost.

The abuses I outlined above have gone on for simply too long. This very Senate committee in 1983 said that quackery and medically related fraud are No. 1 of the top-10-most-harmful frauds directed against the elderly. After almost 20 years, is it not time to act more decisively? We must level the playing field so perpetrators lack any advantage over the regulators. 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. We must keep science and evidence as the framework of our medical system. We need a plan, a timetable, and a designated leadership to make this happen. The cost of not acting is too great.

The National Council Against Health Fraud, of which I am the executive director, stands ready to work with all interested parties to address the problems I have outlined. Thank you very much, Senator.

[The prepared statement of Dr. Baratz follows:]

Current Issues in Protecting the Public from Health Fraud

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

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by

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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 speck 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 practitioners.

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, notwithstanding.

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 hopeconsuming 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 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. Proponents claim 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 andhis 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, 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 Braswell (Florida Department of State, Division of Corporations).

A Web Site 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.

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) were: Florimin—a prebiotic formula to strengthen body (sic) against superbugs, Heart Shield—safeguard your heart, Testerex—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.

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 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 simple, but are difficult. Laws exist to deal with such entities. However, to be effective, regulators must be able to act at speeds equal to the 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 and the FTC have 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:

- 1) 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.

- 2) 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 by which 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.

- 3) 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.

The CHAIRMAN. Thank you, Dr. Baratz.
Dr. Gorski, your testimony, please.

STATEMENT OF TIMOTHY GORSKI, M.D., ARLINGTON, TX

Dr. GORSKI. Thanks very much, Senator. There was a time when all of medicine was unproven and irrational, and it was only our ability to understand and have the tools to collect, analyze and properly interpret evidence that has made the difference. So there was not any quackery, really, until we were able to do that. This committee's counterpart in the House, the Subcommittee on Health and Long-Term Care, Claude Pepper's subcommittee, in 1984 issued a report. It was entitled, "Quackery: A \$10 billion scandal," and it referred very candidly to a vast array of pills, potions and devices with the terms, "worthless," "no scientific evidence," "no physiological or pharmacologic basis," "no rational ability," and so on, and noted that many of these schemes and scams were being perpetrated on America's elderly.

Now, in the 1980's, this was a cottage industry on the fringe, and, of course, we have heard about how Mr. Braswell spent some time behind bars for being engaged in these kind of activities during those years. The advocates called it "alternative medicine" because they knew and they still know that their claims are inconsistent with objective facts and scientific principles. The Pepper report called it quackery and defined it as promotion—that is a key word—promotion of medical schemes or remedies known to be false or which are unproven for a profit, and we have heard about profit today.

So how did this \$10 billion scandal turn into a huge and growing industry that is at once a media darling, a feeder at the public trough and a threat to the public health? Well, in 1993 a report appeared in the *New England Journal of Medicine*, the real *New England Journal of Medicine*, that claimed to consider unconventional medicine. This was a survey that lumped together every conceivable form of health-related behavior, which it said was "Not taught widely at U.S. medical schools or generally available at U.S. hospitals." In fact, Senator, this is the first survey where we get this information that supposedly the use of alternative medicine has been exploding.

Consider what they counted amongst unconventional, later called alternative, medicine: vitamin use of any kind—in fact, at that time Niacin was being used to treat high cholesterol; Physical therapy, as long as it was performed by a chiropractor; imagery, that could be counting sheep for insomnia; commercial weight loss products such as Jenny Craig and Slim Fast; self-help groups; lifestyle diets, which could be anything from keeping kosher to avoiding certain foods for personal reasons; and even massage and relaxation. You get a bonk on the head—I just used alternative medicine there. But these same authors are the same ones that have gone around and claimed that their studies show that a huge proportion of Americans regularly use and demand unproven, disproven and irrational forms of medical care. And this belief is what was used to impose on the National Institutes of Health the Office of Alternative Medicine, which subsequently became the National Center for Complementary and Alternative Medicine, which from the be-

ginning has been staffed and controlled by ideological advocates who are not seriously interested in protecting the public.

Meanwhile, the DSHEA, as we heard, passed in 1994. And that opened the floodgates for the promotion of a new class of drugs outside of the FDA's regulatory jurisdiction and including all those things mentioned in the Pepper report. They could contain parts of animals, plants, minerals, even heavy metals such as silver, chromium, lead, either intentionally or unintentionally. As long as the substances are found somewhere in the universe naturally, they are considered foods. I could take my grass clippings, pack them into capsules, and sell them virtually on any claims that I wished, with little expectation that anything would be done about it.

We heard a little bit about the huge number of promotional gimmicks that are common, television and radio ads, the fake newspapers and journals, the things promoting growth hormone releasers, DHEA and so forth. You have a card there, I think, which gives an example. Mr. Braswell's operation is not the only one that arrives in the mailbox, making extraordinary claims. How about this? "Is your doctor curing you or killing you?"

These kinds of promotions make all kinds of idiotic statements, claiming that you can self-diagnose, for example, ulcers and heart disease by your forehead wrinkles and earlobe creases, or that eating a balanced diet, the kind of thing recommended by the USDA, "contains poisons that are killing you;" that dairy products cause arthritis and osteoporosis—I think the committee has two members from the State of Wisconsin, the Dairy State—and that hormone replacement therapy radically increases the risk of cancer.

Some of these ads are crafted to look like newspaper articles that have been clipped, with a little sticky put on it, saying, "Hey," whatever the person's name is that they are sending it to, "try this," with some initials and, of course, no return address. Friends, co-workers, neighbors and family members can be involved in multi-level marketing schemes. These are the kinds of things that are not going to get reported. The Internet and e-mail makes fraud particularly easy, cheap, and affords many protections for promoters of these fraudulent products. One representative web site says, "Before you try dangerous prescription drugs or risky, painful surgery, discover my safer, more effective, all-natural, miracle-healing program." Also, another page on that web site says, "Here is how to cure people with heart disease without dangerous drugs or surgery," and so forth. And, of course, right at the bottom of that long page is this disclaimer, "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." That is meaningless.

But these promotions exert a very strong psychological appeal, especially to people who are sick, people who are desperate. These promotions assert falsely that the claims are based on solid science and they encourage people to think for themselves and consider the evidence. We all would like to be independent-minded that way. So they appeal to our normal, human weaknesses, as it were. To deflect any doubts, it is often said that these devices or products are little-known or secret. To hear them tell it, these promoters are all modern-day Galileo's, courageously battling an evil conspiracy of

the conventional medical doctors, the AMA, the pharmaceutical industry, and the Food and Drug Administration, all supposedly arrayed against the public for the sake of profit. Often, they will cite the National Center for Complementary and Alternative Medicine or the White House Commission on Complementary and Alternative Medicine as some kind of proof that their claims are legitimate.

There are five ways that the public is harmed by these kind of things: direct harm from adverse effects; indirect harm from the omission or delay of appropriate treatment; economic harm when people are spending their money on worthless products; psychological harm when people realize that they have been duped or harmed; and also social harm, because Americans' understanding of the facts and principles of health and disease are corrupted, which impairs their ability to make wise choices and also to help their country determine the direction of policy in health-related issues.

There are some significant public health hazards that I want to mention. I am going to skip over Ephedra. That is mentioned in my written comments and it was brought up by Dr. Lashof. There are different concerns raised about dietary supplements promoted for anxiety, depression and relaxation. Kava has been mentioned, and let me point out that just because a culture somewhere has used an herb such as kava for a long time "safely," does not mean that it is safe. These kinds of settings are not comparable to that of modern America, where people are drinking alcoholic beverages, driving and flying aircraft loaded with hundreds of passengers, perhaps. One might as well say that drinking contaminated water is safe because people once did it all the time, or that lead is safe because the Romans piped their water through it, or that tobacco is safe because Native Americans smoked it.

St. John's Wort, was already mentioned. I want to mention something on glucosamine, which has been mentioned here. Widely promoted for the treatment of arthritis, this medication interferes with the action of insulin. So it tends to cause diabetes. I hope that you, Senator Breaux, do not have any family tendency to diabetes, but there are Americans, many Americans, who do-or that are at risk because they are obese. Glucosamine bears a striking chemical resemblance to a drug called streptozotocin, which is used to make rats diabetic in the lab. So it is all well and good to have this limited scientific evidence over a few weeks or months, but what is going to be the effect of passing this through the livers and gastrointestinal tracts of Americans for years?

May we have the second card? Perhaps the most serious public health threat in the making is the growing number of dietary supplements being marketed as natural treatments for menopause, generally soy, black cohosh, red clover and other things. The promoters of these products imply or assert that prescription hormone replacement therapy is suspect, dangerous or causes cancer and other diseases. This is the most outrageous example of that that I have come across, a mailing from Medical Recall Notice from Health Notification Service of Henderson, NV. The official-looking contents purport to be a recall of all prescription estrogen and progestin products because of severe and prolonged life-threatening

side effects. How many of our wives, mothers, sisters or grandmothers received this mailing and threw their prescription medication in the trash? According to this mailing, the indicated treatment to be substituted is a natural progestin cream with no harmful side-effects, with the order form conveniently enclosed.

The promoters of dietary supplement products intended to treat menopause often claim that HRT, the hormone replacements, cause women to die from breast cancer, and we know that this is not true. Menopausal women who could otherwise benefit from HRT are participating in a vast, uncontrolled and unmonitored experiment on the basis of false assertions. Many are them are not going to know that they have been duped for 10, 20 years, when they fall and they break their hip. There are over a million fractures due to osteoporosis in this country every year, a good number of which are hip fractures; 20 percent of the people with those fractures are going to be dead within a year.

Finally, it should not be forgotten that many Americans and others living in this country whose primary language is not English live in somewhat insulated communities. It is a big problem in those communities, the kind of advertising that is directed at them, and this is completely under the radar screen of law-enforcement authorities for the most part. Let me just summarize here that these dietary supplements are now really a serious problem and 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 mentioned in that report, not one that were identified have been proven effective or safe, despite hundreds of millions of dollars having been given to advocates of these methods for, "research."

With regard to alternative medicine, about which there is no agreement as to what it actually is besides an advertising slogan, let me simply endorse what the editors of the country's two foremost medical journals, the real journals, have to say. The editors of the *New England Journal* said that there cannot be two kinds of medicine, conventional and alternative, only medicine that has been adequately tested and that which has not. The editors of the *Journal of the American Medical Association* said, also, there is no alternative medicine, only scientifically proven, evidence-based medicine supported by solid data or unproven medicine.

These principles should be applied uniformly and consistently. There cannot be two kinds of drugs, those with a known composition, potency, effects, hazards, interactions, shelf life, and so on, and those about which all these things are little more than a guess. There cannot be two standards in promotional advertising, 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 the other that is not subject to such orthodox, traditional and conventional considerations.

It is not going to be easy to start picking up these 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, for

science, for compassion, and for true freedom of choice in the marketplace can be relied on to assist in this task.

Thank you very much for your time and consideration.

[The prepared statement of Dr. Gorski.]

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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,

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® (cerivastatin), 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% 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]

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.

The CHAIRMAN. Thank you, Dr. Gorski and all the members of the panel.

Dr. Baratz, halfway through your testimony I realized, my God, I take all this stuff. I have taken DHEA. I have taken glucosamine and chondroitin. I just had some in my pocket that I was taking this morning, and I have got a back brace with magnets in it. Here I am, Chairman of the Aging Committee and having this hearing, and I have just found out or started realizing that I, I guess, along with other millions of Americans who are approaching senior status or are, in fact, in that status, take this stuff—and the magnets do not help?

Dr. LASHOF. No. No. No. No.

Dr. BARATZ. No, rhymes with Breaux. [Laughter.]

I think the web site where you bought that was www.xxx.com—C-O-N—not .com.

The CHAIRMAN. I have two of them. I have two back braces with magnets in it, and it is supposed to help your back.

Dr. Lashof, the last publication here, which is the one, the healing breakthrough of the century, when it listed everything that can work for people with everything and that you can live 26 percent longer, they have got some stuff in here that, really, I need to ask you about, I guess. One of the things is this ACF223. They say that this particular doctor did the research by going to a former atomic testing site in the Nevada desert, and examined plants that had survived a nuclear blast and radiation, and they found a seed from one of these native desert plants was found to have survived and actually grown, and therefore the active ingredient in this simple plant was this substance—and it is a very long name. The abbreviations are NDGA. They say that clinical studies show that this NDGA extends the life spans of animals and works against premature skin wrinkling, and the same may be true for humans.

They go on to say that this doctor put together this formula, ACF223, and in rigidly controlled laboratory tests, it was shown to increase life span by 19 to 26 percent. Another thing they quoted here, and I ask you to comment on this, is they quote another doctor, whose name I will not mention, who they say was Director of the National Institutes of Aging, and that is part of NIH, the National Institute of Health, and they quote this person, being the Director of the National Institute of Aging—has conducted countless experiments in clinical trials with ACF 223 nutrients and concludes. “Our life span is directly proportional to the amount of ACF 223 nutrients that we have in our bodies.”

That is a pretty strong statement. Do you have any information that anything like this has ever been done at NIH or the National Institutes of Health, or what are your comments about the material I just read?

Dr. LASHOF. I do not believe it, that is my first comment. It is not a particular product that we have looked at. That had not come to our attention, so I have not specifically examined it. But every time we see that kind of statement, we try to request the scientific data, and we never get it. One thing they do, and I do not know whether that is what they have done there, and you obviously have to talk to the director of the National Institute of Aging, is that he may have done a study of some nutrient which they now claim is

in here, and they will quote that out of context. We find that often, that they will look at some scientific article that tells you something about what a hormone does or what the function of growth hormone is in the body, and then extrapolate from that and claim that their product will now do all these things, and they take scientific stuff out of context.

But we try always, when we get any product that comes to our attention—and basically we are looking for those that are most widely advertised and that are being used a great deal, and then we start looking at all the literature. We ask the company to supply us with data, and we do not get it.

The CHAIRMAN. You and Dr. Heinrich maybe can get in on this—Dr. Heinrich talked about the Dietary Supplement Health and Education Act that Congress passed, and we made a decision at that time that we were not going to subject these supplement products to the same rigorous enforcement that we do for other prescription drugs, over-the-counter generic drugs, that have to be approved by the Food and Drug Administration. This is a new category. It is supposed to be like food products, and therefore they do not have the same rigorous investigation before they are sold to the public.

It seems to me, in my opinion, there is a difference between products that are being targeted to people as a food supplement that may make you lose weight or may make you get rid of your wrinkles, for instance, as opposed to a supplement that actually is supposed to prevent cholesterol problems or diabetes or Alzheimer's, or actually cure aging or potentially cure cancer. It seems to me that when these food-supplemental products are put in various combinations, that that is a difference from just trying to say that you are curing wrinkles, that you are actually talking about curing diseases. Do you think there would be a way for Congress to address that particular issue, that would be helpful, Dr. Lashof?

Dr. LASHOF. I think it is very difficult. You see, they have tried to make the distinction between a cure and this disclaimer, which is always in such tiny print that no consumer can ever read it. They say that is really there as a test for whether you should go to see your optometrist, but trying to separate those two is very difficult, and so they have used the term "function," structure and function. You can make a structure and function claim, and that was their effort, to try to do that. Well, under structure and function, they just say about everything. If it improves your body's ability to do this, that becomes a function, and yet that is what a drug is doing.

The CHAIRMAN. Mr. Braswell did not testify, obviously, this morning—I cannot say what he might have said. But let's assume for a moment that someone who makes these products comes before the committee and says, "Look, I did not say it cured anything. I said it might, it could, it possibly might help, this could help you," and all of these clarifying phrases that keep them within the boundaries of not being sued. What is the problem with that? If I came here and said, "Look, I did not say it was going to cure anything. I just said it might; it might be helpful; it could be helpful; you ought to take it; try it; besides, we give you your money back

if it does not work,” what is wrong with that position with respect to this particular problem we are looking at?

Anybody, Dr. Gorski, Dr. Baratz?

Dr. GORSKI. I was going to jump in and say the Federal Trade Commission has standards that they can apply in these kinds of situations, because the standard is what would a reasonable consumer think. When you put something up saying you are going to support the cardiovascular system, people with atherosclerosis can avoid bypass, et cetera, maybe you have not said you can cure atherosclerosis, but the average, reasonable man-in-the-street consumer is going to assume that.

The CHAIRMAN. I take it it is particularly a problem, obviously, when it appears in a journal that closely resembles a, “legitimate medical journal,” with doctor, pictures and everything else.

Dr. GORSKI. Sure. That is right, and they are inviting the public—which, of course, we would all like to think that we have some control and have some power over our lives to make our own decisions, the self-validating kind of decision.

The CHAIRMAN. Dr. Heinrich, in a GAO investigation of this issue—and I will get to Senator Wyden after this question, did I hear correctly that you said that FDA has never taken a product off the sales list, as a result of these type of investigations of supplements?

Dr. HEINRICH. You are correct. What I said, and we made sure that we checked with FDA, of course, to reaffirm the accuracy of this, but under DSHEA, they have not taken administrative action to remove a particular substance. As I said, they have taken actions, and in our report to you we do list some of the FDA actions that have been taken to remove products that have claimed treatment for a particular disease. But, no, they have issued warning letters against substances that they think are harmful, but they have not—they have relied on—

The CHAIRMAN. But you have in your testimony a quote, “The FDA has not initiated any administrative rulemaking activities to remove from the market certain substances that its analysis—its analysis—suggests post health risk, but has sought voluntary restrictions and attempted to warn consumers.” Do they have the authority to take these products off the market?

Dr. HEINRICH. FDA has the authority to claim that a product is harmful. Then they have to take it to court for court action. But, from FDA’s perspective, the burden of proof then of harm is on FDA and their legal counsel, as opposed to what we have with drugs, where it is the responsibility of the manufacturer to ensure that there is safety and efficacy.

The CHAIRMAN. One of the things—again, this is the concern I think we have—you have also in your statement, the GAO, “Although DSHEA allows FDA to remove from the market dietary supplements that the agency can prove are dangerous, the agency has not prohibited the marketing of any specific substances using its administrative rulemaking authority.” Dr. Heinrich. That is correct.

The CHAIRMAN. Senator Wyden.

Senator WYDEN. Thank you. Thank you, Mr. Chairman. It has been an excellent panel.

Dr. Heinrich, one of the constants to me in the health-care fraud area, and it has changed and we have talked about it, is it seems that somehow the bad guys, after they perpetrate these reprehensible, heinous offenses against seniors, somehow invariably manage to get back in business and go out and continue to prey on seniors. What we have seen this morning raises again a question in my mind about how the government deals with it.

Mr. Braswell apparently has been found to violate a number of civil and criminal laws in the past, with respect to his activities with seniors. He came here this morning and took the Fifth Amendment with respect to a variety of issues we wanted to explore, and again this is a product that is being marketed to the public. I would like to get your sense of whether you think that this is a problem of recidivism, that people who prey on seniors—that there is a pattern that after they do it, that somehow they can leap to another State, they can get offshore, they can go to the Cayman Islands, as we had a witness say this morning was taking place, set up shop and go back to exploiting seniors. Do you think this is a serious problem?

Dr. HEINRICH. Oh, I think it is a serious problem. Part of the issue, though, is it is hard to understand the magnitude of it. But they probably do not have to go as far as offshore. Certainly when we examined the work of the FTC and the FDA, we were impressed by the work that they were doing jointly, monitoring what was advertised on the Internet, and although they do have a joint effort there to really find companies that are making false claims, even after FTC has issued a warning letter to them that they may be breaking the law, we found that a very small percentage of companies actually took any action, and over 60 percent of companies so notified took no action whatsoever.

Dr. LASHOF. If I can barge into that—

Senator WYDEN. Oh, yes, please. Absolutely.

Dr. LASHOF. In California, some of the local district attorneys have been taking action against various companies based on their laws, and they changed the name of the formula. They will take action against one, argue about the advertisement, and a few months later they are advertising under a different name the same stuff that they were just charged with. So it is not one company. It is much more pervasive.

Senator WYDEN. Dr. Heinrich, being a pretty devout reader of your health materials, I have never seen an analysis you have done with respect to this recidivism issue and those who are taking advantage of seniors. Have you ever done something that has taken six or seven, say, of these major health frauds perpetrated against seniors and actually tracked what happens to the offenders, and after they are found to have violated one set of laws, what happens when they, perhaps as your colleague, Dr. Lashof, just mentioned, go and set up somewhere else in a different name? Have you ever done that?

Dr. HEINRICH. I do not think so, not to my knowledge.

Senator WYDEN. Do you think that would be productive if our committee were to ask you to do that, because I will tell you—and, again, this is a product of something I have seen. When I was director of the Gray Panthers and I had a full head of hair and rug-

ged good looks, a number of years ago, you would see the person who ripped seniors off selling shingles door-to-door come back in a slightly different kind of area with a slightly different name. My sense is that it is going on now with some of the biggest health frauds that are perpetrated against seniors, involving millions and millions of dollars. I do not think you all have ever looked at this question of whether there are a handful of recidivists who constantly keep coming back at this and figuring out how to milk this cash cow and exploit the elderly. Do you think it would be productive for you look at that?

Dr. HEINRICH. It certainly would be very, very interesting to see what those cycles look like, of some of the groups that, in fact, seem to reinvent themselves. We found examples of that.

Senator WYDEN. I am going to consult with the chairman and the ranking minority member, because I would like you to do that. I would like you to take six or seven of the major health frauds perpetrated against seniors and I would like us to kind of walk it through, say for 4 or 5 years afterwards, to see what happens to those people, because my guess is just as sure as the night follows the day, these people are coming back with different names, different front organizations, going offshore, as Dr. Lashof stated, slightly revising the product.

If we, for example, as we look at this next round of frauds with the new technologies and look to the biology and genetics, get to the point where we can isolate a handful of people, a relative handful, that is in everybody's interest, because we have already made it clear there are many lawful people in the business. So I am going to talk with the chairman and the ranking minority member about it, but I would like you to that. We, having worked with you many times over the years, are confident you would deal with it in a professional way.

Dr. Lashof, one question for you—and superb testimony, and I have known of the good work that you all do at Berkeley, as well. I went to the web site of several of the health sites recently, and if you are a general person doing a search on a particular health issue, you just get flooded now with essentially the advertised material, and the advertised material, almost invariably, look like authoritative articles and it is pretty hard to distinguish. Are there areas that the Congress should be looking at to try to do a better job of separating out these articles where authoritative, constructive information is imparted to people from areas that really are just hype?

As you know, this is hard to do, because there are First Amendment questions, free speech questions. But I can tell you, having done some searches recently, it is pretty clear we are getting flooded with advertisements that do not look much like advertisements, and I wonder, at the public health school, whether you all have looked at this and have some ideas on it.

Dr. LASHOF. Well, I am afraid that it is a problem for FTC, really, and the amount of resources they would need to police all of the web sites—I would hate to try to make a guess. You can ask them. We have tried very carefully, in the Wellness Letter, to recommend the government sites as the sites people should go to. The FDA has an excellent site. The FTC itself has very good standards that you

can read about on their site, and then CDC and all of the government agencies at NIH. So we urge our readers to consult those sites and, just as a rule, to generally recognize that if is something sounds better than it could be, it probably isn't true, and just to avoid those kinds of sites.

Senator WYDEN. My time is up. I would hope that we could figure out more creative ways to deal with this, and I know you are interested in that, than just sending people to government sites, because, as you know, one of the reasons these alternative products have been attractive to so many is people are skeptical about the government's role in this area. If we could do nothing else, for example, other than to encourage people to look and see whether some of these articles have some peer review, have some people who are authoritative sticking up for them, those kinds of ideas are might prove valuable. But we will be following up with you.

Gentlemen, I am only skipping you in the interest of time, but I know of your organizations and the good work that you do.

Dr. BARATZ. Senator, could we just add two sites that people might want to look at that may help them in that jungle out there? One is a site called www.quackwatch.com, which is an appraisal of dubious claims, so that if someone has some questions about something, they can go there for sort of an objective appraisal of whether those claims hold up; and the other is the National Council Against Health Fraud site, would be ncahf.org, ncahf.org.

I would recommend to Senator Breaux that instead of wasting his money on those magnets, he donate the money to us, because we could use that money to get better consumer information out there on these topics. [Laughter.]

Those magnets do not even penetrate your skin. They are a complete waste of money.

The CHAIRMAN. I will tell you I could not get on an airplane with them the other day. They make me stop and undress.

Senator WYDEN. I am going to get my friend, the chairman, a brand-new Gray Panther card so that he can be working on those things with us.

The CHAIRMAN. Thank you, Senator Wyden, very much.

I want to thank this panel. You have come from long distances and I appreciate very much your help and look forward to working with you. Keep up the good work.

We are delighted to excuse this panel now and delighted to welcome up our last panel today. We are fortunate to have the Attorney General for the State of Maryland as our lead-off witness on this panel, Mr. Joseph Curran; Mr. John Taylor, who is Director of the Office of Enforcement of the Food and Drug Administration; Mr. Howard Beales, who is Director of the Bureau of Consumer Protection of the Federal Trade Commission; and from the Federal Bureau of Investigation, Mr. Dennis Lormel, Chief of the Financial Crimes Section of the Criminal Investigative Division of the FBI.

Gentlemen, we thank you very much. We appreciate your being with us.

Mr. Attorney General, we are delighted you were here for the whole morning hearing and we appreciate your patience. We know your schedule is very busy and we look forward to your testimony.

**STATEMENT OF HON. JOSEPH CURRAN, ATTORNEY GENERAL,
STATE OF MARYLAND, BALTIMORE, MD**

Mr. CURRAN. Well, thank you, Senator. Actually, I am delighted that I had a chance to be here on time and to hear the entire scope of the testimony. It was extremely impressive, as I am sure that you have been impressed, as I have been. I would invite the attention of the committee to some of the testimony of the publisher of the Wellness document in California. It makes a lot of sense to take a long, hard look at the results of the 1994 act to determine ought there to be, should there be, can there be some amendments to deal with what we have heard about. In the alternative, beefing up FTC and FDA certainly would make sense, as helping our own Consumer Protection Division.

I am just going to take a few moments to tell you about one of our experiences that will show you the depths of these types of cases, and I might add, as the Maryland Attorney General, I am able to enjoin a person who is doing business in Maryland. I can stop him in Maryland. I can stop him from shipping out of Maryland. But if he is in Louisiana and shipping into Maryland, I cannot do that. So there are some limitations on those of us who are attorney generals, and I am not sure—well, there is nothing I can do about it, but I will tell you this. We do work with other attorney generals when we learn of something, say in another State.

In our own particular case, in which we cracked down on people who were operating in Baltimore a company called Tee Up, we later found out, after we stopped them, that they did, in fact, move offshore to the Bahamas, and they also moved to Pennsylvania. Happily, we were able to contact the health authorities in the Bahamas and advise them of this particular charlatan, and they stopped him there, and we also alerted the attorney general, my friend Mike Fisher, in Pennsylvania and we were able to stop them there. So that just gives you the scope of what any individual attorney general can do.

What all consumers want, those of us who have reached my age or even those who are much younger, want to make sure that when we go to the supermarket or the health store, that when we buy this particular vitamin, it is safe and it is effective and the ingredients are there. We have heard about some of the charts that talk about enhancing sexual functions or removing wrinkles, and/or maybe helping with some pain, and that may well be. Well, if that happens, and it is a phony thing, then all you have done is lost some time and money. But in our case involving two people in Baltimore, this involved a cure for cancer, a cure for AIDS, 100-percent effective in breast cancer cure, 100-percent effective as a colon- or lung-cancer cure.

I speak to you as a person who was told by a doctor some 10 years ago, "We have bad news for you, you have cancer." So I know what it means when they tell you that. I am happy to say, because of medical treatment, I am 10 years operative and I am OK. But when you first hear that, you are really concerned, "Well, what am I going to do?" So what I was concerned about with these particular people who were selling this—it is an aloe vera, the aloe vera plant. They crush it up and grind it up in some way that it becomes liquid and they put it in a pill, and then they take some-

thing cause cesium chloride and grind it up in some way, and that is also a pill, and these two particular pills will enhance your T-cell quality, they will attack the cancer, and within weeks or months it will be gone.

Well, if you have been told you have cancer, you are frightened, and unlike maybe some of these other drugs that get rid of wrinkles, these are very expensive, about \$600 a month you have to take these two particular products that will get rid of your lung cancer or colon cancer, or cure AIDS or take care of the other conditions that you have. So you are talking about a lot of money. To give you some idea, Senators, in our investigation—I might add, I will compliment the FDA. They alerted us in late 1997—they alerted our Physicians Quality Assurance Board that they believed the publication indicated one of our persons who held themselves out to be a doctor was, in fact, practicing medicine improperly.

So we got the case from FDA, we got into it. We were in court in early 1998, and now they have been shut down, although the case is still on appeal. We found out that during an 18-month period when they were operating they contacted about 3,700 persons across the Nation, just to give you some idea of how many persons were suckered into this, and they spent about \$2.3 million. So it is big business, and I might add that did not cover the money that was paid for intravenous injections.

There is some good news out of this, because the first person said, "Well, let's pick up the bad"—well, the doctor who was administering against FDA regulations in Virginia currently resides in the penitentiary in Virginia. So, that is good news. He was prosecuted by the Federal attorneys in Virginia. The good news is that our case in Maryland, our Consumer Protection Division, we were able to stop them. We have got a judgment of \$3.7 million against them, trying to get back the money they have gleaned from a lot of folks, and we are also trying to recover a penalty. So we are doing that from a standpoint of civil authorities.

The other good news is that the fellow who holds himself out as a doctor will be tried in the Federal District Court in Baltimore in November. He escaped before on an 11-1 hung jury, but he is being tried again. So I thought I would tell you that the Federal Government, the FDA and the attorney generals are working together. But the point I am making is that there are not only these supplements that take away wrinkles, you are talking about a cure for cancer, and when you permit these folks to—and these are across the Nation, not just in Baltimore—when you permit them to make these advertisements to people who have cancer or a family member—if you are a family member and your loved one has been told they have cancer, you are going to spend money—\$20,000 of injections of this aloe vera substance into your body, that is what they were costing.

So the staggering sums of money that a person who has a life-threatening disease is going to pay—and so I would invite you clearly to see to it that if there needs to be more pre-marketing since 1994, more pre-marketing overview of these kinds of advertisements, that may well be the way to go. Happily, in this case, FDA found it early, got it to us; we acted properly; the Virginia Federal authorities acting properly; the Maryland, Baltimore Fed-

eral attorney is prosecuting the guy. So we are putting them in jail. That is fine, but I will tell you this. My experience, Senator Wyden, in telemarketing and other fraud, these guys, they seem to have learned how to do con work good. Telemarketing, you stop them here, they pop up there. Travel clubs, we put them out of business in Baltimore, they go to Topeka or somewhere.

So I do not know about the health guys, whether they are the same ones, but my experience as attorney general for a number of years now in Maryland is that these bad guys seem to have learned how to make money and they continue to do it. So if you are able to get from your survey what these fellows are doing, that would be good information. The good news is that we have swung the big bat and they are in jail and they had been stopped, but they ought not to have been started. They preyed on cancer victims and that is just outrageous, and I am glad they are in jail and hope that the guy in November will go to jail, too, and stay there for a good, long time.

[The prepared statement of Mr. Curran follows:]

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Testimony

Before The

Senate Committee on Aging

Regarding The

Marketing of Dietary and Nutritional Supplements

September 10, 2001

Testimony of J. Joseph Curran, Jr., Attorney General for the State of Maryland

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Testimony
before the
Senate Committee on Aging
regarding the
Marketing of Dietary and Nutritional Supplements

Chairman Breaux and members of the Committee, on behalf of consumers who purchase dietary supplements, I thank you for inviting me to testify today regarding the issues consumers face when they purchase and use dietary supplements. I am testifying today in my capacity as Attorney General for the State of Maryland. I was asked to share with you the circumstances regarding a particular case brought by my Office that involved the sale of dietary supplements throughout the country because many of the product benefits that were claimed by the seller, including that their products were powerful immune boosters, were false and, as a result, consumers were severely harmed.

This case, *Consumer Protection Division v. T-Up, Inc.*, involved the sale of two products, a concentrated aloe product called "T-Up" and a mineral called cesium chloride, which were offered and sold to consumers to both generally improve immune function and to treat cancer, AIDS and other diseases. Although most of the sales of these products were for oral consumption, the company also sold products for intravenous administration at a cost of \$12,000 to \$20,000. The company's claims that their products would help consumers were grossly misleading, if not false, because they were unsubstantiated. Similarly, the company's claims concerning the safety and quality of their products were baseless. Many of the consumers who purchased these products were particularly vulnerable because they were facing life threatening diseases such as cancer or AIDS. They paid hundreds to thousands of dollars for these products hoping to be cured, and instead received little or no benefit, and in some cases were actually harmed. Moreover, some consumers chose these products over other more proven treatments or therapies that might have otherwise helped them.

This case needs to be viewed against the background of federal regulation of dietary supplements. In 1994, Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA).¹ Among the stated purposes the Act was to promote the right of access of consumers to safe dietary supplements.² Since the passage of DSHEA, the dietary supplement industry has experienced enormous growth. In 1994, the industry's total sales were estimated to be at least \$4 billion annually.³ More recent estimates place the industry's annual sales between

¹ Pub. L. No. 103-4127, 108 Stat. 4325 (codified at 21 U.S.C. §§ 321, *et seq.*).

² *Id.* at sec. 2.

³ *Id.* at sec. 2, subpart 12(C).

\$10 and \$12 billion.⁴ One need only to walk into any health food store, supermarket or shopping mall, to find a myriad of vitamins, minerals or other dietary supplements being sold. These products are advertised for a wide variety of purposes including weight loss, nutrition, anxiety relief, memory enhancement, or to treat serious illnesses or diseases such as cancer or AIDS. They are widely advertised in magazines, over the Internet, and on radio or television.

As the market for dietary supplements has grown, the risk of consumer harm as a result of misleading claims and potentially hazardous unregulated products has also grown. There appear to be few standards governing the claims that can be made concerning the content of dietary supplements and in some cases the manufacturing practices of the industry have come into question. In some instances supplements have been marketed as being safe when in fact they contained harmful substances. For example, in June 1997 the FDA issued a warning to consumers against a dietary supplement product containing digitalis, a powerful heart stimulant with side effects that may include nausea, vomiting, dizziness, headache, confusion, hypotension and an abnormal heart rate.⁵ More recently, the FDA warned consumers against using certain Chinese herbal products containing aristolochic acid because they may present a serious risk of kidney damage or cancer.⁶

My Office's experience is that with DSHEA's liberalization of the controls over the dietary supplement industry, there has been a corresponding increase in false or misleading claims that are being made in the advertisement of dietary supplements, including misleading claims of safety, unsubstantiated claims of "miracle cures," and false claims about the ingredients or integrity of products.

In 1997, we learned that a company located in Baltimore, Maryland was marketing its products as treatments and even cures for diseases that included cancer, AIDS, herpes, arthritis, chronic fatigue syndrome, lupus, multiple sclerosis, pneumonia, Chron's disease, emphysema, and a wide variety of other diseases and illnesses.⁷ The name of the company was T-Up, Inc. It

⁴ See Herbs and Supplements: A Year in Review, The Hartman Group, Bellevue Washington (1999) (reporting the sale of dietary supplements in the United States to be \$10.4 billion for the period July 1998 to June 1999); Michael Higgins, Hard to Swallow, ABA J., June 1999, at 60 (estimating the total 1997 sales of dietary supplements at \$12 million).

⁵ See <http://www.fda.gov/bbs/topics/NEWS/NEW00570.html>.

⁶ See FDA Press Release, P01-14 (June 20, 2001), found at <http://www.fda.gov/bbs/topics/NEWS/2001/NEW00765.html>.

⁷ Attached to this testimony is the "T-Up Desk Reference Manual," in which the company listed the many illnesses and diseases it claimed its products could effectively treat.

was owned and operated by "Dr." Allen Hoffman.⁸

According to T-Up, Inc., its T-Up aloe vera product could be used to boost the human immune system and fight cancer and all diseases associated with either a weakened or malfunctioning immune system. The company further claimed that its cesium chloride product could attack and kill cancerous cells by altering the body's pH on a cellular level.

The T-Up aloe product was typically sold in two ounce bottles for oral consumption. Each bottle of T-Up aloe was sold for \$75.00 and was supposed to last one week. Each bottle of cesium was also sold for \$75.00 and would also last about one week if the optimal dosage was used. Accordingly, the typical consumer using T-Up, Inc.'s products spent \$150 a week to treat their illness or disease. The length of the treatment could last years depending on the nature, course and severity of the disease or illness that was being treated. Consumers were also encouraged by T-Up, Inc.'s advertisements to continue using their products after their diseases were cured in order to prevent them from reoccurring.

T-Up, Inc. also sold sterile aloe vera products that were designed for intravenous administration. The intravenous treatments usually lasted two to three weeks and sold for between \$12,000 and \$20,000.⁹

Although T-Up, Inc. never provided my Office with its complete sales data, the evidence that we were provided established that between April 1, 1997 and October 16, 1998, T-Up, Inc. sold products costing \$2,364,783 to 3,706 consumers. These sales figures did not include the larger amounts paid by consumers for T-Up, Inc.'s intravenous treatments. Many of the consumers who used T-Up, Inc.'s products were middle or lower income families who could ill afford to spend the amounts they spent on T-Up, Inc.'s products, but nevertheless chose to do so based on the company's promise of a cure.

T-Up, Inc. promised consumers that its products could boost the human immune system. One of its primary advertisements, a brochure entitled "The Most Powerful and Natural Way to Boost Your Immune System," promised consumers that T-Up aloe vera can boost and strengthen the human immune system. A copy of the brochure is attached to this written testimony. However, when asked to produce any scientific evidence to support this claim, the company was unable to do so.

⁸ Although Allen Hoffman claimed in his advertisements that he was a former Johns Hopkins medical researcher the evidence showed that Hoffman had never performed medical research and that his doctorate was fraudulent.

⁹ The intravenous administration of aloe vera into humans has not been approved by the United States Food and Drug Administration. However, despite the lack of FDA approval for its IV product, T-Up, Inc. referred consumers to physicians willing to illegally perform the intravenous procedure, or Allen Hoffman performed the illegal procedure himself.

Even more outrageous than the company's claim that its aloe vera product could boost the human immune system were its claims that its products could effectively treat or cure cancer, AIDS and other diseases. Typical and illustrative of the many excessive claims made by the company to sell its products is its claim on the first page of the "Boost Your Immune System" brochure that "T-Up appears to be capable of increasing T-lymphocytes and attacking cancer, AIDS, herpes, and other viruses like nothing else before it." The brochure also purportedly describes the results T-Up users experienced, including consumers who allegedly were successfully treated for breast and liver cancer, as well as AIDS. Equally striking were claims made in T-Up, Inc.'s other advertisements.

In a cassette tape distributed to 125,000 consumers through the mail, the company claimed:

The cesium chloride begins to destroy malignant tissue in three days. And my experience recently is that in ten days 50% of a malignancy will disappear. The rest of the malignancy based upon scientific literature should disappear within two to three months.
Very exciting.

The same statement was contained in a Desk Reference Manual supplied by T-Up, Inc. to its employees, portions of which are also attached hereto. Other claims made in the Desk Reference Manual pertaining to the company's successes treating cancer included the following:

- All soft tissue cancers - in arms, legs, chest, etc. We are approaching 100% success rate.
- Breast Cancer - We have had 100% success rate.
- Lung, Esophagus, Colon and Stomach Cancer - almost 100% success rate.

In its advertisements the company also claimed that its T-Up aloe products were "literally 100% effective" at treating HIV. In its Desk Reference Manual, T-Up, Inc. promised that persons with AIDS who used their products regularly "could control the infection and that "98% will live normal lives."

The efficacy claims made by T-Up, Inc. in its advertisements and Desk Reference Manual were further embellished when T-Up, Inc.'s employees met face-to-face with consumers. Wendy Daly, a resident of Alabama, reported that she was told by Allen Hoffman that her father's cancer would be "gone in three to six months" and that "in three to six months daddy would be completely cured of his cancer." Similarly, Hoffman told Delores Triplet, a Maryland resident, that through his research he had discovered how to cure her husband's colon cancer, and Ray Osborne, an Alabama resident, that T-Up, Inc.'s products had cured many other persons' cancers and that it would "take care" of his wife's cancer as well. Dr. Robert Knudsen, a California resident, testified that when he approached T-Up, Inc. concerning its products, he was told that they "will kill . . . [malignant] cells every time."

Jeanne Hammond, T-Up, Inc.'s office manager, admitted that T-Up employees had told consumers that their products were 100% successful in treating breast cancer. Similarly, when Deanna Crabbe and her husband Douglas were considering using T-Up, Inc.'s products to treat Douglas' cancer, T-Up, Inc.'s employees told Ms. Crabbe that T-Up's products were a "miracle," would "work" for her husband, and would "take care" of her husband's cancer. After Douglas Crabbe began using Respondents' products, his condition deteriorated and his cancer spread to his liver. When the Crabbes voiced their concern that the products were not working, Hoffman told them: "Don't worry, by this time next year you'll be laughing about all of this" -- so Mr. Crabbe continued using the products until he died from his cancer one week after completing T-Up, Inc.'s intravenous therapy.

Obviously all of these efficacy claims were false. There is no evidence that aloe vera and/or cesium chloride can boost the immune system, cure cancer, or be used to effectively treat AIDS. During an administrative hearing that lasted 27 days, in which 45 witnesses testified and more than 400 exhibits were introduced as evidence, the Judge who heard the T-Up case could not find a single piece of credible evidence in the record supporting any of the efficacy claims made by T-Up, Inc. and its employees. Despite claiming to possess "stacks" of medical and scientific literature that substantiated their claims, T-Up, Inc. was unable to produce a single credible study that supported the claimed efficacy of their products for the treatment of any disease or illness. Quite to the contrary, the only well controlled studies performed on aloe vera demonstrated that it in fact had no significant beneficial impact on the human immune system. Of course, these studies were not mentioned in any of T-Up, Inc.'s advertisements.

Contrary to T-Up, Inc.'s advertising, in fact, very few of the consumers who utilized T-Up, Inc.'s products reported any positive effects from the products. The vast majority of customers interviewed by my Office reported they experienced no improvement in their health by using T-Up, Inc.'s products. Among the consumers known by my Office to have received the IV treatments, very few remain alive today.

- Many of the consumers who used T-Up, Inc.'s products did so instead of using more conventional treatments. For example, one consumer delayed the chemotherapy that his oncologist had recommended because he believed the T-Up would be effective and less painful. Unfortunately, after the T-Up treatment failed and his cancer progressed, this consumer underwent the chemotherapy that he had delayed, but it could not stop the spread of his cancer. I believe this unfortunate consumer's experience is not an isolated case. In fact other witnesses who testified during our case also described delaying or forgoing recommended treatments, opting instead to use T-Up, Inc.'s products.

I was also troubled by T-Up, Inc.'s claims that its products had been proven safe. Although T-Up, Inc. claimed in its advertisements that its aloe products were so safe, the only way you could be injured by them were to "drown" in them, the evidence developed during our investigation proved otherwise. No testing had ever been performed on either T-Up aloe vera or cesium chloride to establish their safety. Moreover, evidence during the case demonstrated the potential for very serious side-effects caused by T-Up, Inc.'s products.

Existing scientific research establishes that cesium chloride causes cardiac arrhythmia in animals. Although no well controlled studies have been performed establishing the same risk in humans, T-Up, Inc.'s employees acknowledged receiving reports of customers who experienced arrhythmia while using T-Up, Inc.'s products. The wife of one consumer who testified at the hearing described her husband having repeated episodes of irregular heart beat while using cesium. His cardiologist, who treated him during one such bout, confirmed the consumer experienced cardiac arrhythmia caused by his use of cesium chloride supplied by T-Up, Inc. Despite the fact that its cesium products could potentially cause this very dangerous side-effect, T-Up, Inc. sold its cesium chloride product to consumers without the supervision of any physician.

Equally alarming were the side-effects reported by consumers who underwent T-Up, Inc.'s intravenous therapies or who witnessed the side-effects experienced by their loved ones during the treatments. Among the side-effects reported by consumers were significant weight loss (as much as 50 pounds during a two week treatment) accompanied by loss of appetite, diarrhea, and swelling so severe that it caused patients' skin to crack open.

In addition to misrepresenting the safety and efficacy of its products, T-Up, Inc., also misrepresented the nature and ingredients of its products. T-Up, Inc. marketed its aloe product by claiming it was specially filtered and cold processed in order to prevent contamination and to preserve its active ingredient. However, T-Up's manufacturer confirmed that T-Up aloe was not specially filtered and was actually heat treated. Testing of the product by the FDA revealed a wide variety of contaminants in the aloe products.

In its brochure that is attached to this testimony, T-Up, Inc. claimed its aloe vera was superior to other products because of its concentration, a claim the company was also unable to substantiate. In fact, despite the repeated emphasis in its advertisements concerning the concentration of its product, no testing or analysis had been performed by T-Up, Inc. on its products before it made its claims. Evidence presented by the makers of T-Up suggested that other sellers of aloe vera products in this country also sell products that do not contain the concentration or amount of ingredients claimed in the seller's labeling.

In investigating the T-Up, Inc. case, my Office demanded that the company produce adequate substantiation for each of its claims. In defense of its claims, T-Up, Inc. argued that DSHEA relieved it from having to substantiate its claims. My Office and a Circuit Court Judge who has reviewed our case rejected this defense.

My Office has ordered T-Up, Inc. to cease making any claims regarding the efficacy, safety or quality of its products unless they can be substantiated. We have also ordered T-Up, Inc. and its principals to make full restitution to consumers victimized by their unfair and deceptive trade practices, and to pay a substantial civil penalty. While I am pleased that my Office has protected consumers from being victimized by T-Up, Inc., I am concerned about other consumers who will purchase these types of products based on false claims concerning what the products can do and what they contain.

My office believes that consumers who are faced with decisions regarding their own health must make them with the most complete and accurate information available to them. I believe the promises made by T-Up, Inc. regarding the efficacy, safety and quality of its products illustrate the very serious problems consumers face when attempting to decide whether to use a dietary supplement when such products remain largely unregulated.

With a growing market that is becoming increasingly competitive consumers must rely almost exclusively on the manufacturer of the supplement to provide them with accurate information regarding the safety and efficacy of the product, as well as the contents of the product. Frequently, consumers are reluctant to turn to their physicians for such advice¹⁰ and in the current marketplace, consumers can no longer assume that the safety, efficacy and product claims that are being made by the manufacturers of dietary supplements have been proven to be true. With an increasingly competitive market, and a lesser role by FDA regulating that market, I believe companies such as T-Up, Inc. will continue to make unsubstantiated claims regarding their products that will continue to harm consumers in the manner I have just described. Consumers who are considering whether to use dietary supplements must be protected from charlatans who lie about their credentials, exaggerate and distort existing science, and make unsubstantiated claims that, when relied on by consumers, can cause serious financial and physical harm.

This Committee's examination of the marketplace as it pertains to the sale of dietary supplements is appropriate and should be applauded. I believe that any measures considered by this Committee should be recommended with the goal of creating a marketplace where consumers can have access to dietary supplements, but also be confident that the products they are purchasing are safe, effective, have been produced using good manufacturing practices, and contain the ingredients or qualities promised by their manufacturers. I want to commend you, Chairman Breaux, and the members of this Committee, for your recognition of the issues we as consumers face when considering the purchase and use of dietary supplements. I thank the Chairman and each member of this Committee for allowing me the opportunity to appear today and give my testimony.

¹⁰ In its 1998 study of trends in the use of alternative medicines, the Journal of the American Medical Association found that 60% of Americans who use alternative treatments, including dietary supplements, do so without informing their physicians. See Eisenberg, *Trends in Alternative Medicine Use in the United States, 1990-1997*; 280:18 (November 11, 1998).

State of Maryland
OFFICE OF THE ATTORNEY GENERAL

About Attorney General Curran

J. Joseph Curran, Jr., was first elected Attorney General of Maryland in 1986 after serving four years as Lieutenant Governor during the administration of Governor Harry Hughes. In 1998, he was elected to an unprecedented fourth consecutive term as Attorney General.

Born in West Palm Beach, Florida, on July 7, 1931, he attended Baltimore parochial schools, Loyola High School, the University of Baltimore, and the University of Baltimore Law School (LL.B., 1959). Mr. Curran served in the United States Air Force during the Korean conflict, with duty in Japan and Korea.

Mr. Curran began his career in public service in 1958 when he was elected to the House of Delegates while still a law student. In 1962, he was elected to the State Senate where he served on the Judicial Proceedings Committee. During this time, he became an early advocate of open housing laws for Maryland, even though his home was picketed by angry demonstrators. In 1967, Mr. Curran was chosen as chairman of the Judicial Proceedings Committee and held that position for 16 years.

Under Mr. Curran, the Maryland Attorney General's Office has been a national leader in consumer protection, criminal investigations, Medicaid fraud prosecution, securities regulation, and antitrust enforcement. General Curran has been at the forefront in the battle to fight the war on gun violence in Maryland. In 1986, Mr. Curran played a leading role in the successful handgun referendum to ban over the counter sales of so-called "Saturday Night Specials" in Maryland. In October of 1999, General Curran released "A Farewell to Arms," a report which called for the unprecedented restriction on the ownership of handguns in an effort to reduce the epidemic of gun violence in Maryland.

In an effort to save lives and sharply reduce teen cigarette smoking, Mr. Curran made a historic decision when he recommended Maryland join the \$206 billion settlement proposal offered by the tobacco industry to 46 states, the District of Columbia, and five territories. As a result, Maryland received an award of \$4.4 billion.



"As Attorney General, I am the chief lawyer in the state. My office represents the state in all matters in which the state is a party or has an interest."

During General Curran's tenure, Maryland began efforts to limit children's exposure to media violence. Mr. Curran's report, "Tune it Out, Media Violence, Children, and Crime," concluded that Media Violence is responsible for approximately 15 percent of all juvenile crime. Following the release of the report, Curran's office provided more than 600,000 Media Violence Diaries, interactive tools for parents to monitor their children's exposure to violent material.

While in the General Assembly, Curran sponsored or was the leading spokesman for many significant bills, including those creating the Court of Special Appeals and the District Court system. He consistently supported bills to improve the courts and the corrections system, toughen drunk-driving laws, guarantee equal rights, and require handgun permits. He also sponsored legislation to modernize Maryland's divorce and alimony laws, reform adoption and guardianship laws, and protect victims of domestic violence. As Lieutenant Governor, Mr. Curran served as legislative liaison for Governor Hughes' Administration bills and was appointed to chair task forces on drunk driving, the insanity defense, victims services and liability insurance. As Executive Liaison with the Department of Economic and Community Development, Mr. Curran helped to bridge gaps between the public and private sectors statewide.

Mr. Curran is married to the former Barbara Marie Atkins. They are the parents of five children: Mary Carole, Alice, Catherine, J. Joseph III (Max), and William (deceased). Catherine is married to Baltimore City Mayor, Martin J. O'Malley. The Currans reside in the Homeland section of Baltimore City.

In the past decade, medical research has shown that the function of the immune system is the most critical element in the body's ability to naturally maintain or strengthen its state of health. Cancer, arthritis, AIDS, diabetes, chronic fatigue, M.S., and herpes all seem to stem from immune system deficiencies. Now, a new product named T-UP looks as if it could be

THE MOST NATURAL AND POWERFUL WAY TO

Boost Your Immune System

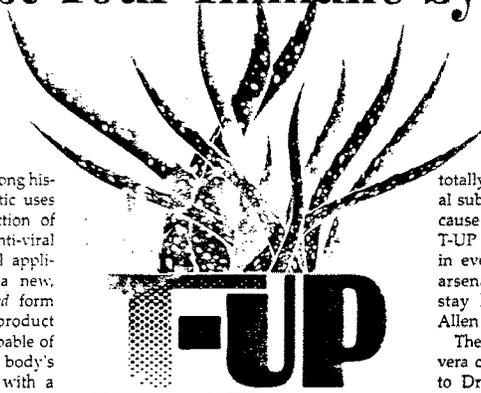
This statement has not been evaluated by the FDA.

Aloe has had a long history of therapeutic uses for burns, reduction of pain, as well as anti-viral and anti-bacterial applications. Now a new, highly concentrated form of Aloe in a product called T-UP is capable of boosting the body's immune system with a vengeance. In fact, T-UP appears to be capable of increasing T lymphocytes

and attacking cancer, AIDS, herpes, and other viruses like nothing else before it.

Developed and produced exclusively under the direction of Allen Hoffman, Ph.D., T-UP has the incredible attributes of being natural, nutritional and non-toxic as well as powerful.

What actually happens is that T-UP builds up the number of T-4 and T-8 lymphocytes in the body. Then, when the T-4s and T-8s increase to sufficiently balanced numbers, they actually help the body strengthen itself. It doesn't matter if you are involved in conventional treatment. T-UP is a



totally natural, nutritional substance and will not cause any harm. "In fact, T-UP probably should be in everyone's household arsenal to become and stay healthy," says Dr. Allen Hoffman.

The health value of Aloe vera comes as no surprise to Dr. Wendell Winters, associate professor of Microbiology at the University of Texas Health Science Center in San Antonio, who has been researching Aloe vera for the past 16 years. He authored his first major scientific paper on the plant in 1981. "In fact," says Winters, who heads the Phytobiology Research Department, "we think of Aloe as a pharmacy in a plant."

Another report from the M.D. Anderson Cancer Center suggests that the Aloe vera gel can stop immune system damage caused by sunburns. In fact, over one hundred studies in the past ten years show the efficacy of this extraordinary plant in a myriad of problems.

Among the one hundred forty substances contained in Aloe, there are several that reduce inflammation along with some that promote tissue growth and healing. In the past ten years, researchers around the world have confirmed the ability of Aloe, in highly concentrated solution, to stimulate the growth of white blood cells.

In 1994, Aloe vera was approved by the U.S. Food and Drug Administration for human testing against the human immune deficiency virus, HIV, which is believed to cause AIDS. Furthermore, the Dietary Supplement Health and Education Act of 1994 allowed public access to the use of naturally occurring substances for medical use. One of the most recent entries into this market is T-UP, a unique, highly concentrated product, of specially grown and specially processed Aloe. Clinical tests demonstrate the ability of T-UP to increase T lymphocytes which in turn produce cytokines which destroy microbes and cancer cells.

THE STOREHOUSE OF RESEARCH ON ALOE

The research studies of H. Reginald McDaniel, chief Pathologist at the Dallas/Fort Worth Medical Center, confirm the ability of Aloe vera to stimulate and dramatically strengthen the natural immune system.

According to McDaniel, "The material in this plant turns on the defensive intracellular mechanisms to fight against not only the viruses but also tumors." In fact, McDaniel, believing that the potential of Aloe extract is unmatched, says, "The development of the Aloe vera extract may be the most important single step forward in the treatment of diseases in the history of medicine."

On going research, begun in 1995 by Hoffman, Peterson, Bazzan and Hennessee involving the daily ingestion of the ultra-concentrated T-UP whole leaf Aloe vera product, has resulted in dramatic improvement in hundreds of patients. These findings confirm previous studies by McDaniel and other researchers in the U.S., Canada, Europe, and Japan.

THE DEVELOPMENT OF T-UP

One day, in 1994, Dr. Allen Hoffman was having lunch in a small clinic in Pennsylvania and started reading some old medical journals. These

NATURE'S NATURAL PHARMACY

IMMUNE FUNCTION BOOSTERS:

Aloe contains at least twenty three polypeptides (immune stimulators), which help control a broad spectrum of immune system diseases and disorders. The polypeptides plus the anti-tumor agents, emodine and lectins, explain Aloe's ability to control cancer.

NUTRITIONAL VALUE OF ALOE VERA:

Chemical analysis shows that Aloe vera contains vitamins, minerals, triglycerides, carbohydrates, amino acids, enzymes, and of course water. The vitamins found in Aloe include B-Complex, B-1, B-2, B-3, Choline, Folic Acid, C, and Carotene (a precursor to Vitamin A) all of which are vital to general health in body systems and some of which are vital to the formation of certain enzymes.

ANTI-CHOLESTEROL PROPERTIES:

The β -sitosterol, contained in Aloe, is also a powerful anti-cholesteromatic that helps to lower harmful cholesterol levels. This substance makes Aloe particularly beneficial for heart patients.

Many researchers have proposed a possible synergistic relationship between all of the substances contained within the Aloe vera plant. Synergistic means the ability of all the chemical and physical components of the plant, working together to effect a greater benefit than the total sum of each working individually. If

correct, this theory might explain the fact that Aloe presents no toxic or allergic effects, even though it contains agents which, if isolated and used alone, can cause toxic or allergic effects. It is obvious that further chemical examination of Aloe vera is required to determine what causes it to work.

articles described a method for treating HIV infected people that was almost 100% effective.

"These journal articles were almost 5 years old," he recalls. "At the time, I thought, if these things are five years old and we haven't heard of them, there must be something wrong. It probably doesn't work." But, Hoffman is a Ph.D. with credentials in chemistry, biology and medical technology.

FUNCTIONAL, ANTI-VIRAL, ANTI-BACTERIAL**THREE ANTI-INFLAMMATORIES:**

Aloe vera contains at least three anti-inflammatory fatty acids: cholesterol, campesterol and B-sitosterol (plant sterols) which make it a highly effective treatment for burns, cuts, scrapes, abrasions, allergic reactions, rheumatoid arthritis, and rheumatic fever. Taken as a liquid, it is helpful for acid indigestion, ulcers, and many other inflammatory conditions of the digestive system and other internal organs, including the stomach, small intestine, colon, liver, kidney, and pancreas.

ANTISEPTIC AGENTS:

The Aloe vera plant produces at least six antiseptic agents: lupeol, salicylic acid, pectin, urea nitrogen, cinnamonic acid, and sulfur.

The presence of these substances, which are recognized as antimicrobial agents or antiseptics because they kill or control mold, bacteria, fungus, and viruses, provide Aloe with the ability to eliminate many internal and external infections.

NATURAL PAIN KILLERS:

The lupeol and salicylic acid in the Aloe juice account for its effectiveness as a pain-killer.



He had spent twenty-three years in medical laboratories and he was curious. As a consequence, he created his own specially processed variation of the substance described in those papers and gave it to three people who were HIV infected and were very ill. He called the substance T-UP.

HIV, the human immunodeficiency virus, which has been associated with AIDS, attacks T-cells. Of

course, other viruses and some drugs also damage the immune system. Cancers can invade the bone marrow, halting the production of crucial immune cells. Chemotherapy, which works by selectively killing fast-growing cancer cells, will also kill fast growing immune cells, thereby suppressing immune function. In other cases, immunosuppressive drugs are deliberately prescribed to patients receiving a transplanted heart, kidney, or other organ to prevent its rejection as a foreign invader. In AIDS, physicians actually follow the course of the syndrome by specifically measuring the T-cell count.

Of crucial interest are helper T-cells, which stimulate antibody response and may also help create immunologic memory. Normally, a cubic centimeter of human blood contains more than five hundred helper T-cells; in AIDS patients the figure may approach zero.

"Yet, three weeks after having given these three people T-UP," says Hoffman, "their T cells were way up and we had three people who were literally jogging around the clinic." Next, he took that same formula to Baltimore, found people who were HIV infected, and gave it to them.

RESEARCHING T-UP ON AIDS VOLUNTEERS

The next round of research in Baltimore indicated that they could double the number of T4 lymphocytes, the cells that people with HIV lose, in roughly three weeks. But, it was evident that more than that was going on because people using the substance were saying they they had not felt that good in years. An increase in T cells alone could not create those results.

After some further research, Dr. Hoffman discovered that these patients were not only increasing the number of T cells but, at the same time, the P-24 core antigen, which is an indicator of the entire viral load, was being diminished. "We found that, upon exposure to the Aloe vera substance, numerous viruses were being destroyed. Most important to AIDS, was the discovery that cells coated with Aloe vera appeared to be protected from invasion by the HIV virus," explains Hoffman.

If the research team had the opportunity to treat some of these patients for eighteen consecutive months, approximately 50% of these people would sero-convert, meaning that there is a 50% chance of their blood testing negative at a medical laboratory. "However," he cautions, "even those

Our Poor Immune Systems

It has long been recognized that certain chronic, low-grade bacterial infections can protect against many degenerative diseases. As bacterial infections have come under control, the incidence of cancer and of viral disease has mounted inversely. The excessive use of antibiotics (and especially of the penicillins and tetracyclines) has a triple capacity for mischief. They can suppress the RES, encourage the emergence of antibiotic-resistant organisms, and, by removing the stimulus of infection on the immune system, impair resistance to subsequent infections.

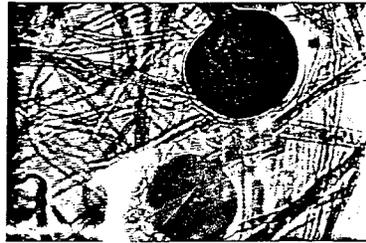
Elimination of low-level bacterial challenges by improved hygiene, vaccinations and antibiotics has probably atrophied our reticuloendothelial systems, even as our increasingly unhealthy environment and life styles burden them.

In the November 4, 1974 issue of Lancet, Dr. J.A. Raeburn, of the University of Edinburgh, suggested that the widespread use of antibiotics, especially at crucial stages of fetal development, may produce immunodeficient infants from genetically susceptible women. He noted that immunodeficiencies in newborns were first reported in 1952, after the use of antibiotics had become widespread. He considered it unlikely that these conditions had been previously overlooked from a lack of medical knowledge or unavailability of diagnostic tests. Ironically, antibiotics that revolutionized medical practice with cheap and effective control of many infections may also have produced immune-deficiency states.

patients who test negative for HIV may still carry the disease because, unfortunately, the HIV virus often hides in the lymph nodes. While this may sound disappointing," he adds, "it still represents a huge improvement in their health, an improvement in appearance, and an improvement in their quality of life. For many, it's a return to normalcy."

ALOE AND CANCER

Four months into the project something surprising happened. All of the cancers that accompanied AIDS began to disappear. As research progressed, they found that, when they stimulated the production of the T4 lymphocytes, they were



In essence, the entire immune system was being mobilized into a major defensive action. The interferon and interleukens were attacking the viruses, and the tumor necrosis factor, in concert with the naturally occurring emodines and lectins in Aloe, were destroying the malignant tumors.

also stimulating the production of interferon, interleukens and tumor necrosis factor. In essence, the entire immune system was being activated into a major defensive maneuver. The interferon and interleukens were attacking the viruses, and the tumor necrosis factor, in concert with the naturally occurring emodines and lectins in Aloe, were destroying the malignant tumors.

OFF SHORE MEDICAL TREATMENTS

While the oral consumption of T-UP stimulates some powerful defensive actions in the body, some individuals, with extremely advanced diseases do not have the luxury of the twelve or eighteen weeks needed to have the T-UP rev up their immune system. It is more time than they have

available. In those instances another solution is necessary.

While the FDA allows Aloe vera nutraceuticals to be orally ingested by humans, it allows veterinarians to inject these substances into animals. Research has shown that when you inject this directly into an animal tumor, that tumor often reduces more rapidly. But, people in this country do not have that option available.

"So," explains Hoffman, "we recommend that



"After destroying the malignant tumor, we expected to see a hollow breast that would require an implant and plastic surgery. Instead we were surprised to see the growth of new healthy tissue where the once malignant tissue had been."

patients, who are extremely ill, go to hospitals or clinics outside of this country where they can receive this substance both orally and intravenously. "In these facilities, they inject T-UP directly into the tumor and," observes Hoffman, "when they do this, it is nothing short of amazing."

TREATING BREAST CANCER OFF SHORE

A recent case involved a woman that mainstream medicine had given up on. She had three tumors in her breast, two were encapsulated and one was diffuse and metastasizing via the lymph nodes. It had spread to her lymph nodes and from there it was spreading to the rest of her body.

Everything indicated that she was going to die. So, the woman elected to pursue more aggressive Aloe treatment off shore.

Following ten days of such treatment, she returned to the United States with one tumor reduced by 40% and the other by 19%. The tumor that was diffuse, that is the tumor that was not encapsulated and was metastasizing to the rest of her body, was two centimeters smaller and completely encapsulated in normal tissue. The treatment was not only killing cancer cells, it was stimulating the production of new healthy tissue.

"I thought that after they destroyed the malignant tumor we would simply see a hollow breast that would require an implant and plastic surgery," recalls Hoffman. "Instead, we were surprised to see the growth of new healthy tissue where the once malignant tissue had been." After another sixteen weeks of oral consumption of T-UP, the patient's breast was restored to normal size and the patient showed no sign of cancer.

REBALANCING AUTO-IMMUNE DISORDERS

The ability to bring the body back to balance is particularly important in auto-immune problems where the body attacks itself, such as rheumatoid arthritis and lupus erythematosus. One characteristic of certain auto-immune diseases is demyelination, or losing the insulation on the nerve cells. Cells that produce myelin parallel the nerve pathways and provide insulation. People with an auto-immune disorder may have an immune system that attacks the nervous system and strips the insulation from the nerves.

"Forty million people in the world have AIDS. There are many more millions with cancer. One out of every six people in this country has been exposed to herpes. And obviously, if we can control one virus, we can control the others. So, we are talking about millions and millions of folks we can help. We are going to try and help as many as possible." Allen Hoffman

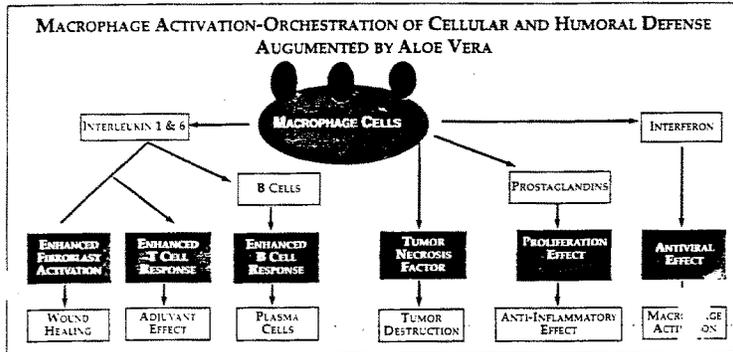
"One person with a neuropathy came to me about a year ago and wanted to be treated with T-UP." Hoffman wanted to help, but he was concerned, "You must get your doctor involved. If you are having an auto-immune disorder and I stimulate your immune system, it might make matters worse. It might even harm you."

However, what they found was that T-UP increased both T4 and T8 lymphocytes. So while the T4 lymphocytes stimulated the immune system, the T8 lymphocytes regulated the intensity of the auto-immune response. In that process, the T8s

Even patients who have had the gland removed find the Aloe solution valuable for removing any last traces of the cancer cells.

MANAGING THE HERPES VIRUS

One out of every six people in this country has been exposed to herpes. The herpes virus, much like many of the other viruses, can be controlled with the administration of Aloe vera. Furthermore, with direct exposure to the virus, the Aloe vera substance will be virocidal. Unfortunately, in herpes, the virus appears to hide beneath the



brought the immune system back into balance and, as the T-UP product slowed the auto-immune activity, the nerve damage stopped. Since then, they have treated numerous neuropathy cases successfully with T-UP.

ELIMINATING LIVER TUMORS WITH ALOE VERA

In the treatment of liver cancer, T-UP has been extremely successful because the liver is highly vascular and there is no problem getting into it. In a film produced by Dr. Reginald McDaniel, time lapse photography was done on a cancer patient who had seventeen liver tumors. The patient was considered terminal. After seventeen weeks of Aloe vera treatment by Dr. McDaniel, those gigantic grapefruit size tumors all disappeared.

In fact, T-UP is effective in the treatment of most malignancies except pancreatic and brain cancers. Prostate cancer, which is slow growing tissue, responds particularly well to treatment with T-UP.

myelin sheathing of the nerve cells. This means that, although the T-UP could kill millions of viral particles, some may escape, hide and reappear at a later time. However, while taking Aloe vera, one should not suffer an outbreak. There should be no sign or symptom that the virus is in the body.

Many young people who have herpes cannot afford to take this substance on a regular basis. In that situation, upon feeling the beginning of an outbreak, they can apply the Aloe vera both internally and externally. They can drink it and also rub some of the T-UP salve directly on those areas that are getting inflamed. The combined treatment will stop the outbreak and remove the discomfort. If they are lucky, they will not need to deal with the herpes for another three or more months.

RELIEVING GASTROINTESTINAL PROBLEMS

There are millions of people in this country that suffer with gastrointestinal problems such as

WHOLE LEAF ALOE...EVERYTHING YOUR BODY NEEDS

The current trend in medicine is to step back from viewing the body as an agglomeration of individual organs which can be treated with high tech medicines designed specifically to treat a particular disease or dysfunction. Implicit in this philosophy is that we focus on treating people rather than diseases. At the forefront of this effort is maintaining and strengthening the body's natural immune system. In addition to its ability to stimulate the immune system, Aloe has a wide range of nutritional elements that contribute to restoring health.

AMINO ACIDS: Aloe vera juice contains twenty of the twenty-two Amino Acids known to be needed for good nutrition; eight or nine of these are essential and must be supplied from an outside source because the body cannot manufacture its own. The other thirteen or fourteen can be built within the body by the essential eight or nine. Aloe has been shown to contain all of the essential eight or nine. The complete list of Amino acids known to exist in Aloe include lysine, histidine, arginine, aspartic acid, asparagine, threonine, serine, glutamine, hydroproline, proline, glycine, alanine, cystine, valine, methionine, isoleucine, leucine, tyrosine, glutamic acid, and phenylalanine.

CARBOHYDRATES: Carbohydrates assist digestion and assimilation of nutrients in food and supply energy for muscular exertion. They also control protein breakdown, the distribution of sodium, potassium, chloride, water balance, and are essential to healthy skin.

ENZYMES: Without enzymes, the chemical reaction of vitamins, minerals, and hormones cannot take place. Enzymes present in Aloe include alkaline phosphatase, sgotransaminase, sgptransaminase, lactic dehydrogenase, amylase, lipase, oxidase, peroxidase, catalase, bradykininase, camma transaminase, carboypeptidase and cellulase.

MINERALS: Aloe has been shown to contain as many as thirteen of the seventeen minerals needed for good nutrition. Minerals found in Aloe include calcium, magnesium, potassium, chloride, iron, zinc, manganese, copper, chromium, sulfur, aluminum and sodium. All these minerals are vital in the growth process and essential to the function of all body systems.

TRIGLYCERIDES: Triglycerides include fats, oils and waxes. They carry the fat soluble vitamins, provide the fatty acids essential for growth and general health of all body tissue and supply energy.

heartburn, ulcers, pancreatitis and Crohn's Syndrome. In these areas, Aloe's anti-inflammatory properties and nutritional elements work together to restore the body to health.

Dr Jeffrey Bland of the Linus Pauling Institute, in his medical paper, "Effect of Orally Consumed Aloe Vera Juice on Gastrointestinal Function in Normal Human Subjects", published in 1985, discusses the benefits of Aloe on the various problems that arise in the gastrointestinal tract.

HEALING OR HELPING

Today, research has shown that T-UP can bring the T4 lymphocytes up to normal levels. In the beginning, it can even create abnormally high levels of T cells to overwhelm the microbial invasion.

It will also diminish the viral load until it is virtually undetectable. But, of course, the real hope is, for some people and some diseases, that T-UP can boost the immune system sufficiently so that the body can maintain a healthy state all by itself and that no further therapy will be necessary.

Hoffman claims that this will be possible for some people, but not everyone. "Each illness presents new challenges. Some illnesses are chronic and need to be treated for a lifetime. Included in this category are rheumatoid arthritis, lupus erythematosus, HIV and herpes. However, illnesses that involve infective processes, such as chronic fatigue, cystitis and glomerulonephritis, require only a finite period of therapy."

BEWARE OF DILUTED PRODUCTS

T-CELL
PRODUCTION

*"a product needs a 25%
to 40% concentration
of Aloe to be effective."*

BRANDS A B C D E T-UP

Gene Hale, executive coordinator of the Aloe Science Council in Fort Worth, says you have to put enough Aloe in a product to make it work. Hale says most experts believe a product needs 25% to 40% to be effective. "You can't drink too much Aloe," Hale said. "Studies show the only way you can kill a rat with Aloe is to drown him in it."

What is really important for people to understand is that it would take approximately 63 gallons of the Aloe vera they can buy on the store shelves to equal just one teaspoon of the specially grown and specially processed, super concentrated T-UP product.

WILL ANY ALOE WORK?

T-UP is a specially grown, uniquely processed, highly concentrated Aloe product which is substantially different than anything available. In many of the Aloe vera products that you find on store shelves, they take two drops, put them in two quarts of water and then label the product "100% Aloe vera." The drops may have been pure Aloe but the product is highly diluted and mostly water.

What Hoffman's team found, in studying over one hundred research articles published in medical and scientific journals, is that there was a *direct correlation between the concentration of Aloe vera used, the dosage and the degree of success.* If you buy Aloe vera from the store shelves it would take between fifty to sixty-three gallons of that Aloe vera to equal one teaspoon of the T-UP concentrate. It is absolutely necessary to take at least enough Aloe concentrate to deliver 500 mg of mucosaccharides and 500 mg of polypeptides in order to stimulate T cells. With less than that amount, even 400 milligrams, nothing happens.

To date, T-UP has been taken by thousands of people. The only side effect is diarrhea, which affects less than 5% of the users, and this usually subsides within two or three days. This is controlled by cutting the dosage back significantly until the body acclimates itself to the substance.

Then the amount is brought back up to a full dosage and at that point there are no side effects. Safety studies submitted to the FDA show no toxicity in any of the tissues in the body. *The only way you could die from Aloe is to drown in it.*

WHERE IS T-UP AVAILABLE?

At this point in time the labs are capable of producing sufficient quantities of the T-UP substance to treat many thousands of people each week.

Physicians who are interested in using the product are offered a training program which explains the basic science, the treatment parameters such as dosage levels for various types of problems and the recommended duration of treatment.

T-UP is currently not available in drugstores and/or other retail outlets. T-UP can only be obtained from T-UP headquarters located in Baltimore, MD and some regional sales offices.

TO ORDER T-UP
TOGETHER WITH
INSTRUCTIONS FOR ITS USE
CALL: 410-486-5200
FAX: 410-486-1426

1838
Greene Tree
Road
Baltimore,
MD 21208



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T - UP, INC.

DESK REFERENCE MANUAL

CesiumTypes of diseases that are treated with Cesium

All soft tissue cancers - in the arms legs, chest, etc. We are approaching 100% success rate.

Early Pancreatic Cancer (within three to six months) it does a pretty good job. Late Pancreatic Cancer - doesn't do a very good job.

Breast Cancer - We have had 100% success rate.

Liver Cancer - Exceptionally well.

Leukemia - Fairly well.

Lung, Esophagus, Colon and Stomach Cancer - almost 100% success rate.

Wegener's Granulomatosis - We think so- we are not really sure. We are good with Renal cell kidney cancers.

Morton's Neuroma - Ask if the Neuroma is benign (normal tissue). If it is malignant we can kill it, if it is benign we cannot.

Hodgkins disease - Yes, just like cancer.

Melanoma - Yes, just like cancer.

***Brain Tumors - We cannot treat at all. We encourage people to go to an Oncologist and talk about Chemotherapy.

***When death is imminent, use surgery, radiation, or chemotherapy.

About Cesium

Cesium is a naturally occurring mineral in salt form attached to Chloride. Can be easily dissolved.

Cesium has a higher attraction for malignant cells and almost no attraction for normal cells. Within three days, it binds itself to the malignant tissue

and constantly alkalizes them. Tumors cannot live in an alkaline environment. Within ten days, 80% of a malignancy disappears. The other 80% in two - three months.

Treatment for Cancer Patients

Always Cesium and T-UP. The T-UP strengthens the immune system and attacks the tumors.

Dosage of T-UP - Most people start with 1 tsp.(5 ml) which equals to 1/2 capful every day for two - three days. Some as high as 4 tsp. a day mixed with 1 quart of water or juice. Drink 1/3 of this mixture in the morning, 1/3 during the day and remainder at bedtime. Soy lecithin and flax seed oil should be taken as supplements. They enhance the absorption of the aloe by 10 times. Take the recommended dosage on the container for the lecithin and flax seed oil. After the first three days, the aloe dosage may be increased up to 6 teaspoons. This should be done gradually. The treatment depends upon what patient has, age, and size. Cancer patients really need to get up to 4 teaspoons.

Side Effects

The only side effect from the T-UP has been diarrhea for the first two or three days. This is controlled by cutting the dosage back significantly until the body acclimates itself to the substance. Then the dosage is brought back up to a full dosage and at that point there are no side effects.

Dosage of Cesium

Take a minimum of 6 capsules (500 mg ea.) per day. This is sufficient to change the pH of malignant tissue to 8.5 or higher. Never take less than 3 grams per day in six tablets. It is six or more tablets a day or nothing. One or two tablets every hour of waking day. You will never get to a toxic dosage. Toxic level is (135 grams) or 270 capsules per day. No one will ever get to these levels. If the patient can tolerate taking more, then we suggest taking as much as 12 capsules which is ideal. Twelve capsules is the maximum.

Side Effects

Numbness of the lips, and nose. These are good signs that tell us the Cesium is working. Achy, flu like conditions when the Cesium is killing lots of cancer cells. If you cannot put up with these symptoms, call the doctor.

What is the cost for a typical cancer treatment?

Three months is approximately \$1,800.00. This treatment is not covered by insurance.

*****CHEMOTHERAPY WILL NOT INTERFERE WITH THIS TREATMENT. THEY HAVE SEPARATE PATHWAYS.**

Chemotherapy kills white cells and platelates. Destroys immune system.

About the Aloe

The aloe must be grown in a green house. We use the whole plant not just the gel. We do not use heat process we cold process the aloe. It takes 10 lbs. of aloe to make our 2oz. concentrate. The aloe must be grown hydroponically not in the ground. It is sterilized by filtering. The aloe has to be grown for about 18 months to be any good.

T-UP (Aloe)Types of problems that are treated with T-UP

AIDES patients - We cannot cure the disease AIDES, but we can treat the symptoms so that people can live normal lives. Approximately 50 % of the patients seroconvert after 18 months of treatment; 80% of those who do not seroconvert have an increase in T-4 lymphocytes; 98 % will live normal lives. There is a decrease in the viral load. The new cells are coated with the aloe and the virus cannot enter them. Optimal dose is 3 teaspoons per day. Start with 1 tsp. and work up.

Chronic Fatigue Syndrome - We can treat like any other viral infection. Within six weeks, lab work appears to be negative and patients were feeling better. Patients do not have to take forever usually six to eight weeks is enough. When its gone, its gone. Dosage: Up to 4 tsp. - gone in eight weeks.

Inflammatory Disorders - (Crohn's disease)-We stimulate T8 lymphocytes and suppress auto-immune. It just seems to disappear. The aloe is used as an anti-inflammatory - soothing. Patient should feel quite well in a number of weeks. Dosage: 1-4 tps. aloe . If they are sensitive, they should start out with 1/2 tsp. They should remain at the dosage that they feel the relief at.

Bladder and Kidney infections - T-UP is used as an anti-inflammatory and the infection can be wiped out within a day. The T-UP can be taken orally or in a douche form. Dosage: 1 - 2 taps. a day orally. Gone in 2 weeks.

Herpes - Herpes hides behind the myelin, behind the nerve. If they drink the T-UP every day, they will never have an outbreak again. We have the T-UP in a gel/paste for topical use. Drink for 1-2 days - outbreak disappears. If you take the aloe every day, you will never have an outbreak again. Dosage: Cheap way - just use the salve on the lesions.

MS - (Autoimmune disease). Stimulates T8s to suppress and patients will gradually improve over several months. We can't rebuild the myelin but we can stop the damage from occurring. Regrowing of the myelin takes some time but we can help. Dosage: Start with 1 tsp. and go up to 4tsp.

Shingles - Caused by the Herpes virus. (this is a retrovirus- we don't know if we can treat it). Start with 1 tsp. of aloe and go up to 4tsp. After it is gone, take minimum dose to suppress. We only know if you use the salve the outward appearance will disappear.

Osteoarthritis - The aloe acts as an anti-inflammatory which relieves pain. Taken on a regular basis to coat the joints and make it not painful. (90% success rate). Dosage : 1 - 4 taps.

Rheumatoid arthritis - The aloe stimulates the T8's to suppress the autoimmune destruction. It actually stops the disease from progressing, also stops the pain. We are approaching 100% success rate because it works on all people. 90% remission of signs and symptoms for all people. Dosage: Somewhere between 1-4 taps.

Lupus - (Autoimmune disease). The aloe stimulates the T-8's to suppress the autoimmune reaction. We have an a 100% success rate. Dosage: Patient needs to keep taking the aloe. This does not cure the disease.

Diabetes - Patients blood sugar level is usually reduced by about 50 mg% with regular use at minimal dose. The aloe is soothing for all people. This is something you would have to take on a regular basis. If blood sugar level is over 150mg %, then patient needs to be on insulin. The aloe in this case is not a great idea since they need to stay on the insulin. If patient is maintaining their blood sugar level by diet, this would be a great treatment.

Lou Gerrigs disease - We are not sure we will see.

Chronic Progressive M.S. - Patients seem to get better. The aloe stops the destruction over a period of a month.

Chronic Disruptive Pulmonary Disease - Yes, use the aloe in a nebulizer.

Environmental Disease - We will see. Patients need a team of Physicians and nurses.

Fibromyalgia - (sister to Chronic Fatigue). We don't know if we can treat it. Patients can give it a try.

Parkinsons Disease - No.

Legionnaires Disease - Yes this is bacterial. Patients should be on an antibiotic. This is easily treated with antibiotics.

Bronchitis - Yes. Spray with atomizer until gone. Use 1/8 oz. of the Aloe concentrate and 2oz. of saline in the atomizer.

Pneumonia - Easily treated with antibiotics. Ask if patient is being treated with antibiotics.

Diabetic Neuropathy - (deterioration of the joints). Caused by destruction of the myelin sheath, probably has severe diabetes. Shouldn't bother with the aloe. If their blood sugar is between 100 - 150 mgs. then it would be a great idea.

HPV (Human Papov Virus) - Yes. (This is a real serious problem). Start with 1 tsp. of the aloe and work up to 4 tsp. and use the salve. 1 capful of the aloe in a douche 2x a day. Once this is gone, it's gone.

Allergies - Yes. Orally 1 tsp. - 4 tsp. (as high as they can). Take as long as you're exposed to the allergen.

Candida - Yes. The aloe is used as an antifungal. Use 1 capful of the aloe in a douche 2x a day. Hard to get rid of. It's always there.

Psoriatic Arthritis - (1st. stage of Rheumatoid Arthritis). Treat like any other arthritis. 1 tsp. - 4tsp. of the aloe concentrate daily.

Hearthurn - We don't know.

Ulcers - Yes. 1 capful daily. Keep taking it until ulcers disappear.

Asthma - Yes. Use as needed in an atomizer or nebulizer. 1/8th oz. of the aloe concentrate and 2 oz. saline through the lungs.

About T-UP

Aloe strengthens the immune system by stimulating the growth of white blood cells. T-UP increases the T lymphocytes which in turn produce cytokines which destroy microbes and cancer cells. The material in this plant turns on the defensive intercellular mechanisms to fight against, not only the viruses, but also tumors.

The CHAIRMAN. Mr. Attorney General, thank you. Let me just ask you a quick question before we get to the others. Not only did you, I guess, show the product, aloe vera injections, did not cure cancer, it also produced some adverse side effects; didn't it?

Mr. CURRAN. We had testimony from our medical people that the product itself caused heart arrhythmia in animals. Now, they might say, "Well, we didn't have it on humans," but we know that the testing that was done on animals demonstrated it was an adverse effect, and the cardiologist, I believe, in California also testified for us that his patients, having taken this cesium, likewise had a problem.

I might add, in one of the publications they said—and this is very tricky—they said, "Well, our product has been studied by the FDA." The truth of the matter is—that is true. The FDA did, in fact, authorize a Canadian clinic to study this aloe impact on 12 AIDS patients, and they found out it did not work. But they were able to say we have had a clinical study permitted by FDA. It did not say, "Comma, and it didn't work." They just said, "Period." So that is how they can play with these ideas that FDA authorized a study. Sometimes they do, but when they found out that it does not work, they do not say that.

The CHAIRMAN. Thank you very much, Mr. Attorney General, for being with us and being so patient. We appreciate your testimony and the effort that you have made in this area. It has been outstanding.

Next, we will hear from the FDA and Mr. John Taylor.

Mr. Taylor.

STATEMENT OF JOHN TAYLOR, DIRECTOR, OFFICE OF ENFORCEMENT, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. TAYLOR. Good morning, Mr. Chairman, members of the committee. I am pleased to be here this morning to participate in this discussion of health fraud, specifically as it relates to dietary supplements. You do not have to look far to find a health product that is potentially fraudulent or a consumer who is totally unsuspecting. Promotions for fraudulent products appear daily in newspapers and magazine ads and television infomercials. They accompany products sold in stores and through mail-order catalogs. They are also passed along by word-of-mouth.

The Internet is another method by which fraudulent products can be promoted. As beneficial as this technology can be, it also creates a new marketplace for activity that is already illegal, such as the sale of unapproved new drugs, prescription drugs dispensed without a prescription, and products that are marketed with fraudulent claims about these health products' benefit. As you have pointed out, consumers respond to these promotions hoping to find a cure for their illness, to improve their well-being, or even their appearance.

In general, these promotions are not specifically targeted to one population, such as senior citizens, as the goal is to quickly establish a broad consumer base and maximize sales before being found out. Given the types of claims that these products make, one could

certainly extrapolate, however, that some of these products are intended primarily for senior citizens.

FDA is first and foremost a science-based public health agency. However, we are also a law enforcement agency. It is in both of these capacities that we strive to meet our mission of protecting consumers against health fraud. Strong law enforcement tools, coupled with a strong base of medical and scientific expertise to evaluate marketed health products are vital to the agency's ability to meet its mission in protecting the public health.

When Congress passed the Dietary Supplement Health and Education Act, it created a unique regulatory framework for dietary supplements. Its purpose was to strike the right balance between providing consumer access to and truthful information about dietary supplements, while preserving regulatory authority for FDA to take action against supplements that present safety problems or that are labeled or promoted in a false or misleading fashion.

As you know, the regulation of dietary supplements is, for the most part, a post-marketing program, and they are regulated by FDA's Center for Food Safety and Applied Nutrition, also known as CFSAN. In dietary supplement enforcement cases, the burden of proof is on FDA to show that a product or ingredient presents a risk after they are on the market. CFSAN, however, is not the only FDA center that plays a significant role in combating health fraud relating to dietary supplements, as many of the products the agency has successfully taken off the market were products marketed as dietary supplements that turned out to be drugs.

FDA's Center for Drug Evaluation and Research, or CDER, is responsible for ensuring that safe and effective drugs are available to the American public. They work to accomplish this mission through a commitment that lasts for the lifetime of the product, from the early stages of drug review and approval to monitoring the products once they reach the marketplace. FDA shares Federal oversight of dietary supplements with the Federal Trade Commission. FDA regulates safety, product monitoring and product labeling.

FTC has primary responsibility for regulating the advertising of these products. When a problem arises with a product regulated by FDA, the agency can take a number of actions to protect the public health. For dietary supplements, as with other products, initially the agency works with marketer of the products to correct the problem voluntarily. If that fails, we can ask the marketer to recall a product voluntarily, seek through the courts seizure of the product and/or injunctions against firms or individuals who market the products.

We can also detain or refuse entry of products presented for import at U.S. ports, and when warranted, criminal penalties, including prison sentences, are also sought through the courts. Health fraud can be brought to the agency's attention in a variety of ways. For example, FDA's investigators often identify violations while conducting inspections. FDA may also identify a violation or suspected fraudulent product through routine marketplace surveys, searches, consumer complaints, informants or through referrals from the FTC and other Federal, State or local government authorities.

Despite the complexities involved in building and bringing an enforcement action, the agency has been successful in bringing cases against fraudulent products in all categories of FDA-regulated products. There are several examples in my written statement of successful cases that the agency has brought in conjunction with the Department of Justice and, in some cases, the FTC. I would be happy to discuss any of these cases with the committee during questioning.

The agency has a number of other ongoing activities directed at combating health fraud. Many of these activities are the result of a strategy plan begun by FDA in 1992 to improve its processes for targeting and coordinating regulatory activities among its various components and Federal, State, local regulatory and law enforcement agencies. This strategy also focused on improving the agency's efforts to educate the public about the importance of making wise choices concerning their health care. The full range of activities is described in my written statement, but let me give an example. In 1992, FDA began sponsoring a national health fraud working group. The working group is currently comprised of representatives from the Association of Food and Drug Officials, the National Association of State Attorney Generals, FTC, Health Canada and FDA representatives from its various components.

This group meets on a regular basis to facilitate the coordination of regulatory activities, information exchange and leveraging of each member agency. In addition, the agency is engaged in several consumer education efforts with the FTC, including a facts-for-consumer brochure entitled, "Miracle Health Claims: Add a Dose of Skepticism," that is focused on fraudulent claims and spotting quackery and health fraud.

FDA has also made Internet surveillance an enforcement priority. The agency's partnership with the FTC and others in Operation Cure-All further demonstrates FDA's commitment to monitoring violative conduct on the Internet. Over the past 2 years, FDA has sharpened its focus on the issue of Internet promotion and the sale of drugs as online activities have expanded. While FDA tries to be vigilant against health fraud, many fraudulent products escape regulatory scrutiny, maintaining their hold on the marketplace for some time to lure increasing numbers into their web of deceit. For every such marketer that we put out of business, another or more appear. As long as there are vulnerable populations to prey upon, there will continue to be those unsavory and unscrupulous characters who do so.

Mr. Chairman, combating health fraud is a challenge, especially in light of the advent of the Internet, and one to which the agency is committed to addressing. Our partnership with our law enforcement, public health, State and local, and international colleagues expands FDA's reach and impact. Good enforcement strategies and enforcement actions, vigilant oversight of the marketplace, and sufficient legal authority to remove these products from the market is not enough. Successfully combating health fraud must include educating our citizens to recognize fraud when they see it and warning them of the potential dangers that some of these products pose. Only through these steps can we help the public make fully informed decisions about their health care purchases, and thereby re-

duce the number of people who may fall prey to these fraudulent products.

Thank you for the opportunity to participate in this hearing. We look forward to working with you as we grapple with health fraud as a Nation. I would be happy to answer any questions you might have.

[The prepared statement of Mr. Taylor follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Statement of

John M. Taylor

Director, Office of Enforcement, Office of Regulatory Affairs

Food and Drug Administration

Before the

**Special Committee on Aging
John B. Breaux, Chairman**

United States Senate

September 10, 2001

Release Only Upon Delivery

Introduction

Good morning, Mr. Chairman, Members of the Committee. I am John M. Taylor, Director, Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration (FDA or the Agency). I am pleased to be here this morning to participate in this discussion of “health fraud,” specifically as it relates to dietary supplements. I will describe FDA’s role, some successes, and challenges in combating this threat to public health – particularly as it is targeted to our senior citizens and other vulnerable populations.

Health Fraud

What is health fraud? Health fraud is the deceptive promotion, advertising, distribution, or sale of articles represented as being effective to diagnose, prevent, cure, treat, or mitigate an illness or condition, or provide a beneficial effect on health but has not been scientifically proven safe and effective for such purposes. You do not have to look far to find a health product that is potentially fraudulent, or a consumer who is totally unsuspecting. Promotions for fraudulent products appear daily in newspaper and magazine ads and television “infomercials.” They accompany products sold in stores and through mail-order catalogs. They also are passed along by word of mouth.

The Internet is another method by which fraudulent products can be promoted. The use of the Internet by our nation’s citizens, from school age children to seniors, has opened

up vast new opportunities for the exchange of information and for enhancing commerce in all types of consumer products. The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors in the nation's finest academic health centers. The Internet also permits an increasing number of individuals to obtain a plethora of medical information that often helps them to understand health issues and treatment options. As beneficial as this technology can be, it also creates a new marketplace for activity that is already illegal, such as the sale of unapproved new drugs, prescription drugs (Rx) dispensed without a prescription, and products marketed with fraudulent claims about health benefits. Furthermore, because the Internet is a worldwide communications system, U.S. citizens are now susceptible to fraud from sources outside the U.S. as well as domestically.

Consumers respond to these promotions, spending billions of dollars a year on fraudulent health products, according to Stephen Barrett, M.D., head of Quackwatch Inc., a non-profit corporation that combats health fraud. Hoping to find a cure for their illness, improve their well-being, or even their appearance, consumers often fall victim to products and devices that do nothing more than cheat them out of their money, steer them away from useful proven treatments, and possibly do more harm than good.

In general, these promotions are not specifically targeted to one population – such as senior citizens – as the goal is to quickly establish a broad customer base and maximize sales before being “found out.” Given the types of claims that these products make,

however, one could certainly extrapolate that some of these products are intended primarily for senior citizens. While FDA's law enforcement efforts cannot be defined by population and demographics, our education and outreach efforts do certainly strive to reach specific populations, which I will describe later.

FDA's mission is to protect and promote the public health. While we are first and foremost a science-based public health agency, we also are a law enforcement agency. It is in both of these capacities that we strive to meet our mission of protecting consumers against health fraud. Strong law enforcement tools – including a cadre of seasoned law enforcement agents and sufficient statutory authority – coupled with a strong base of medical and scientific expertise to evaluate marketed health products are vital to the Agency's ability to meet its mission of protecting the public health.

Let me first provide a brief background on dietary supplements and drugs and the statutory framework under which they are regulated.

Background

Dietary Supplements

Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product that is ingested, is intended to supplement the diet and, among other requirements, contains a "dietary ingredient." The "dietary ingredients" in these products may include vitamins, minerals,

herbs or other botanicals, amino acids, and dietary substances such as enzymes. Dietary ingredients also can be metabolites, constituents, extracts, concentrates, or combinations of the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, liquids, or bars. Information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Instead, DSHEA placed dietary supplements in a special category under the general umbrella of “foods” and requires that every supplement be labeled as a dietary supplement.

The dietary supplement industry has grown exponentially since the enactment of DSHEA. Today’s multi-billion dollar dietary supplement industry is now one of the world’s fastest growing industries. In the past, dietary supplements were mainly sold to adults in health food stores. These products can now be purchased in supermarkets, retail stores, and even through the Internet, making them available to a much wider range of consumers of all ages.

The Washington Post reported last month on just herbal supplements. The Post stated that “Americans alone bought \$4.5 billion worth of such popular preparations as St. John’s wort, echinacea and many others. . . .” Further, according to a graph in the article, the \$4.5 billion spent by Americans last year is up from around \$3 billion in 1996. The full range of dietary supplement product sales is reported to have reached \$17.1

billion in 2000.¹ Between 1994 and 2000, consumer spending on dietary supplements nearly doubled, and sales continue to grow at better than ten percent a year.²

In a survey conducted last year by PREVENTION Magazine (“Survey of Consumer Use of Dietary Supplements,” Rodale Press, 733 Third Ave., New York, New York 10017-2000) over 158 million consumers use dietary supplements. Further, the survey found that consumers use dietary supplements to help them achieve their self-care goals and as a means of ensuring good health. They also use them for “medicinal” purposes such as treating and preventing various illnesses, colds, flu, increasing mental sharpness, and alleviating depression. The consumer’s desire for self-care and the widespread use of dietary supplements raises a number of issues, including the possibility of:

- harmful interactions between dietary supplements and prescription or over-the-counter (OTC) pharmaceutical products;
- substituting unproven treatments for proven medical treatments;
- taking products that have no health benefit;
- adverse effects; and,
- the focus of this hearing – health fraud.

When Congress passed DSHEA, it created a unique regulatory framework for dietary supplements. Its purpose was to strike the right balance between providing consumers access to dietary supplements and truthful information about them, while preserving

¹ “U.S. Dietary Supplements Market Size Expressed as Dollar Sales by Top Six Product Categories for 1994 to 1998 and Forecast for 1999 and 2000,” National Business Journal, 2000, Dialog file No. 93, San Francisco: The Dialog Corporation, 2000.

² Nutrition Business Journal, San Diego, 1998.

regulatory authority for FDA to take action against supplements that present safety problems or that are labeled or promoted in a false or misleading fashion.

As you know, the regulation of dietary supplements is, for the most part, a post-marketing program, and they are regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN). Since Congress considered dietary ingredients marketed prior to the passage of DSHEA to be safe, dietary supplements containing these ingredients are permitted to be freely marketed, just like regular foods (e.g., fresh fruits and vegetables, processed foods and beverages, and seafood). Should safety problems arise after marketing, the adulteration provisions of the statute come into play. Under DSHEA, a dietary supplement is adulterated if, among other reasons, it or one of its ingredients presents "a significant or unreasonable risk of illness or injury" when used as directed on the label or under normal conditions of use (if there are no directions). The burden of proof is on FDA to show that a product or ingredient presents such a risk.

Drugs

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to assure that safe and effective drugs are available to the American public. They work to accomplish this mission through a commitment that lasts for the lifetime of the product – from the early stages of drug review and approval to monitoring the products once they reach the marketplace.

Consumers usually think of drugs as the medicines they take to treat illnesses, but most Americans use CDER-regulated drug products every day to maintain health. Drugs

include more than just medicines. For example, fluoride toothpastes, antiperspirants, dandruff shampoos, and sunscreens are all considered “drugs,” within the meaning of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Most drugs CDER regulates are manufactured by a chemical process. They can include:

- Prescription drugs: medicines that must be administered under a doctor’s supervision or require a doctor’s authorization for purchase;
- OTC drugs: medicines that are available to consumers without a doctor’s prescription. Consumers can successfully diagnose many common ailments and treat them with readily available OTC products; and,
- Generic drugs: medicines that are chemical clones of a drug sold under a brand name. There are generic versions of prescription drugs and OTC drugs.

Ailing Americans and their health care providers have at their disposal more than 10,000 FDA-approved drugs that have met the world’s most rigorous reviews for safety and effectiveness. Drug companies seeking to sell a “new drug” in the U.S. must first test it, and prove that it is safe and effective for its intended use before it can be approved for marketing. CDER adheres strictly to its high requirements for drug approval, which are recognized as the world’s gold standard.

Among its other activities, CDER is taking steps to make drugs safer for older adults, who consume a proportionately larger share of the nation’s medicines. Adults over 65

buy 30 percent of all prescription drugs and 40 percent of all OTC drugs. Almost every drug that comes through FDA for approval has been examined for effects in the elderly.

In 1997, FDA finalized a rule that requires drug companies to include a separate “Geriatric Use” section in their drugs’ labeling. Drug companies do not have to perform additional studies, but must include available information in a specific format and location on the label.

Of all the problems older adults face in taking medications, drug interactions are probably the most dangerous. When two or more drugs are mixed in the body, they may interact with each other and produce uncomfortable or even dangerous side-effects. This is especially a problem for older adults because they are much more likely to take more than one drug. Two-thirds of adults over the age of 65 use one or more drugs each day, and one-quarter of them take three drugs each day.

There also is evidence that older adults tend to be more sensitive to drugs than younger adults, because of their generally slower metabolism and organ functions. As people age, they lose muscle tissue and gain fat tissue, and their digestive systems, liver, and kidney functions diminish. All this affects how a drug will be absorbed into the bloodstream, react in the organs, and how quickly it will be eliminated. Not all combinations are bad. However, unless supervised by a doctor, taking a mixture of products can be dangerous.

FDA as a Law Enforcement Agency

As I mentioned, while we are a science-based public health agency, FDA also is a law enforcement agency. FDA is charged with protecting American consumers by enforcing the FD&C Act, its implementing regulations, and several related public health laws (e.g., the Public Health Service [PHS] Act).

FDA shares Federal oversight of dietary supplements with the Federal Trade Commission (FTC). FDA regulates safety, product manufacturing and product labeling. FTC has primary responsibility for regulating the advertising of these products.

When a problem arises with a product regulated by FDA, the Agency can take a number of actions to protect the public health. For dietary supplements, as with other products, initially, the Agency works with the marketer of the product to correct the problem voluntarily. If that fails, the Agency also can ask the marketer to recall a product voluntarily; seek, through the courts, seizure of violative products and/or injunction against firms or individuals who market violative products, and detain or refuse entry of products presented for import at U.S. ports. When warranted, criminal penalties – including prison sentences – are sought through the courts, as well as against those who violate the law.

As an agency that protects the health of all Americans, FDA must keep in touch with consumers and firms dealing with regulated products all over the U.S. FDA's ORA is the lead office for all field activities for the Agency, and represents about one-third of FDA's personnel. Stationed in more than 150 District Offices, Resident Posts and Laboratories from coast to coast and in Puerto Rico, ORA's highly trained staff provides the eyes, ears, and long arm of the Agency that assures the implementation of FDA's public health standards.

Some of the major activities of ORA include:

- Consumer Safety Officers and inspectors conduct about 16,000 domestic and foreign inspections per year to assure that regulated products destined for the U.S. market are in compliance with the law and meet the Agency's standards;
- Scientists in ORA's 13 laboratories analyze about 30,000 products each year to determine their adherence to the law and the Agency's standards; and,
- Public affairs specialists reach out to consumer groups, health-care professionals, and State health authorities to explain FDA policies and encourage compliance with the law and FDA standards.

My office, the Office of Enforcement (OE), is one of four offices in ORA. OE is the lead office for setting regulatory and compliance policy for the Agency, and coordinates and directs FDA's overall compliance efforts.

In addition, the Office of Criminal Investigations (OCI), within ORA, is FDA's criminal investigative arm. OCI is a traditional criminal investigative agency staffed by experienced Special Agents drawn from a wide variety of agencies throughout Federal law enforcement. Their job is to identify and investigate suspected criminal violations of the FD&C Act, PHS Act, and related Title 18, United States Code violations.

ORA works in close cooperation and coordination with all of FDA's Centers (the Centers) in enforcing the law. With regard to health fraud specific to dietary supplements, CFSAN has the lead and is responsible for the oversight of dietary supplements. CDER also has a role to play, as many of the most successful cases the Agency has brought concerned products purporting to be dietary supplements that were actually drugs within the meaning of the FD&C Act and failed to meet the regulatory requirements that drugs must meet prior to their introduction into interstate commerce.

How A Case Is Made

Health fraud, as with any other violation of the FD&C Act or PHS Act, can be brought to the Agency's attention in a variety of ways. For example, FDA's investigators often identify the violations while conducting inspections. FDA may also identify a violation or a suspected fraudulent product through routine market-place surveys, searches on the Internet; adverse event reports; complaints from consumers; competitors or public interest groups; informants; or through referrals from the FTC or other Federal, State, or local government authorities.

As with all of FDA's activities, priorities are established based on benefit/risk to public health. The Agency's regulation of health fraud products is based on a priority system that depends on whether a fraudulent product poses a direct or indirect risk to public health. The susceptibility of the population is an element that is considered when determining risk. For example, terminal cancer patients would be considered highly susceptible, as many have exhausted conventional or standard of care treatments, and are desperate to try anything that may promise a cure.

Products that present a direct health hazard to the user are the Agency's highest priority. Such products include those, which have a reasonable potential for causing direct serious adverse effects, or there is documentation of injury or death. Examples of such products include tiratricol, dinitrophenol, and gammabutyrolactone (GBL). When such products are encountered, the Agency will use all available civil and administrative remedies to assure that the product is quickly removed from the market. Publicity is used to warn consumers and health professionals about such products. The decision to open a criminal investigation is based primarily on the public health threat level, indications of criminal intent, and the scope of the violation, as well as the potential impact of an effective prosecution.

Products that are not themselves hazardous can still present an indirect health hazard in that the consumer may delay or forego proven medical treatment and the use of proven

drug therapies. Examples include unproven products promoted for the treatment of cancer, Alzheimer's disease, arthritis, heart disease, and high blood pressure.

In addition to these direct and indirect health risks, priorities are also established with respect to risks posed by such products in undermining the integrity of the new drug application (NDA) and OTC Drug Review processes. The NDA and OTC Drug Review procedures provide consumers with assurance that Rx and OTC Drugs are both safe and effective. To avoid undermining these procedures, it is essential for FDA to maintain vigorous surveillance, provide prompt industry guidance and outreach, and take enforcement action regarding fraudulent products. Coupled with a credible threat of enforcement, the Agency's actions assure that manufacturers are properly motivated to bear the costs of developing "new drugs" in conformance with the NDA provisions and that the playing field is fair and equitable for those who do.

Examples of FDA Enforcement Actions

Despite the complexities involved in building and bringing an enforcement action, the Agency, working with the Department of Justice's (DOJ) Office of Consumer Litigation, has been successful in bringing cases against fraudulent products in all categories of FDA-related products. Let me discuss a few examples.

Christian Brothers

Last November, Christian Brothers Contracting Corporation and its President, Jason Vale, signed a consent decree of permanent injunction in which they agreed to stop manufacturing, processing, and distributing the firm's amygdalin products, also referred to as Laetrile, Vitamin B-17 or apricot kernels. This case was developed in conjunction with the FTC and DOJ. Despite repeated warnings by FDA, the products continued to be promoted through numerous websites for the cure, treatment, and prevention of cancer.

Amygdalin is a glucoside found in the kernel or seeds of many fruits and is frequently referred to as "Laetrile" or "Vitamin B-17." While some of the proponents have recommended it for the treatment and control of cancer, FDA has never approved these claims. There are no published clinical studies that demonstrate that laetrile is safe and effective and cancer patients who take it sometimes forgo conventional therapies to their detriment.

World Without Cancer Inc., The Health World International, Health Genesis Corporation, and David E. Arjona, an officer of the three corporations

Last summer, FDA and DOJ, with the assistance of FTC, sought a temporary restraining order, preliminary injunction, and permanent injunction against the marketing of unapproved new drugs by three corporations and one individual. The products, laetrile, in injectable and tablet form, and apricot seeds, were promoted as cancer treatments

through their Internet websites. Despite FDA warnings to these companies in 1998, they continued to promote their products as remedies for cancer. In January 2001, District Court Judge Shelby Highsmith entered a Consent Decree of Permanent Injunction in this case with regard to defendants World Without Cancer, Health Genesis Corporation, and David E. Arjona. The preliminary injunction and Consent Decree of Permanent Injunction required the defendants to cease using the websites to promote the sale or offer for sale their laetrile products.

United States v. Syntrax Innovations, Inc., et al

This case involved a drug called Triax Metabolic Accelerator, marketed by Syntrax as a dietary supplement for the treatment of obesity and to promote weight loss. FDA scientists determined that Triax posed a serious health hazard to those who consumed the product. The product contained tiratricol, a potent thyroid hormone, that FDA medical review identified as a hazardous compound that could cause heart attacks and strokes. FDA alleged that Triax could not be a dietary supplement because it was promoted to treat a disease (obesity) and because it did not contain any of the dietary ingredients identified in the definition set forth in DSHEA.

This case began as a seizure by DOJ, but the government amended the complaint to request injunctive relief. Syntrax originally contested the case, but later conceded that Triax is a drug. On February 14, 2001, a District Court Judge entered an order of injunction to prevent the distribution of Triax by Syntrax Innovations.

Hit Products

This case demonstrates the extremes to which promoters of fraudulent products will go to create a market for their products. These products were marketed towards a younger consumer base. Hit Products, Inc., and Organic Diversions, Inc., were marketing products made from a mixture of herbs that promised users effects comparable to illegal street drugs. FDA categorized these products as “street drug alternatives” and charged that they were misbranded and unapproved new drugs in violation of the FD&C Act. Therefore, the government seized the violative products.

The court found FDA’s position on street drug alternatives “highly persuasive” and criticized the defendant’s characterization of the products as dietary supplements as a “veiled attempt to circumvent” the FD&C Act. The court “decline[d] to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by masquerading potentially dangerous substances as dietary supplements.” This case was the Agency’s first suit following issuance of a guidance document in April 2000 informing the public that any product promoted as an alternative to illegal street drugs would be regarded by FDA as a misbranded and unapproved new drug.

Nature’s Nutrition Formula One

FDA determined that this pre-DSHEA product, which was marketed between 1992 and 1994 as an all natural “nutritional supplement” that contained plant ingredients, was

actually made with two pharmaceutical-grade chemicals, ephedrine hydrochloride and caffeine anhydrous. FDA received more than 100 reports of injuries and adverse reactions related to the product, ranging from serious and life-threatening conditions, such as irregular heartbeat, heart attack, stroke, seizures, hepatitis and psychosis, to relatively minor and temporary conditions such as dizziness, headache and gastrointestinal distress. At least one death was associated with the use of this product.

This case was developed by the alerts provided from the adverse event reports, ORA's field staff, and the work of OCI together with DOJ. FDA learned that the Chemins Company, Inc., which manufactured the product, went to great lengths to hide its actions from the Agency and concealed the actual ingredients of Formula One. As a result, the government initiated a criminal prosecution against the company and its president, James Cameron.

On July 7, 2000, a Federal judge sentenced James Cameron to 21 months in jail and fined him and this corporation \$4.7 million. In his plea agreement, Mr. Cameron admitted that he and his company labeled Formula One as "all natural" but secretly spiked the product with synthetic ephedrine hydrochloride and caffeine anhydrous. He also admitted that the product's labeling failed to disclose the use of the chemicals on the list of ingredients, and that he and his employees had misled FDA investigators and hindered inspections of Chemins. The sentence marked the culmination of a three-year investigation. Mr. Cameron, whose company continues to make dietary supplements, began serving his sentence in September 2000.

In addition, FDA and DOJ have pursued seizures of a number of unapproved drugs that have been promoted on the Internet as dietary supplements, including GBL and 1,4-butanediol. FDA also has sought product recalls and achieved the voluntary destruction of 18 products containing these substances.

Other Activities To Combat Health Fraud

The Agency has a number of ongoing activities directed at combating health fraud. Many of these activities are the result of a strategy plan begun by FDA in 1992, to improve their processes for targeting and coordinating regulatory activities between ORA, field, headquarters units, the Centers, Office of General Council and other Federal/State/local regulatory and law enforcement agencies. This strategy also focused on improving the Agency's efforts to educate the public about the importance of making wise choices concerning their health care.

Health Fraud Working Group

In 1992, FDA began sponsoring a National Health Fraud Working Group. The Working Group is currently comprised of representatives from the Association of Food and Drug Officials, State Attorneys General, FTC, Health Canada, and FDA representatives from the center and field offices. This group meets on a regular basis to facilitate the coordination of regulatory activities, information exchange, and leveraging of each member agency.

The Working Group is currently considering ways in which their activities and outcomes can be improved upon. Preliminary discussions include the benefits that may be achieved by expanding the membership to include representatives from non-governmental organizations that combat health fraud.

AIDS Health Fraud Task Force Network

FDA sponsors a network of AIDS Health Fraud Task Forces throughout the U.S. The Task Forces, which are currently located in 19 States, maintain a proactive approach to combat fraudulent products and treatments affecting people with HIV/AIDS and their families. The network strives to promote awareness and prevent fraud through education that empowers individuals to make informed decisions about their health care. The Task Forces have developed hotlines, workshops, conferences, and advocacy sharing as an alert mechanism to new fraudulent product promotion. The media has been utilized to broaden awareness in the diverse communities that are served by the Task Force. Members of the Task Force Network include persons living with HIV/AIDS, community-based organizations, treatment advocates, health care practitioners, educators, Federal and State government officials, and local health departments.

“Operation Cure.All”

In 1997, FTC, FDA, Health Canada, and various State Attorneys General organized and implemented an ongoing and comprehensive law enforcement and consumer education campaign against the fraudulent marketing of supplements and other health products on the Internet. The agencies have moved to stop Internet scams for supplements and other

products that purport to cure cancer, HIV/AIDS and countless other life-threatening diseases.

FDA has made Internet surveillance an enforcement priority; the Agency's partnership with FTC, and others, in "Operation Cure.All," further demonstrates FDA's commitment to monitoring violative conduct on the Internet. Collaboration on all "Operation Cure.All" activities maximizes FDA's effectiveness in communicating to the Internet community that the various regulatory and law enforcement agencies are working together to combat health fraud. All activities are coordinated in order to ensure consistent results in areas where FTC, FDA, the States and Health Canada have jurisdiction.

Since its inception, "Operation Cure.All" has resulted in 48 cyber-letters directed at sites selling colloidal silver products with egregious disease claims as well as several enforcement activities directed against the marketing of fraudulent products.

In addition, the Agency has engaged in several consumer education efforts with FTC including a "Facts for Consumers" brochure that is focused on fraudulent claims and spotting quackery and health fraud. Today, we are announcing with FTC the publication of a recently revised brochure, "Miracle Health Claims: Add A Dose of Skepticism."

Internet Activities

Over the past several years, FDA has sharpened its focus on the issue of Internet promotion and sale of drugs as online activity has expanded. In 1996 and again in 1999 FDA held public meetings to discuss and examine the issue of promoting, prescribing and dispensing drugs online.

In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan to expand and improve its activities in addressing the unlawful sale of drugs over the Internet. The illegally marketed drugs targeted by the plan include a variety of fraudulent products, including counterfeit drugs, drugs marketed with fraudulent health-related claims, and unapproved new drugs masquerading as dietary supplements. The plan is based on internal deliberations, meetings with Federal and State regulatory and law enforcement bodies, as well as organizations representing consumers, health care practitioners, and the pharmaceutical and pharmacy industries. The elements of the plan include, among others:

- Public Outreach: FDA Talk Papers, articles in the *FDA Consumer* magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online.
- Professional Outreach and Partnering: Periodic meetings with State and Federal regulatory and law enforcement bodies, consumers, health care practitioners and industry to share information and strategize about how to address the challenges the Internet presents.

- Coordinating Activities with other State and Federal Agencies: Established cooperative working relationships with DOJ, the Drug Enforcement Administration, the Federal Bureau of Investigation, FTC, U.S. Postal Service, U.S. Customs Service, and other appropriate Federal and State law enforcement agencies.
- International Cooperation: Because FDA and other Federal agencies possess limited investigatory jurisdiction over sellers in foreign countries, we must work with foreign governments to bring action against such individuals.

Take Time To Care Campaign (TTTC)

One of the Agency's most successful campaigns has been FDA's Office of Women's Health (OWH), "Take Time To Care" Campaign. While the campaign is not specifically targeted to preventing or educating against health fraud, the success of the program in educating women about using medicines wisely certainly should lessen the chances that the women educated will fall prey to the marketers of fraudulent products.

Started in 1997 as a pilot, expanded in 1998, and rolled out nation-wide in 1999, the intent of the campaign was to educate women and their families about safe medicine use. The key element of the campaign is the "My Medicines" brochure. Colorful and compact, it includes tips for taking medicines correctly as well as a personal record card for tracking medicine use. Like the entire TTTC campaign, the brochure is designed

primarily for women, who use more medication than any other group and often manage medications for their whole family. The purse-sized brochure promotes four key messages: Read the Label, Avoid Problems, Ask Questions, and Keep a Record.

In order to maximize FDA's OWH impact, the OWH initiated partnerships with local health and social service organizations, pharmacies, senior centers, religious congregations, universities, women's groups, and workplaces. In 1999, the National Association of Chain Drug Stores (NACDS) joined OWH as an official co-sponsor. As a result of their work and innovative collaboration, the campaign in partnership with 80 national organizations and NACDS distributed over 6 million "My Medicines" brochures in a single month. This now successful national campaign was the subject of a presidential proclamation and received a public endorsement from the American Medical Association.

Conclusion

While FDA tries to be vigilant against health fraud, many fraudulent products escape regulatory scrutiny, maintaining their hold in the marketplace for some time to lure increasing numbers into their web of deceit. For every such marketer that we put out of business, another or more appear. As long as there are vulnerable populations to prey upon, there will continue to be those unsavory and unscrupulous characters who do so.

Mr. Chairman, combating health fraud is a challenge, especially in light of the advent of the Internet, and one to which the Agency is committed to addressing. Our partnerships with our law enforcement, public health, State, local and international colleagues expand FDA's reach and impact. Good enforcement strategies and enforcement actions, vigilant oversight of the marketplace, and sufficient legal authority to remove these products from the market is not enough. Successfully combating health fraud must include educating our citizens to recognize fraud when they see it, and warning them of the potential dangers that some of these products pose. Only through these steps can we help the public make fully informed decisions about their health care purchases, and thereby reduce the number of people who may fall prey to these fraudulent products.

We have a strong education program, and we applaud hearings such as this, which bring this issue to national prominence. Thank you for the opportunity to participate in this hearing. We look forward to working with you as we grapple with health fraud as a nation. I would be happy to answer any questions you might have.

The CHAIRMAN. Thank you, Mr. Taylor. Right on time.
Mr. Beales, welcome.

**STATEMENT OF HOWARD BEALES, DIRECTOR, BUREAU OF
CONSUMER PROTECTION, FEDERAL TRADE COMMISSION,
WASHINGTON, DC**

Mr. BEALES. Thank you Mr. Chairman, members of the committee. I am Howard Beales, Director of the Bureau of Consumer Protection at the Federal Trade Commission. I am pleased to have the opportunity to testify at this important hearing. The Commission's full statement, which we have submitted for the record, are the views of the Commission, but my oral statement and my responses to questions are my own and may not reflect the views of the Commission or any individual commissioner.

The FTC is the nation's primary general jurisdiction consumer protection agency. Protecting consumers from false, deceptive or unsubstantiated health claims has long been an essential part of our mission. We believe these efforts are important, because health fraud often targets a very vulnerable segment of our population, those suffering from serious or incurable health conditions and diseases. In such circumstances, even outrageous claims that ordinary consumers would dismiss as fraudulent can be, and are, effective.

These false, misleading and unsubstantiated health claims can injure consumers in a number of ways. First, they cause economic injury, taking consumers' money in return for ineffective products. Even more importantly, they may threaten consumers' health if victims are deterred from seeking effective treatment. Moreover, in some cases, the products themselves are dangerous. To control these types of claims, the Commission has filed numerous law-enforcement actions challenging false or deceptive therapeutic claims for products claiming to cure a broad range of chronic diseases, including cancer, arthritis and heart disease.

Despite these efforts, deceptive health claims persist. Over the past 5 years, the Internet has become the medium of choice for many companies marketing unproven health products. In response, the Commission initiated Operation Cure.All, a comprehensive effort targeting health fraud on the Internet. Operation Cure.All utilizes law enforcement, consumer education and business education. In addition to the FTC, participants include the FDA, several State attorneys general and Health Canada. On June 14 of this year, the Commission announced the most recent group of Operation Cure.All cases. Among the claims the Commission challenged were claims for colloidal silver, like this product here, which is basically distilled water containing 3 to 20 parts-per-million of silver ions. These products cost \$15 to \$25 a bottle.

Internet advertising for these products claimed they were an effective treatment for 650 different diseases or ailments, including cancer, arthritis and diabetes. Another product involved in our recent Cure.All sweep was the so-called Black Box, which you see in the poster over here. This was a device that purportedly delivers an electric current to the body. Promotional materials for the product claimed that it neutralizes viruses and kills bacteria in the bloodstream and organs. Together with something called the "Magnetic Pulser," the Black Box was supposedly effective in treating

cancer and rheumatoid arthritis. The black box sold for \$170; adding the magnetic pulser pushed the cost to \$355.

Still another product is this anti-aging product, called Longevity Signal Formula, marketed to prevent or reverse aging, significantly increase life expectancy, significantly reduce the risk of atherosclerosis and cure arthritis. This product cost \$79 for a 30-day supply. Our law enforcement efforts play an important role in our health fraud program, but law enforcement is a means to an end. The primary goal of consumer protection is to prevent consumer injury in the first place. Consumer education is another critical tool in that effort.

Today, we are releasing a publication produced jointly with FDA, called "*Miracle Health Claims: Add a Dose of Skepticism.*" This is an example of the brochure. It provides specific information about the efficacy and safety of popular products, as well as information similar to the Commission's Tip-offs for Rip-offs, which you see on the poster over here, that is advice to consumers about how to spot and avoid health fraud.

The brochure, as well as our other educational materials, provide consumers with both a toll-free number, 1-877-FTC-HELP, and a web address, www.FTC.gov, to file consumer complaints. To fight fire with fire, we have used the Internet to obtain broad distribution of our consumer education messages. Our web-based, health-related consumer education materials have been accessed over 80,000 times since October 1 of last year.

In addition to law enforcement and consumer education, the third prong of our efforts to combat health fraud has been an extensive industry education campaign. We have published a guide for small businesses on how to avoid making false or substantiated health claims. We have sent e-mail advisories to more than 1,000 web sites making questionable therapeutic claims. Law enforcement, however, remains critical. Additional non-public investigations are under way.

The Commission, in coordination with our law enforcement partners, will continue its aggressive enforcement program to combat health fraud. In addition, we will continue to expand our consumer and industry education efforts, and to continue our search for new ways to address problems in this important area.

Thank you very much, and I look forward to your questions.

[The prepared statement of Mr. Beales follows:]

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Prepared Statement of the Federal Trade Commission

on

“Health Fraud and the Elderly: A Continuing Health Epidemic”

Before the

U.S. Senate Special Committee on Aging

Washington, D.C.

September 10, 2001

I. Introduction

Mr. Chairman and members of the Committee, I am Howard Beales, Director of the Bureau of Consumer Protection, of the Federal Trade Commission. I am pleased to have this opportunity to provide information concerning the Commission's efforts to ensure the truthfulness and accuracy of marketing for health products and services. My comments will focus in particular on our work to combat fraudulent claims for products marketed as treatments or cures for serious diseases, many of which are particularly prevalent among elder citizens, including cancer, heart disease, and arthritis.¹

The mission of the Federal Trade Commission is to prevent unfair competition and to protect consumers from unfair or deceptive acts or practices in the marketplace. As part of this mission, the Commission has a longstanding and active program to combat fraudulent and deceptive advertising claims for health products.² Since the fall of 1997, the Commission has filed twenty-seven cases against companies using false or deceptive claims to market unproven products that allegedly cure such ailments as cancer, arthritis, sleep apnea, impotence, osteoporosis, or circulatory diseases.

Despite these efforts, unfounded or exaggerated health claims remain common in the marketplace, and combating health fraud remains one of the Commission's top priorities. Cooperative law enforcement that focuses on marketers who promote products that jeopardize the health of users as well as those who make unfounded therapeutic claims for serious diseases is a keystone of that effort. Although aggressive law enforcement is crucial, the best consumer protection comes from preventing consumers from being deceived in the first instance. Thus, the Commission emphasizes consumer education to help consumers spot and avoid health

fraud. Finally, we also work to provide businesses with the guidance necessary to avoid violating the law.

We believe these efforts are important because health fraud often targets a very vulnerable segment of our population -- those suffering from serious or incurable health conditions and diseases. The victims are often fearful and desperate. As one commentator observed, “[I]t is difficult to explain, and often impossible to comprehend, the degree of suffering seen in some cancerous conditions, cases of arthritis, and certain nervous disorders.”³ In such circumstances, therapeutic claims, even outrageous claims that ordinary consumers would dismiss as fraudulent, can be and are convincing enough to persuade consumers to purchase these products.

In other circumstances, a number of factors, including lack of information and false beliefs about health and the causes of disease, may also contribute to a particular consumer’s susceptibility to health fraud.⁴

II. Consumer Injury

At the consumer level, the costs of these products and services range from a few dollars to tens of thousands of dollars for cancer treatments offered in foreign “clinics.” In most cases, these products and services are not covered by insurance.

In addition to economic injury, some products and services can pose a serious health threat. The promise of worthless or unproven remedies can deter victims from seeking the best available treatments. In some instances, particularly in the area of cancer, marketers have even told victims that it is not necessary for them to seek conventional treatment. For example, one website for an unproven treatment told consumers:

Does this mean you can cancel your date for surgery, radiation and chemotherapy? YES! After curing your cancer with this recipe it cannot come back. THIS IS NOT A TREATMENT FOR CANCER: IT IS A CURE! But if you do not wish to make your doctor angry, you could follow her or his wishes, too. Be careful not to lose ANY VITAL ANATOMICAL PARTS in surgery though, because you may need them later when you are healthy!⁵

In some patients, delaying treatment may worsen the condition.

Deferred treatment is not the only risk, however; some products and services are themselves dangerous. This is a concern the Commission takes very seriously. Safety is a primary criterion the Commission uses in its case selection process, as illustrated by our recent cases against marketers of products containing comfrey, an herbal product that, when taken internally, can lead to serious liver damage.⁶

III. Law Enforcement

The Federal Trade Commission, Food and Drug Administration, U.S. Postal Service, and state law enforcement and regulatory agencies all play a role in protecting consumers, especially seniors, from health fraud. Over the years, there has been a high degree of cooperation among these agencies, including the sharing of information and technical and scientific expertise as well as the coordination of law enforcement efforts. For example, to combat health fraud on the Internet, the Commission initiated *Operation Cure.All*,⁷ a comprehensive consumer and business education and law enforcement and regulatory initiative targeting deceptive and misleading Internet promotion of products and services as cures or treatments for serious diseases. In addition to the FTC, participants in *Operation Cure.All* include the Food and Drug Administration,⁸ several state attorneys general, and Health Canada.

The initial phase of *Operation Cure.All* consisted of two Internet surfs⁹ conducted in

1997 and 1998. As a result of these surfs we found over 1600 sites world-wide making questionable claims for products marketed as treatments for heart disease, cancer, HIV/AIDS, diabetes, arthritis, and multiple sclerosis. Of these, over 800 were located in North America, with the vast majority in the United States. To put these numbers in perspective, it took surfers only about 3 hours each to find these sites, which we believe represent only the tip of the iceberg. The results from these surfs were used to identify areas for targeted law enforcement, *e.g.*, magnetic therapies, and, as discussed below, in our industry education efforts.

This year, the Commission has filed eight cases as part of *Operation Cure.All*, targeting companies that market a variety of devices, herbal products, and other dietary supplements to treat or cure cancer, arthritis, Alzheimer's, diabetes and many other diseases. Among the products for which marketers made unsubstantiated health benefit claims were a DHEA hormonal supplement, St. John's Wort, various multi-herbal supplements, colloidal silver, comfrey, and a variety of electrical therapy devices.¹⁰

The following are illustrative of the kinds of claims that the Commission challenged in its *Operation Cure.All* cases this year:

THIS IS NOT A TREATMENT FOR CANCER: IT IS A CURE! .
 . . It takes 5 days to kill the parasites that cause intestinal cancer.
 The cancer is then killed (*herbal product*)

We cannot list all 650 diseases that colloidal silver is effective against but here is a list of some of the common ones: Common cold, stomach ulcers, acne, burns, shingles, arthritis, strep, tuberculosis . . . (*colloidal silver*)

[T]here are . . . literally hundreds of scientific studies supporting the components of this breakthrough formula. Here are some of the most dramatic new findings. . . . And finally, a breakthrough study on nearly 1,000 subjects published in the prestigious journal of

epidemiology showing a significant reduction in the risk for atherosclerosis. . . . the leading cause of death in Western nations.
(*anti-aging DHEA product*)

Herb Veil 8 has been used in the successful removal of carcinoma, adenocarcinoma, and melanoma. (*botanical product*)

This formula is a "power house" and has been used on (and restored to health), cancer of the spine, arthritis, and polio, and has helped rebuild torn cartilage and sinews, fractures, etc. etc..."
(*product containing comfrey*)

Prior to this year, the FTC had filed eight *Operation Cure.All* cases. The challenged products include Cat's Claw,¹¹ shark cartilage,¹² cetylmyristoleate (CMO),¹³ Essiac Tea,¹⁴ and magnetic therapies.¹⁵ In all these cases the companies made strong claims about treatments or cures for serious diseases with little or no evidence to support the claims.¹⁶

Other Commission initiatives include conducting Internet investigation training courses for more than 2000 individual law enforcement staff, including representatives of 20 countries, 30 states, and 22 federal agencies. The Commission also maintains a comprehensive consumer complaint data base, Consumer Sentinel. Complaints come into the system through telephone and mail inquiries to our Consumer Response Center as well as through our online complaint form at www.ftc.gov. Complaints are also forwarded to the system from many public and private partners. Complaint information in the system is available to over 300 law enforcement agencies.

While the Internet Training Course and Consumer Sentinel cover many more areas than health fraud, these initiatives have contributed significantly to law enforcement efforts in the health area as well. For example, the Internet training we provide to health fraud investigators at federal and state agencies improves efficiency in conducting investigations of Internet companies

marketing questionable products. In addition, Consumer Sentinel has become a valuable source of leads and other information about companies that may be engaged in deceptive marketing of health products.

The FTC is committed to obtaining strong remedies that will adequately protect consumers against health fraud. As already noted, the provisions of the Federal Trade Commission Act empower the Commission to prevent unfair or deceptive acts or practices in or affecting commerce¹⁷ and false advertisements for foods, drugs, devices, cosmetics and services.¹⁸ In addition to prohibiting false claims, these provisions require, in most cases, that marketing claims about the efficacy or safety of a health-related product or service must be supported by competent and reliable scientific evidence.¹⁹ In general, competent and reliable scientific evidence consists of tests, studies, or other scientific evidence that has been conducted and evaluated according to standards that experts in the field accept as accurate and reliable.²⁰

Given the number of companies marketing health products and our limited resources, we cannot investigate and prosecute every possible case. Factors that are considered in case selection include (1) the safety of the product or service, (2) whether the product or service is being marketed as a treatment or cure for a serious disease or health condition, (3) the egregiousness of the claims, (4) the scope of the marketing and sales, and (5) the extent to which bringing a particular case will serve the Commission's industry compliance and consumer education mission.

Enforcement actions can take one of two forms. The Commission can file an administrative action or it can file its action directly in federal district court. Federal district court actions are particularly appropriate where the case involves a potentially unsafe product, or

when immediate injunctive relief is necessary to stop an ongoing deceptive advertising campaign or to preserve assets for consumer redress. In either case, the Commission may seek broad remedial relief.²¹

In addition to prohibiting specific deceptive product claims, Commission orders in the health area typically prohibit unsubstantiated claims for other foods, drugs, dietary supplements, devices or services. In cases where a company utilizes third party distributors, Commission orders often require the company to notify its distributors of the Commission's action and to monitor future advertising. Where appropriate, the Commission attempts to obtain the payment of consumer redress or, where redress is impractical, disgorgement of ill-gotten gains to the U.S. Treasury. Also, in appropriate cases, the Commission may order a company to undertake a specific consumer education program. For example, in the Commission's action against a company marketing a product known as Essiac Tea²² as a scientifically proven cancer cure, the Commission's consent order required that the company send notices to past purchasers advising them that there is no reliable evidence that Essiac Tea is effective against cancer.²³

IV. Consumer and Business Education

The Commission recognizes that the primary goal of consumer protection is to prevent consumers from being injured. For that reason, the Commission maintains a comprehensive consumer education program. Today we are releasing a publication produced with the FDA, called "Miracle Health Claims: Add a Dose of Skepticism." This brochure provides specific information about the efficacy and safety of popular products as well as information about spotting and avoiding health fraud. Another brochure, "Who Cares: Sources of Information About Health Care Products and Services," published jointly with the National Association of

Attorneys General, informs consumers about where they can go for information about arthritis cures, alternative medicine, and other health issues, and where they can file complaints about health fraud. The Commission also works with other federal agencies, like the Administration on Aging, and organizations like the AARP, to get our health fraud messages to older audiences.

The Commission also uses the Internet to distribute its consumer education messages. The Commission's Website, www.ftc.gov, provides links to reliable sources of health information, including www.healthfinder.gov, developed by the Department of Health and Human Services, and consumer education tips such as those found in "Virtual Health Treatments Can Be Real World Deceptions."²⁴ Our web-based consumer education material has received nearly 80,000 accesses since October 1, 2000. These materials are also available in printed form. In addition, the Commission maintains a number of "teaser" sites like "Arthriticure," "Virility Plus," and "Nordicalite," which can be found using common search engines and are set up to mimic health fraud sites. When consumers attempt to order the products, however, they get a message that if the site were real, they could have been scammed. Then, most importantly, consumers are advised of the tip-offs that the site was a scam and where to turn for reliable information. The Commission's three health-related teaser sites have received over 20,000 accesses from October 1999 through August 2001.

The Commission engages in an extensive industry education campaign. For example, in 1998 the Commission published "Dietary Supplements: An Advertising Guide for Industry."²⁵ This publication provides easy-to-understand explanations of advertising standards for the marketing of health products, along with many useful examples. In addition, Commission staff has sent more than a thousand email advisories to websites that are making questionable

therapeutic claims. These emails alert website operators to the questionable nature of their claims and provide links to resources to help them determine whether they are in compliance with applicable law. Based on our random sampling of sites that have received these advisories, approximately 25% take some form of remedial action, either taking the website down or removing the questionable claims.

V. Conclusion

Health fraud poses a direct and immediate threat of both economic and physical injury to persons already suffering from serious conditions and diseases. The elderly are particularly vulnerable because of the high incidence of health-related problems in this age group. With thousands of marketers pushing worthless or unproven remedies, and limited enforcement resources, there is reason for concern.

On the positive side, consumers now have more accurate, reliable health information available to them, through the Internet and other sources, than ever before, and consumer surveys show that consumers are using these resources in record numbers.²⁶ Federal and state agencies, as well as many of our foreign counterparts, recognize the need to coordinate and share scarce resources in the battle against health fraud. As our past experience demonstrates, this cooperation is an absolutely essential ingredient of success. The Commission will continue its aggressive law enforcement and consumer and industry education program to combat health fraud, and to the extent possible, increase its efforts in this critical area of consumer protection.

Endnotes

1. The written statement presents the views of the Federal Trade Commission. My oral statement and responses to questions are my own and are not necessarily those of the Commission or any individual Commissioner.
2. Our authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits “unfair or deceptive acts and practices” in commerce and Section 12, which prohibits the “false advertisement” of foods, drugs, devices, services, and cosmetics. 15 U.S.C. §§ 45, 52.
3. Warren E. Schaller & Charles R. Carroll, *Health Quackery & the Consumer* 28 (1976).
4. Schaller & Carroll at 26-7.
5. *FTC v. Western Dietary Products Co. (Skookum)*, C01-0818R (W.D. Wash., filed June 6, 2001).
6. *FTC v. Western Botanicals, Inc.*, S-01-1332 DFL GGH (E.D. Cal., filed July 25, 2001) (Stipulated Permanent Injunction); *FTC v. Christopher Enterprises, Inc.*, 2:01CV-0505 ST (C.D. Utah, filed July 6, 2001) (Stipulated Preliminary Injunction).
7. “*Operation Cure.All*” Targets Internet Health Fraud: *FTC Law Enforcement and Consumer Education Campaign Focuses on Stopping the Quacks and Supplying Consumers with Quality Information*, June 24, 1999, available at <http://www.ftc.gov/opa/1999/9906/opcureall.htm>.
8. As part of the *Operation Cure.All* initiative, FDA filed an action seeking a permanent injunction against a website operator selling products containing shark cartilage, a glycoalkaloid, and arabinoxylana as treatments for cancer and other serious diseases; sent 48 *Cyber Letters*, untitled letters sent via electronic mail, to sites making drug claims for colloidal silver; issued warning letters to several firms marketing devices that purportedly send electrical energy into the body to destroy parasites and/or shatter cells to cure serious diseases, such as cancer; and issued public warnings about products containing aristolochic acid, a toxic contaminant, and comfrey.
9. In an Internet surf, participants use common search engines to find relevant Internet sites based on a set of predetermined search terms, for example, “cancer therapy.” Once a site is identified, it is forwarded to a collection center, where the site is reviewed again to verify that it satisfies the selection criteria. In the two health claims surfs the FTC organized, the selection criteria were whether the site appeared to be making questionable claims that the product or service being offered was effective in the treatment, prevention or cure of cancer, arthritis, heart disease, HIV/AIDS, diabetes, or multiple sclerosis.
10. Press releases for *Operation Cure.All* cases filed this year are available at <http://www.ftc.gov/opa/2001/06/cureall.htm> and <http://www.ftc.gov/opa/2001/07/chrisenter.htm>. Cases filed this year include *Panda Herbal Int'l, Inc.*, No. C-4018 (Aug. 8, 2001) (consent) (St.

John's Wort and Herb Veil 8 marketed as treatment for HIV/AIDS and skin cancer, respectively); *ForMor, Inc.*, No. C-4021 (Aug. 8, 2001) (consent) (St. John's Wort marketed as treatment for HIV/AIDS; and colloidal silver and shark cartilage marketed as treatments for cancer and arthritis, among many other diseases); *MaxCell Bioscience, Inc.*, No. C-4017 (Aug. 8, 2001) (consent) (multi-ingredient product containing DHEA marketed to reverse aging and prevent age-related diseases); *Michael Forrest d/b/a Jaguar Enterprises of Santa Ana*, No. C-4020 (Aug. 8, 2001) (consent) (miracle herbs and black box, magnetic pulser, and Beck-Rife units marketed as treatments for cancer and arthritis); *Robert C. Spencer d/b/a Aaron Company*, No. C-4019 (Aug. 8, 2001) (consent) (colloidal silver marketed as treatment for cancer and many other diseases); *FTC v. Western Dietary Prods. Co. (Skookum)*, C01-0818R, *supra*, note 5 (herbal cure packages and "zappers" marketed as treatments for cancer); *FTC v. Western Botanicals, Inc.*, *supra*, note 6 (comfrey); *FTC v. Christopher Enterprises, Inc.*, *supra*, note 6 (comfrey).

11. *Body Systems Technology, Inc.*, No. C-3895 (Sept. 7, 1999) (consent). Cat's Claw was promoted primarily as an effective treatment for cancer, HIV/AIDS, and arthritis. Copies of all *Operation Cure.All* cases are available at the FTC's Website, www.ftc.gov.

12. *Lane Labs-USA, Inc.*, No. 00W3174 (D.N.J.; filed Jun. 28, 2000) (Stipulated Final Order); *Body Systems Technology*, *supra*, note 11. Shark cartilage was promoted to treat or cure cancer.

13. *John Sneed and Melinda Sneed d/b/a Arthritis Pain Care Center*, No. C-3896 (Sept. 7, 1999) (consent); *CMO Distribution Centers of America*, No. C-3942 (May 16, 2000) (consent); *EHP Products, Inc.*, No. C-3940 (May 16, 2000) (consent). CMO was marketed to treat arthritis.

14. *Michael D. Miller, d/b/a Natural Heritage Enterprises*, No. C-3941 (May 16, 2000) (consent). Essiac Tea was promoted as a treatment for cancer.

15. *Magnetic Therapeutic Technologies, Inc.*, No. C-3897 (Sept. 7, 1999) (consent); *Pain Stops Here! Inc.*, No. C-3898 (Sept. 7, 1999) (consent). Magnetic Therapeutic Technologies and Pain Stops Here marketed magnetic devices to treat or alleviate numerous medical problems and diseases, including cancer, liver disease, arthritis and high blood pressure.

16. In addition to *Operation Cure.All*, the Commission has filed a number of other cases challenging health product promotions appearing in print, television and direct mail. For example, in *FTC v. Rose Creek Health Products, Inc.*, the Commission challenged claims that *Vitamin O*, which appears to be a saline solution with added oxygen molecules, is effective for the treatment of cancer, heart disease, and joint disintegration. *FTC v. Rose Creek Health Prods. Inc.*, CS-99-0063-EFS (E.D. Wash. 2000) (Stipulated Permanent Injunction). Claims challenged in other cases involve use of yohimbe and other natural ingredients as a treatment for impotence, *American Urological Corp.*, 98-CV-2199 (N.D. Ga. 1999) (Stipulated Permanent Injunction); shark cartilage as a treatment for cancer and arthritis, *Nutrivida, Inc.*, No. C-3826 (Sept. 16, 1998) (consent); a powdered nutritional supplement consisting of wheat germ, wheat bran, soybean extract, and seaweed extract as a treatment for rheumatism and to prevent aging,

Venegas, Inc., No. C-3781 (Jan. 27, 1998) (consent); a topical spray consisting of oils, vitamins, and trace ingredients as a treatment for sleep apnea, *Med Gen, Inc.*, File No. 002 3211 (Mar. 29, 2001) (consent subject to final approval); a natural toxic purifier as a treatment for depression and arthritis, *Mega Systems Int'l Inc.*, No. C-3811 (June 8, 1998) (consent); a mixture of vitamins and plant derivatives as a treatment for circulatory problems, hemorrhoids and varicose veins, *Efficient Labs, Inc.*, No. C-3768 (Sept. 19, 1997) (consent); and a mixture of camphor, chondroitin sulfate, and glucosamine sulfate for the treatment of severe pain, *SmartScience*, No. C-3980 (Nov. 2, 2000) (consent). Sales for the challenged products totaled in the tens of millions of dollars.

17. 15 U.S.C. 45(a). A representation, omission, or practice is deceptive if (1) it is likely to mislead consumers acting reasonably under the circumstances; and (2) it is material, that is, likely to affect consumers' conduct or decisions with respect to the product at issue. FTC Deception Policy Statement, *appended to Cliffdale Associates*, 103 F.T.C. 174, 175-76 (1984), available at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>. A practice is unfair if the injury to consumers it causes or is likely to cause (1) is substantial; (2) is not outweighed by countervailing benefits to consumers or to competition; and (3) is not reasonably avoidable by consumers themselves. 15 U.S.C. § 45(n); *see also* Unfairness Policy Statement, *appended to International Harvester Co.*, 104 F.T.C. 949, 1070 (1984), available at <http://www.ftc.gov/bcp/policystmt/ad-unfair.htm>.

18. 15 U.S.C. § 52. "False advertisement" is defined as "an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual." 15 U.S.C. § 55(a)(1).

19. *Removatron Int'l Corp.*, 111 F.T.C. 206, 297 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989); *Thompson Medical Co.*, 104 F.T.C. 648, 821-22 note 59 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

20. *See, e.g., Michael D. Miller*, No. C-3941 (May 16, 2000) (consent), which defines "competent and reliable scientific evidence" as:

tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

21. In order to prevent the responsible individuals from evading a Commission order simply by forming a new corporation, FTC orders frequently cover both the corporation and the individuals in the corporation who controlled or participated in the deceptive or fraudulent practice.
22. Essiac Tea is a mixture of four herbs (burdock root, sheep sorrel, rhubarb root, and slippery elm bark).
23. *Michael D. Miller, d/b/a Natural Heritage Enterprises, supra*, note 14.
24. "Virtual Health Treatments Can Be Real World Deceptions," available at <http://www.ftc.gov/bcp/online/edcams/miracle/index.html>.
25. "Dietary Supplements: An Advertising Guide for Industry," November, 1988, available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>. Since its publication, 11,125 copies of the Guide have been distributed and it has been accessed on our website 91,900 times.
26. According to one survey, almost 100 million Americans have used the Internet to find health information, on average three times per month. Humphrey, T; "Cyberchondriacs Update," Harris Interactive, April 18, 2001, available at www.harrisinteractive.com/harris_poll/index.asp?PID=229. In most instances, users are looking for information about specific conditions or diseases.

The CHAIRMAN. Thank you, Mr. Beales.
With the Federal Bureau of Investigation, Mr. Lormel?

STATEMENT OF DENNIS M. LORMEL, SECTION CHIEF OF FINANCIAL CRIMES, CRIMINAL INVESTIGATIVE DIVISION, FEDERAL BUREAU OF INVESTIGATION

Mr. LORMEL. Thank you sir. We would like to thank the committee for the opportunity to participate today, also to commend the committee for the initiative to raise awareness as to the vulnerability of the elderly and seriously ill to falling prey to unscrupulous con artists and fraudsters concerning dietary and nutritional supplements, as well as other fraud schemes. The FBI views promoting awareness to the vulnerability of the elderly and seriously ill to health care and other fraud schemes as an important preventative component in dealing with the crime problem.

True deterrence is a combination of proactive, preventive measures and enforcement actions. I have submitted to you our written statement, which also includes four anecdotal case summaries, which unfortunately mirror some of the schemes you have heard about. I would like to focus my comments this morning to the response in your invitation as to what the bureau is specifically doing. First off, health care fraud is recognized within our white-collar crime program as the No. 1 investigative priority. Unfortunately, we deal pretty much in insurance-related health care frauds. So the schemes you have pretty well outlined here this morning we do not consider or work as health care specific.

One of the things that I would ask the committee to consider is expanding health care legislation to allow us more jurisdiction in terms of other related health care criminal conduct such, as what you have heard here this morning, because many of the schemes, as I say, are outside the scope of Medicaid or private insurance that we traditionally investigate. With that, though, we do have a presence in this area. We investigate these cases pretty much as fraud by wire or mail fraud matters, and with specific reference, Senator, to the invitation letter, you inquired as to the FBI's efforts in the area of health care fraud, focusing on dietary and nutritional supplements.

In that regard, we work closely with our companion agencies, and as I said, we work the cases mostly as wire fraud and mail fraud cases, and outside the scope of traditional health care. We participate with other agencies—was one of your inquiries—how do we participate. We have limited investigative resources in this area, so the partnership with other law enforcement agencies, particularly FDA, as it relates to the dietary supplements and nutritional supplements, is important. We partner with the Postal Inspection Service, with the IRS, with State attorneys general and Medicaid officers in pursuing these criminal investigations.

In a broader context, in the traditional health care arena, we work with HHS and we work with DCIS and the above agencies that I mentioned before. Also, we deal in partnering with outside agencies such as AARP. As I mentioned earlier, promoting awareness is very important to us. We have an aggressive campaign where we use retired individuals to help us promote awareness and

to act in concert with us in an undercover capacity in a lot of the investigations we conduct.

We have an initiative, in the traditional sense of telemarketing fraud, which we call Canadian Eagle, in which we deal extensively with Canadian officials and cross-border crime schemes and issues. One example of the cooperation, I think, between the bureau and FDA, in particular, is the ongoing case in Kansas City involving the pharmacist who has now provided short dosages of particularly cancer drugs, and obviously the elderly is a component of the people there. The FBI and FDA are working very closely in that case, in that regard.

You asked about programs in place to protect the general population and, in particular, the elderly. We have joint outreach and educational programs, as I mentioned, with AARP and through vehicles such as our Internet Fraud Complaint Center. As the FTC has Consumer Sentinel, we have the Internet Fraud Complaint Center, and we are able to assess and analyze Internet Fraud type of complaints, and we are hopefully—in that process, we aggregate the complaints and we are able to refer out cases, not only to the FBI, but to State and local law enforcement entities throughout the country and, in fact, around the world.

Types of proactive investigative techniques that we undertake to ferret out these products and frauds include short-term undercover operations targeting the fraudsters. We use retired individuals, retired FBI agents, and we do so in concert with AARP as we can identify cases. We conduct assessments and analysis, as I mentioned, through the Internet Fraud Complaint Center, and refer cases back out. We certainly pursue traditional investigative techniques as appropriate, and we look to initiate regional and national investigative initiatives where we can really promote the high level of visibility, and certainly in terms of the visibility, better make people aware of the crime problems.

Senator Wyden, in your comments, I think you were right on the mark in terms of tasking GAO. I would encourage you, sir, if you would, to expand that beyond just the health care arena, because these fraudsters are across the board in all areas. I have been very general in terms of my comments, sir, and if you have got some specific questions, I would be very happy to pursue them and to follow up with any other additional information you would like from us.

[The prepared statement of Mr. Lormel follows:]

September 10, 2001

STATEMENT FOR THE RECORD
DENNIS M. LORMEL, CHIEF,
FINANCIAL CRIMES SECTION
FEDERAL BUREAU OF INVESTIGATION

BEFORE THE
UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING
WASHINGTON, D.C.

GOOD MORNING MR. CHAIRMAN AND MEMBERS OF THE SPECIAL COMMITTEE ON AGING. I AM PLEASED TO APPEAR TODAY ON BEHALF OF THE FEDERAL BUREAU OF INVESTIGATION AND SHARE WITH YOUR COMMITTEE THE FBI'S EFFORTS TO ADDRESS FRAUDULENT SCHEMES WHICH PROMISE EVERYTHING FROM IMPROVED MEMORY, SEXUAL VITALITY, CURING OF TERMINAL ILLNESSES, RELIEF FROM CHRONIC PAIN AND, THE ULTIMATE PROMISE, A LONGER LIFE. THESE SCHEMES TARGET THOSE WHO ARE MOST CONCERNED ABOUT REVERSING THE EFFECTS OF AGING, THE ELDERLY.

COMBINING RESOURCES WITH OTHER FEDERAL AND STATE INVESTIGATIVE AGENCIES HAS BEEN A WINNING FORMULA FOR THE FBI IN THIS AND MANY OTHER TYPES OF INVESTIGATIONS.

THE JOINT INVESTIGATIVE APPROACH NOT ONLY BRINGS ADDITIONAL RESOURCES IN TERMS OF MANPOWER AND INVESTIGATIVE TOOLS, BUT ALSO GIVES INVESTIGATORS ACCESS TO EXPERTISE PROVIDED BY REGULATORY AGENCIES SUCH AS THE FDA AS WELL AS A LARGER SELECTION OF APPLICABLE CRIMINAL AND CIVIL STATUTES FROM BOTH THE FEDERAL AND STATE LEVELS.

LET ME FIRST EMPHASIZE THAT THE FBI HAS IDENTIFIED ELDER FRAUD AND FRAUD AGAINST THOSE SUFFERING FROM SERIOUS ILLNESS AS TWO OF THE MOST INSIDIOUS OF ALL WHITE COLLAR CRIMES BEING PERPETRATED BY TODAY'S MODERN AND HIGH TECH CON-MAN. THE INTERNET, HIGH SPEED DIALERS, MAIL DROPS, AND COMPUTERS ARE JUST SOME OF THE TOOLS AVAILABLE TO THE FRAUDSTER TO SEPARATE A VICTIM FROM HIS MONEY. MANY ELDERLY CITIZENS RELY ON PENSIONS, SOCIAL SECURITY AND LIFE SAVINGS TO SUPPORT THEMSELVES. THE SERIOUSLY ILL AND THEIR FAMILIES ARE DESPERATE TO FIND SOME GLIMMER OF HOPE. THE LOSSES INFLICTED BY THESE UNSCRUPULOUS CON-MEN AND THEIR ORGANIZATIONS ARE BOTH FINANCIALLY AND EMOTIONALLY DEVASTATING TO THESE VICTIMS.

IT HAS BEEN THE EXPERIENCE OF THE FBI THAT THE ELDERLY

ARE PREYED UPON BY THESE UNSCRUPULOUS INDIVIDUALS FOR SEVERAL REASONS:

- 1) OLDER AMERICAN CITIZENS ARE MOST LIKELY TO HAVE A "NEST EGG" , OWN THEIR HOME AND/OR HAVE EXCELLENT CREDIT ALL OF WHICH THE CON-MAN WILL TRY TO TAP INTO. FRAUDSTERS ARE VERY FAMILIAR WITH THE OLD SAYING, "YOU CAN'T GET BLOOD FROM A STONE." LIKE ANY OTHER BUSINESSMAN, THE FRAUDSTER WILL FOCUS HIS EFFORTS ON THE SEGMENT OF THE POPULATION MOST LIKELY TO BE IN A FINANCIAL POSITION TO BUY WHATEVER HE IS SELLING.
- 2) INDIVIDUALS WHO GREW UP IN THE 30'S, 40'S AND 50'S WERE GENERALLY RAISED TO BE POLITE AND TRUSTING. TWO VERY IMPORTANT AND POSITIVE PERSONALITY TRAITS, EXCEPT WHEN IT COMES TO DEALING WITH A CON-MAN. THE CON-MAN WILL EXPLOIT THESE TRAITS KNOWING THAT IT IS DIFFICULT OR IMPOSSIBLE FOR THESE INDIVIDUALS TO SAY "NO" OR JUST HANG UP THE PHONE.
- 3) OLDER AMERICANS ARE LESS LIKELY TO REPORT A FRAUD BECAUSE THEY EITHER DON'T KNOW WHO TO REPORT IT TO OR ARE TOO ASHAMED AT HAVING BEEN SCAMMED. IN SOME CASES, AN ELDERLY VICTIM MAY NOT REPORT THE CRIME BECAUSE HE OR SHE

IS CONCERNED THAT RELATIVES MAY COME TO THE CONCLUSION THAT THE VICTIM NO LONGER HAS THE MENTAL CAPACITY TO TAKE CARE OF HIS OR HER OWN FINANCIAL AFFAIRS.

4) WHEN AN ELDERLY VICTIM DOES REPORT THE CRIME, THEY OFTEN MAKE POOR WITNESSES. THE CON-MAN KNOWS THE EFFECTS OF AGE ON MEMORY AND HE IS COUNTING ON THE FACT THAT THE ELDERLY VICTIM WILL NOT BE ABLE TO SUPPLY ENOUGH DETAILED INFORMATION TO INVESTIGATORS SUCH AS: HOW MANY TIMES DID HE CALL? WHAT TIME OF DAY DID HE CALL? DID HE PROVIDE A CALL BACK NUMBER OR ADDRESS? WAS IT ALWAYS THE SAME PERSON? DID YOU MEET IN PERSON? WHAT DID HE LOOK LIKE? DID HE/SHE HAVE ANY RECOGNIZABLE ACCENT? WHERE DID YOU SEND THE MONEY? WHAT DID YOU RECEIVE IF ANYTHING AND HOW WAS IT DELIVERED? WHAT PROMISES WERE MADE AND WHEN? DID YOU KEEP ANY NOTES OF YOUR CONVERSATIONS? THE REALIZATION THAT THEY HAVE BEEN VICTIMIZED MAY TAKE WEEKS OR, MORE LIKELY, MONTHS AFTER CONTACT WITH THE CON-MAN. THIS EXTENDED TIME FRAME WILL TEST THE MEMORY OF ALMOST ANYONE.

5) LASTLY, WHEN IT COMES TO PRODUCTS THAT PROMISE

INCREASED COGNITIVE FUNCTION, VIRILITY, PHYSICAL CONDITIONING, ANTI-CANCER PROPERTIES AND SO ON, OLDER AMERICANS MAKE UP THE SEGMENT OF THE POPULATION MOST CONCERNED ABOUT THESE ISSUES. IN A COUNTRY WHERE NEW CURES AND VACCINATIONS FOR OLD DISEASES HAS GIVEN EVERY AMERICAN HOPE FOR A LONG AND FRUITFUL LIFE, IT IS NOT SO UNBELIEVABLE THAT THE PRODUCTS OFFERED BY THESE CON-MEN CAN DO WHAT THEY SAY THEY CAN DO.

THOSE SUFFERING FROM CANCER, HEART DISEASE, MULTIPLE SCLEROSIS, DIABETES, HIV, PARKINSON'S DISEASE AND OTHER SERIOUS ILLNESSES ARE TARGETED FOR ONE SIMPLE REASON. THE CON-MAN KNOWS THAT MANY OF THESE INDIVIDUALS ARE DESPERATE TO FIND SOME REASON TO BELIEVE THAT A "MIRACLE CURE" EXISTS. THESE PEOPLE, MANY OF WHOM ARE ELDERLY BUT SOME WHO ARE NOT, ARE WILLING TO PAY WHATEVER PRICE IS ASKED AND SUBJECT THEMSELVES TO WHATEVER RISK IS REQUIRED TO GAIN AN ADVANTAGE OVER THEIR DISEASE. REGRETTABLY, IN MOST CASES, IT IS THE CON-MAN TAKING ADVANTAGE OF THESE INDIVIDUALS. IN ADDITION TO THE FINANCIAL LOSS, THESE PATIENTS OFTEN LOSE VALUABLE TIME AWAY FROM CONVENTIONAL

MEDICAL TREATMENT WHICH COULD HAVE RESULTED IN A HIGHER QUALITY OF LIFE AND/OR PROLONGED LIFE. ALTHOUGH THE FBI HAS IDENTIFIED SEVERAL INSTANCES WHERE DIETARY AND NUTRITIONAL SUPPLEMENTS PROMISE ANTI-AGING EFFECTS HAVE BEEN UTILIZED TO DEFRAUD AMERICAN CITIZENS, THE NUMBER OF COMPLAINTS AND RELATED DOLLAR LOSSES HAVE NOT INDICATED A SUBSTANTIAL CRIME PROBLEM FALLING WITHIN THE JURISDICTION OF THE FBI. HOWEVER, THE FBI HAS BEEN INVOLVED IN SEVERAL INVESTIGATIONS CONCERNING "MIRACLE CURES" IN WHICH THE BUREAU HAS JOINED FORCES AND SHARED RESOURCES WITH THE FOOD AND DRUG ADMINISTRATION (FDA), THE U.S. POSTAL INSPECTION SERVICE (USPIS) AND OTHERS.

SEVERAL EXAMPLES OF PREVIOUS CASES ARE AS FOLLOWS:

IN MARCH 2001, GREGORY E. CAPLINGER, DBA, INTERNATIONAL INSTITUTE OF MEDICAL SCIENCE HOSPITAL AND CLINICS, WAS INDICTED IN THE EASTERN DISTRICT OF PENNSYLVANIA ON 39 COUNTS OF WIRE FRAUD. CAPLINGER HAD FALSELY REPRESENTED HIMSELF TO BE A BRITISH AND U.S. TRAINED PHYSICIAN WITH A DOCTOR OF SCIENCE DEGREE WHO WAS BOARD CERTIFIED IN INTERNAL MEDICINE, IMMUNOLOGY AND ONCOLOGY. CAPLINGER

USED THESE FALSE CREDENTIALS AND OTHER MISREPRESENTATIONS TO CONVINCE SERIOUSLY ILL PATIENTS TO TRAVEL FROM THE UNITED STATES AND CANADA TO THE DOMINICAN REPUBLIC FOR TREATMENT. HE CONVINCED PATIENTS TO TRAVEL TO THE DOMINICAN REPUBLIC TO PARTICIPATE IN HIS IMMUNOLOGICAL PROTOCOL AT HIS CLINIC WHICH USED AN MEDICATION CALLED "IMMUSTIM." CAPLINGER CLAIMED THAT "IMMUSTIM" WAS A MEDICATION EFFECTIVE IN THE TREATMENT OF CANCER, HIV/AIDS, EPSTEIN-BARR VIRUS, HEPATITIS, CHRONIC FATIGUE SYNDROME, ALLERGIES AND OTHER IMMUNOLOGICAL DYSFUNCTIONS. CAPLINGER RECEIVED IN EXCESS OF \$500,000 FROM PATIENTS AND APPROXIMATELY \$2,000,000 FROM INVESTORS HE CONNED INTO PROVIDING HIM FUNDING FOR HIS "CLINIC".

CAPLINGER FLED THE COUNTRY ON THE SEVENTH DAY OF HIS TRIAL AND EVENTUALLY TURNED HIMSELF IN TO AUTHORITIES IN THE DOMINICAN REPUBLIC. INVESTIGATION IN THIS MATTER ALSO DETERMINED THAT CAPLINGER WAS NOT A DOCTOR AND HAD BEEN SITED FOR PRACTICING MEDICINE WITHOUT A LICENSE IN 1984 IN FLORIDA. HE ALSO PLEAD GUILTY TO CHARGES OF PRACTICING MEDICINE WITHOUT A LICENSE IN THE STATE OF NORTH CAROLINA

IN 1988. IN 1993 HE PLEAD GUILTY TO THEFT CHARGES IN FLORIDA FOR TAKING MONEY FROM THE ELDERLY AFTER PROMISING TO TREAT PATIENTS FOR ALZHEIMER'S DISEASE. CAPLINGER IS AWAITING SENTENCING AND COULD RECEIVE 195 YEARS IN JAIL AND A FINE OF \$9.75 MILLION.

THE FBI IS ALSO INVOLVED IN A NUMBER OF ON-GOING CASES WHICH I AM NOT AT LIBERTY TO DISCUSS IN DETAIL AT THIS TIME. HOWEVER, I CAN PROVIDE YOU WITH A SUMMARY OF SEVERAL CASES WITHOUT IDENTIFYING THE SUBJECTS OF THESE INVESTIGATIONS.

IN SEPTEMBER 1999, THE SALT LAKE CITY OFFICE OF THE FBI INITIATED A JOINT INVESTIGATION WITH THE FDA. THIS INVESTIGATION CENTERED ON THE ACTIVITIES OF AN INDIVIDUAL TREATING SERIOUSLY ILL PEOPLE WITH AN "ALL NATURAL" PRODUCT HE PRODUCED, THE INGREDIENTS OF WHICH HE HAS ADVISED CAME TO HIM IN A "DREAM." ACCORDING TO THE SUBJECT OF THIS INVESTIGATION, THIS PRODUCT WAS EFFECTIVE IN TREATING MIGRAINE HEADACHES, CANCER, MULTIPLE SCLEROSIS, PARKINSON'S DISEASE, CHRONIC PAIN, SPINAL CORD INJURIES AND OTHER ILLNESSES. THE SUBJECT ADVISED PATIENTS THAT HIS "ALL

NATURAL" PRODUCT CONTAINED BOTANICAL EXTRACTS, B VITAMINS AND AMINO ACIDS. EXTENSIVE CHEMICAL ANALYSIS OF THE PRODUCT PERFORMED BY THE FDA DETERMINED THAT AMONG OTHER THINGS, IT CONTAINED PROCAINE AND LIDOCAINE. THE COST OF THESE TREATMENTS, WHEN PERFORMED IN THE SUBJECT'S CLINIC, WAS \$10,000 EACH. INFORMATION DEVELOPED THROUGH INVESTIGATION DETERMINED THAT THE SUBJECT HAD CONTRACTED WITH A PHARMACIST TO MIX HIS PRODUCT AND PAID THE PHARMACIST \$15.00 PER VILE. THE COST TO PATIENTS WAS \$500.00 PER VILE. HUNDREDS OF VICTIMS SOUGHT TREATMENT FROM THIS INDIVIDUAL WITH MANY PARENTS BRINGING PARAPLEGIC CHILDREN, WHO HAD SUFFERED SPINAL CORD INJURIES, IN THE HOPE THAT TREATMENT BY THE SUBJECT MIGHT RESULT IN THEIR BEING ABLE TO WALK AGAIN. MANY OF THE VICTIMS DIDN'T HAVE THE FINANCIAL RESOURCES TO PAY FOR THE TREATMENTS AND RESORTED TO MORTGAGING THEIR HOMES AND BORROWING FROM RELATIVES. IN ONE CASE, A CHURCH MOBILIZED ITS PARISHIONERS AND THROUGH FUND RAISING ACTIVITIES, WERE ABLE TO PAY THE COST OF THE TREATMENTS FOR ONE CHILD. MANY OF THE PATIENTS LEARNED OF THIS "MIRACLE TREATMENT" THROUGH CHATROOMS

ON THE INTERNET FREQUENTED BY THOSE SUFFERING FROM SPECIFIC AND SERIOUS DISEASES AND AILMENTS. SEARCH WARRANTS WERE EXECUTED AT THE SUBJECT'S HOME, ONE CLINIC IN SALT LAKE CITY AS WELL AS THE HOME OF THE PHARMACIST WHO RESIDED IN CALIFORNIA.

IN NOVEMBER 2000, THE RICHMOND OFFICE OF THE FBI INITIATED A WIRE FRAUD INVESTIGATION AGAINST AN INDIVIDUAL RESIDING IN HENRICO COUNTY, VA, WHO WAS REPRESENTING HIMSELF AS A DOCTOR AND A SURGEON. THIS INDIVIDUAL CLAIMED TO HAVE FOUND AN HERBAL CURE FOR VARIOUS TERMINAL CANCERS. HE WAS SELLING A MEDICINE "SOUP" WHICH HE CREATED AND CLAIMED WOULD CURE CANCER. THE CHARGE FOR A 45 DAY SUPPLY OF THIS "SOUP" WAS \$10,000. THE SUBJECT OF THIS INVESTIGATION ADVISED PROSPECTIVE CLIENTS THAT HE HAD CURED THE QUEEN OF THAILAND OF CERVICAL CANCER AND CURED HIS OWN WIFE OF STAGE IV BRAIN CANCER. HE ALSO CLAIMED TO HAVE CURED MORE THAN 100 OTHERS WITH HIS "SOUP". ONE VICTIM, IDENTIFIED THROUGH INVESTIGATION, PAID \$85,000 FOR "SOUP" AND A SKIN TREATMENT TO CURE HIS SKIN CANCER.

SOME OF THE "PATIENTS" LEARNED ABOUT THE "SOUP"

TREATMENTS BY WORD OF MOUTH AND OTHERS VIA THE INTERNET. SOME OF THE PATIENTS WERE TOLD THAT THEIR MEDICAL DIAGNOSIS WAS WRONG AND THEY DID NOT HAVE CANCER. HE TOLD THEM THEY WERE ONLY SUFFERING FROM A VIRUS WHICH, NOT COINCIDENTLY, HIS "SOUP" WOULD CURE. IN SOME INSTANCES, VICTIMS WERE INSTRUCTED TO DISCONTINUE THEIR CONVENTIONAL MEDICAL TREATMENT AND TO RELY SOLELY ON HIS SOUP. TO DATE, INVESTIGATION HAS DETERMINED THAT THE SUBJECT RECEIVED OVER \$350,000 FROM THE SALE OF HIS SOUP AND BOGUS MEDICAL TREATMENTS.

THE SUBJECT WAS ARRESTED ON 2/16/2001 AFTER INVESTIGATION DETERMINED THAT HE HAD BEGUN TO LIQUIDATE VARIOUS BANK ACCOUNTS. APPROXIMATELY \$207,660 AND TWO VEHICLES WERE SEIZED AT THE TIME OF HIS ARREST.

IN APRIL 1999, THE SAN DIEGO OFFICE OF THE FBI INITIATED AN INVESTIGATION OF AN INDIVIDUAL WHO ADVOCATED A REGIME OF HERBAL CONCOCTIONS, THE USE OF AN ELECTRIC DEVICE REFERRED TO AS A "ZAPPER", AND THE REMOVAL OF ALL METAL FROM THE PATIENTS MOUTH, TO CURE CANCER. ONE OF THIS INDIVIDUALS PATIENTS HAD BEEN DIAGNOSED WITH BREAST CANCER THROUGH

CONVENTIONAL MEDICAL PROCEDURES. A MALIGNANT TUMOR, APPROXIMATELY 1.5 CENTIMETERS IN SIZE, WAS DISCOVERED AND THE PATIENT'S MEDICAL DOCTOR RECOMMENDED SURGERY TO REMOVE IT. THIS PATIENT, CONVINCED THAT THE SUBJECT OF THIS INVESTIGATION COULD CURE HER CANCER AND ON HIS RECOMMENDATION, HAD ALL OF HER TEETH CONTAINING FILLINGS REMOVED BY A DENTIST. FOLLOWING TREATMENTS AND TESTS COSTING SEVERAL THOUSAND DOLLARS, THE SUBJECT ADVISED THE PATIENT THAT HER CANCER WAS "HEALING". AT THE URGING OF FAMILY MEMBERS, THE PATIENT RETURNED TO HER REGULAR PHYSICIAN AND LEARNED THAT THE TUMOR WAS NOT HEALING AND HAD ACTUALLY GROWN TO 14 CENTIMETERS.

THIS INVESTIGATION DETERMINED THAT THE SUBJECT WAS ALREADY WANTED ON A STATE ARREST WARRANT IN NASHVILLE, INDIANA, FOR THE UNLAWFUL PRACTICE OF MEDICINE. HE WAS ARRESTED ON THE OUTSTANDING WARRANT AND RETURNED TO INDIANA FOR PROSECUTION.

THE FBI IS ALSO INVOLVED IN SEVERAL OTHER ON-GOING INVESTIGATIONS WHICH, DUE TO THE SENSITIVE NATURE OF THESE INVESTIGATIONS, CAN NOT BE DISCUSSED AT THIS TIME.

THE FBI WILL CONTINUE TO IDENTIFY, INVESTIGATE AND WORK TO PROSECUTE THOSE WHO WOULD TAKE ADVANTAGE OF THE

ELDERLY AND THE SERIOUSLY ILL.

AT THIS TIME I WOULD BE HAPPY TO ANSWER ANY QUESTIONS.

THANK YOU.

The CHAIRMAN. Thank you very much, Mr. Lormel. Thank the panel members, all of you, for this. I know we have got a problem out there. We have got literally thousands of these manufacturers out there that are manufacturing this, and it seems to me that we are not doing, as a government, nearly enough to eliminate the snake-oil salesmen, as I have termed them, who operate in the 21st century, not on the street corner, but by very sophisticated targeting of seniors through mass-marketing efforts, and generate hundreds of millions of dollars that we saw one company making annually. It is a \$27 billion industry annually, all of it certainly is not fraudulent. In fact, the vast majority of it, I think, is very positive and very good.

But this is something that I think really deserves more attention than we seem to be giving it as the government. I am concerned that, in 1994, when we passed as Congress the Dietary Supplement Health and Education Act, referred to as DSHEA, that we did not help you folks in the enforcement area get to the problem actors in this supplement business. Am I correct in that observation? What, in general, is your opinion from an enforcement standard that you are involved in, of the effect of the Dietary Supplement Health and Education Act that Congress passed? Did it help you get rid of the bad actors? Did it not have any effect at all? Did it make it more difficult?

Mr. CURRAN. I can say anecdotally, in the case of Tee Up, Senator, the rip-off was out there before we learned of it. In other words, there was not any pre-market review. Thirty-seven hundred persons spent a lot of money already. You did not have a witness who was supposed to be here, Mrs. Crabb. The other thing that we were concerned about is that, in our case, folks who could have been helped in a legitimate area chose to go to this snake oil person. Mrs. Crabb's husband had esophagus cancer and was thought to be living another 18 months or 2 years, took this snake oil stuff and died within 2 weeks. That is the fellow over in Virginia who is in prison right now, happily, that doctor.

So my concern as an AG is that—we catch them after they do their deed. I wish that there was some way to make them be prescreened or premarketed, and then if it is good stuff, like I dare say there may well be, then fine.

The CHAIRMAN. There has been an explosion of these supplement sales, a 380-percent increase between 1990 and 1997. I am just wondering whether the actions by Congress contributed to the explosion of the growth in this area.

Mr. Taylor, I want some comments from FDA on this.

Mr. TAYLOR. Well, I am not sure if the legislation contributed to the growth of the industry, but I can tell you that, from an enforcement or law enforcement standpoint, the very fact that in dietary supplement enforcement cases, that the burden is on the agency to prove that the product poses a risk is a significant change and a significant difference from how we handle other cases.

The CHAIRMAN. Let's just talk about this. That is significant. We essentially changed the burden of proof on who has to approve whether this stuff is good or bad. Is that right?

Mr. TAYLOR. Well, there is no pre-approval, so it is just sort of a post-market model. As a result, once the product is on the mar-

ket, if FDA has decided that they wish to remove a product from the market because it poses a significant and unreasonable risk to the consumer, the burden is on FDA to establish scientifically that indeed the product does pose a risk.

The CHAIRMAN. Obviously, just for the information of the committee, what is the difference with regard to pharmaceuticals, over-the-counter generics?

Mr. TAYLOR. Sure. In the context of drugs, the burden is on the company to show that the product is safe and effective. So if we were going to bring an enforcement action against a pharmaceutical product, we could bring the enforcement action and the burden is not on us to show that it is harmful. It is on the manufacturer to show that indeed the product is safe and effective.

The CHAIRMAN. So the question to FDA is how much has the passage of the Dietary Supplemental Health and Education Act of 1984—how much of an effect has it had on the enforcement ability of FDA?

Mr. TAYLOR. It makes it much more challenging to bring enforcement actions.

The CHAIRMAN. I note that from GAO's testimony, that they say that the act allows FDA to remove from the market dietary supplements that the agency can prove are dangerous, but the agency has not prohibited the marketing of any specific substances using its administrative rulemaking authority. In fact, they say that FDA has not initiated any administrative rulemaking activities to remove from the market certain substances that its analysis suggest pose health risks, but has sought voluntary restrictions and attempted to warn consumers.

We had the first panel here talk about \$200 million in annual sales by a company that publishes the Journal of Longevity, and we had other people come in and say that it does not work, that it could potentially be harmful, and it targets and preys on seniors. Has the FDA done anything in regard to that particular activity by that particular enterprise?

Mr. TAYLOR. FDA is currently looking into that, those activities and that enterprise, and I do not want to say anything that would negatively impact on that inquiry. However, I would like to address the GAO's statements. The GAO is correct. There are two mechanisms that FDA could use to administratively remove a dietary supplement product. One avenue is a determination by the Secretary, and only the Secretary, that the product poses an imminent harm. The other mechanism is to use rulemaking to establish that a product maybe should be removed from the market.

That is in the administrative context, and no, we have not taken any products off the market through administrative channels. However, we have used enforcement actions to remove products marketed as dietary supplements that we felt actually were drugs masquerading under that protection and we have used injunctions in several instances to remove products that were marketed as dietary supplements off the market, and as part of the relief that we achieved in these injunctions, is language that would allow us to bring contempt actions if we found later on that these defendants were continuing to manufacture unapproved drugs under the guise of dietary supplements.

The CHAIRMAN. That is going after them under the old drug regulations and not under DSHEA?

Mr. TAYLOR. Yes. What happens is that—and you will note in my written testimony that we have several cases where companies have marketed products, claiming that these products are dietary supplements even though the products make mitigation, cure, and treatment claims. If you make mitigation and cure or treatment claims, then under the act the product is a drug, even if you market that product as a dietary supplement. That is the theory and the argument that we have used in several of the enforcement actions that are noted in the written testimony.

The CHAIRMAN. It seems to me that the Dietary Supplement Health and Education Act has greatly hamstrung and hand-tied your ability to assure the American people that these supplements that are increasing by huge amounts are, in fact, safe. The GAO went on to say that FDA's adverse effect reporting system for dietary supplements receives reports of only a small portion of all adverse events, and the reports that you receive are often incomplete, because no one has to report. These are voluntary. People are embarrassed. I am not going to report to the Federal Government that I was so stupid I bought something that did not work. I did not want to tell you about my magnets in my back, but I guess I did. [Laughter.]

So they do not want to report this stuff. In fact, for something more serious than magnets in my back and my back brace, GAO says that they found documents disclosed in a recent court case showed that a manufacturer of a product containing Ephedra had received more than 1,200 complaints of adverse events related to the product but FDA told us that they were aware of few, if any, of these reports before this lawsuit was filed. Does that not indicate a real breakdown between the amount of adverse reactions that are out there and the information that you are getting? If not, why not?

Mr. TAYLOR. Well, certainly you are correct. The very fact that it is a passive, voluntary system suggests that under-reporting does occur. However, there have been some instances where the adverse event reporting system has acted as a sentinel or signal of a growing problem. One example is a drug called gamma butyrolactone, which is a GHB precursor, and in the winter or the fall of 1998 and the winter and spring of 1999, we noticed an unusual level of adverse events that led us to bring actions against many of the manufacturers of these products, and these products were marketed for a myriad of claims, mostly energy enhancing, muscle enhancing, but they were also marketed for the purpose of addressing wrinkling and some other aging conditions.

So you are right that our adverse event reporting system, because it is passive, because it is voluntary, does have some weaknesses. But there have been instances where it has indeed provided us a signal that a problem is on the horizon or is already before us.

The CHAIRMAN. What about inspection of the manufacturing facilities? You have the authority to do that, but the information I have is that they are about—your own information tells me that

there are about 1,500 facilities that manufacture this stuff, and that last year you all inspected 53.

Mr. TAYLOR. That is correct. The number of inspections in the dietary supplement program are far fewer than in our other programs.

The CHAIRMAN. Is that because of a congressional act of Congress or because you do not have the resources to do it? Are we telling you not to do it?

Mr. TAYLOR. Well, no. I think that the final promulgation of the good manufacturing practice regulations will, first of all, do two things. One, it will help us locate some of these facilities, but more importantly it will set a standard that will help ensure that the dietary supplements are safe and properly labeled.

The CHAIRMAN. Right now you do not even know where they are?

Mr. TAYLOR. We know where some are, but because there is no registration requirement, it obviously is difficult to identify some of the sources of these products. But if you look at all of our other programs, the pharmaceutical program, the medical device program, a vast majority of our inspections are geared toward ensuring that companies are manufacturing their products in conformance with the good manufacturing practice regulations, because it is those regulations that set the standards for quality assurance and quality control in an industry.

The CHAIRMAN. I will tell you, if you are only doing 53 out of 1,500, that is just barely touching the tip of this problem.

Mr. TAYLOR. You are correct.

The CHAIRMAN. I have gone too long.

Senator Wyden.

Senator WYDEN. Thank you. Thank you, Mr. Chairman.

Gentlemen, thank you. Thank you very much for excellent, excellent testimony, and I hope you walk away knowing that you have seen Chairman Breaux, who has got a lot of responsibility, be with you for 3 hours, because we are committed to turning this situation around, and I just have a few questions I want to ask of you before we wrap up.

The first is we had sworn testimony this morning that Mr. Braswell's money finds its way to the Cayman Islands, is what we were told this morning. If that is the case, how does the government deal with that, and do you need additional tools to deal with it? I have said repeatedly that one of the areas that I think has changed most with respect to health care fraud is how much of this moves quickly around the world. But, since we had testimony with respect to the Cayman Islands this morning, I would be interested in having your assessment about how you would deal with that, if that, in fact, is what happened. May we start with you, Mr. Lormel?

Mr. LORMEL. Yes, certainly. I think without making specific reference to that case, because it is an ongoing investigation the IRS has, we conduct numerous investigations with a money laundering nexus, and venues like the Caymans are very attractive to somebody who is looking to park considerable amounts of money. We certainly can use assistance with the governments at play. We have worked very closely, I know from the Department of Justice standpoint, through MLATs, mutual legal assistance treaties, with

the different municipalities to try to get access and cooperation from the banking authorities in those venues. But certainly, as long as the fraudsters know that there is a safe haven for money, that money is going to move in that direction.

Senator WYDEN. So if that is where the money were to end up, and I was trying to characterize it as you did. It has been an assertion, but that was an assertion under oath that the money found its way there. In this particular case, where we are talking about a potential recidivist, as of now there is nothing the government can do about it?

Mr. LORMEL. Yes, sir. That is correct. What we would have to do is come into a situation where we had an indictment or some type of legal action, so that we could freeze monies and hopefully, through the Federal court system, we would forfeit the money back to the government.

Senator WYDEN. Does it require a change in Federal law to bring about those forfeitures?

Mr. LORMEL. I don't know that it requires a change in Federal law, as much as obtaining the cooperation of the foreign governments involved. I think, in that regard, we are making inroads, particularly in a place like the Caymans. That individual is going to be surprised to find out that there are cooperative initiatives underway in the law enforcement realm.

Senator WYDEN. For you other three, before I move onto other topics, in the international area, are there additional steps that you would favor the Congress pursuing?

Mr. CURRAN. The one example that we had in Maryland—I called to the authorities in the Bahamas, who were very receptive, so, one-to-one, they understood the problem, knew it was a fraud, and they stopped it. So that is a good news story and did not need anything other than a phone call, actually. That worked out well.

Mr. TAYLOR. I think my answer would be similar to the FBI and the State of Maryland. We have contacts in other countries overseas, and without commenting on the set of facts that are before us, we certainly have had other instances where money has moved offshore and we have been able to address a situation after indictments or some other judicial steps have been taken. So I think we do have the tools. We just have to look at the facts and formulate a strategy.

Mr. BEALES. At the FTC, we have been involved in trying to work out judgment recognition agreements in various international fora, in order to be able to collect on our judgments. We have also, in some cases, been successful in obtaining an order requiring someone to bring money back into the United States that was then available to satisfy a judgment.

Senator WYDEN. Mr. O'Neil did not think the system worked for him. Mr. O'Neil, at considerable exposure to himself, went to government agencies, went to, apparently, some of the people who work for all of you, and did not feel that people made the kind of effort that was necessary to deal with it. It is not a particularly encouraging account. In your view, how should the system have worked? Again, let's divorce it from this case, because this is a case under investigation. These are charges. They were made under oath, so they are particularly significant. But how should the sys-

tem have worked for Mr. O'Neil, again, because he is bringing to the attention of the government an instance that was already one that should have set off some red light, given the previous history?

Mr. Lormel.

Mr. LORMEL. Yes, if I may. We are dealing with Mr. O'Neil's perception and sensitivity there. The IRS does have an investigation and it is ongoing, but by the nature of these cases, they are so complex and they do not come to some type of closure or action in a relatively short frame. The frustration in going to numerous agencies, as apparently he did—and, sir, I would be very interested, as an aside, to find out if they came to the bureau and sit with you, and we could weigh what exactly happened or should have happened. I think perhaps, from the enforcement standpoint, there needs to be better sensitivity in dealing with the Mr. O'Neils who bring these complaints in, because certainly you are dealing with a case here that is outside the norm, and as he indicated, which is somewhat intimidating to him individually.

I hope that—and I know from the bureau's perspective, and I would have to think my colleagues' likewise—would not have been intimidated to take a case like that on, although that is the perception that is given because of, perhaps, the lack of communication back or dialog that he was looking for. Particularly, when you look again at a complaint of that magnitude, he sees it, he lives it first-hand, certainly when they bring us those facts, there are so many variables that go into whether or not we have jurisdiction, so there are jurisdictional concerns.

I think you guys have pointed to the fact that a case like this, there is so much wiggle room in terms of does the bureau have jurisdiction or does one of the other agencies have jurisdiction? So there are so many considerations at play, I would like to know what all the dynamics were in the dealings that Mr. O'Neil had, because I think that we could allay some of his concerns when you go point-by-point. However, there is a perception. It is a significant problem. We need to address it.

Mr. TAYLOR. Senator Wyden, since FDA was one of the agencies that was specifically cited, I find it unfortunate that his experience with FDA was not to his liking. I think it, quite frankly, is our responsibility to listen to his complaints. We have set up a web site that specifically deals with complaints about violative sites and violative conduct, and there is a connection on our Internet site. That does not always mean that we will be able to build a case. Obviously, there are complexities involved in building a case, but I think it certainly is our duty to listen to what he has to say, and if the information is useful, weigh that against a decision whether not to take some type of regulatory action.

Senator WYDEN. Let me ask it this way. When I asked Mr. Glen essentially about that, Mr. Glen said that the people who were contacted should have immediately brought together a sort of inter-agency kind of effort. He said we should have had the various consumer protection agencies, the various law enforcement agencies, invited several of the international bodies—I think you mentioned Canadian authorities and others—and we should have moved quickly in a concerted kind of way. My sense is that, for instances, again, where we are talking about potential recidivists, people who

have already been found to have violated laws that prevent preying on the elderly, that that would be a practical way to do it in the future. Is that what happens now? Is there an interagency effort where FBI, FTC, the FDA, the relevant State authorities come together and say, "Look, we are all people who care about following up here. Let's divide up the task." Is that done today?

Mr. TAYLOR. Well, I can tell you all the law enforcement agencies represented at this table were part of a law enforcement symposium that was held in San Antonio in July, and we discussed many of these issues. I think one of the things that the advent of the Internet did was, I think, highlight for all of us our limitations, and I think has reawakened the need to make sure that if it is something that jurisdictionally we cannot handle, that there is a mechanism for sharing that information with another agency, whether it be on a State or Federal level, that can work the matter.

That is why many of the working groups that I talked about earlier comprise members from all of these groups. There really is a need to ensure that enforcement is more seamless, so that we do not see some of the gaps that we have seen in the past.

Senator WYDEN. Well, I am going to explore this with you some more, because that seems to me what should have been done here, is when Mr. O'Neil came to your various agencies, there should have been some way to bring all of you who work in this area together, divide up the task, see who would have information, and clearly that was not done. It is always easy to Monday morning quarterback, but I think that needs to be done in the future.

Mr. LORMEL. Senator, if I may, just to follow on to that, that certainly would be the optimum situation. We deal more on a case-by-case dynamic, and it makes it somewhat difficult in terms of resources to be able to ideally deal with that. But you are right, we need to take a look. There are a number of working groups at the national and regional levels that do meet and deal with those cases. Again, I think we need to look at the specific dynamics at play here and then weigh it against the national picture.

Senator WYDEN. Well, that really leads me to my last point, Mr. Lormel, for you, and you are absolutely right. This is a case-by-case situation, and that is why I asked earlier about people who are repeat offenders, and I appreciate the kind words you had to say. What I would like to do in this area is I think there needs to be a way to set off some red lights, a kind of warning signal through the Federal Government when you are talking about people with a track record of exploiting older people. We do this in other law enforcement areas.

One of the things I am proudest of is I worked with all of you and Arlen Specter on the armed career criminal law, where we say when you are talking about repeaters, we are, in effect, going to have some warning lights that go off so we really target them and, of course, there are enhanced penalties. Tell us a little bit more then, since you were kind enough to say you liked it when I suggested it earlier, how you think it would be useful to target the recidivists and these repeat offenders? Clearly, case-by-case discretion has to be a part of it. But if you were going about trying to laser in on people with a track record of preying on older people, how would you do it?

Mr. LORMEL. Starting from within, just internally, from the bureau's perspective, before taking it to the other agencies, because clearly we need to have a joint operational initiative, and I would clearly call it that. We would have some type of operational initiative, and we would set up the parameters, basically, of the fraudsters we are looking at. We are looking at repeat offenders. You are talking significant dollar amounts, so you are talking cases that have a history.

So the first step is going to be to study our indices and do an analysis, and target proactively those offenders that are out there, bring in the other jurisdictional agencies with an interest. Again, as I would in a response to a crisis situation with an operational plan, put together an operational strategy and then proceed, and call it a national initiative. Perhaps this is an area that warrants such.

Senator WYDEN. I have imposed on the chairman's time. This has been an excellent, excellent panel. You all are on the front lines, and it is our job to get you the tools to do your work. So we will be working closely with you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Wyden, and thank you for your attendance throughout the hearing today. We really appreciate it and look forward to working with you, as well. I have one question and some closing comments.

Mr. Beales, I asked Mr. Taylor the question about whether, in his opinion—and I will ask you the same—of the Dietary Supplement Health and Education Act that was passed in 1994. Has it made your job as an FTC employee easier or more difficult in trying to find fraudulent bad actors in the area of dietary supplements?

Mr. BEALES. I think from the FTC's perspective it has not made any difference at all. The basic standard that claims have to be substantiated is the law enforcement standard that we would apply to any other product and that we have applied in other areas with a great deal of success.

The CHAIRMAN. So you are looking at advertising claims. You were doing that before this. You will do the same after?

Mr. BEALES. That is right. It really is not different. If I could just add one comment about recidivism, at the FTC we have a project called Project Scofflaw that actively looks for potential recidivists in violation of our past orders and then looks to see what kinds of steps are appropriate or remedy these recurrent violations. Some are referred for criminal prosecution. We have been successful in getting criminal contempt for violations of our orders, and some we pursue ourselves.

The CHAIRMAN. I want to thank this panel. I want to thank the previous witnesses, some who came and testified, which was a difficult task for them. We appreciate them and their traveling long distances to provide the testimony, and for our enforcement people for being with us today.

Mr. Attorney General, thank you for your good work in Maryland. I am disturbed by one of the conclusions in the GAO study that we asked them to do, which concludes, "At the risk of harm to seniors from anti-aging and alternative health products, it has

not been specifically identified as a top public health priority or a leading enforcement target for Federal and State regulators.” I know there are exceptions.

I think we have heard one today from the attorney general, but when you have an industry that has increased in sales by 380 percent between 1990 and 1997, that is a \$27 billion annual industry, marketing products, particularly to seniors—products who, in many cases, claim to be cures for everything from cancer to high cholesterol, to heart problems, to diabetes, to Alzheimer’s, that is still basically self-regulated, it seems to me that we have a very serious problem that needs to be addressed.

It seems to me that the Dietary Supplement Health and Education Act that Congress passed in 1994 has essentially changed the burden of proof on products that are being sold that guarantee health benefits to our citizens—was a very significant act. It seems to me that this is a huge business that is growing every day. I will also point out that many of the products are good, solid, do a great deal of good for the people that take them, but at the same time we have seen today that there is a concentrated effort through modern-day, 21st-century marketing efforts to market these products aggressively and specifically to the most vulnerable people among us. Not only do they cost a great deal of money that many of the people in the category that buy them do not have, they also present potential medical problems for the people who take them because of their interaction with other drugs, because they sometimes take the supplements instead of the prescribed drugs from their doctors, and we are seeing some of the results of these efforts.

I would hope that this committee would be able to look at making some recommendations in this area. At the very least, I think that this committee will continue to be involved in changing the attitude that this, in fact, should be a top public health priority for this government. We intend to see that it is made such. This hearing has been very helpful, and this will conclude the hearing.

[Whereupon, at 1:19 p.m., the committee was adjourned.]

APPENDIX

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NATURE'S LIFE

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September 24, 2001

United States Senate Special Committee on Aging
Room G-32 Dirksen Senate Office Building
Capitol Hill, Washington, DC 20510-6400
Attention: Patricia Hameister

Ms. Hameister,

On September 10th your committee held a hearing entitled *"Swindlers, Hawksters and Snake Oil Salesmen: The Hype and Hops of Marketing Anti-Aging Products to Seniors."* I would like to express my appreciation for the time and energy that you, Chairman Breaux, and the Committee devoted to the important topic of dietary supplements. The focus of the hearings, on illegal and potentially fraudulent marketing of consumer products to senior consumers, is also a topic worthy of not only scrutiny, but action.

The primary action needed, however, is not congressional legislation but rather regulatory enforcement, albeit encouraged and motivated by congressional oversight. The last decade was marked by two seminal pieces of congressional legislation governing dietary supplements: the Nutrition Labeling and Education Act of 1990 (NLEA), and the Dietary Supplements Health and Education Act of 1994 (DSHEA). Both have survived intact the dual rigors of executive regulations and judicial decisions.

The DSHEA in particular has suffered constant attacks since its passage, primarily from the well-financed spokespeople of the medical and pharmaceutical industries – always testifying, in their opinion, that dietary supplements are dangerous and inadequately regulated. This opinion is inaccurate in the extreme: as recently as last year, the last commissioner of the FDA, Dr. Jane Hanney, testified before the Senate Agricultural Committee, and the House Government Reform Committee, and unequivocally stated that she had adequate legislative authority to regulate dietary supplements.

The selection of people invited to testify before the Senate Select Committee on Aging implies that the intent of the committee was to lambaste unethical and predatory businesses selling ineffective nostrums to seniors. The primary "target", very justifiably, was the indicted criminal Draswell, and his continuing efforts to defraud American consumers, and specifically seniors. We loudly applaud the hearing, and encourage the committee to take appropriate legislative action to eliminate such illegal behavior. A representative from the Government Accounting Office testified, and included in their testimony their recent report on Dietary Supplements. The primary points of the report that we can and do actively support as appropriate action:

> The FDA has not used its already legislated powers to properly enforce against unsafe products and untruthful claims, even though they have the legislative authority and industry support to do so.

> The FDA does not have an effective Adverse Events Reporting System for dietary supplements, even though they have the legislative authority and industry support to develop one.

> The FDA has not finalized, nor mandated, Good Manufacturing Practices for Dietary Supplements, even though they have the legislative authority, and industry support to do so- including an already industry-developed set of GMPs to use.

Quality You Can Trust

Another highly credible witness from the Berkeley *Wellness Letter* (U. Of California) testified in agreement with the same points highlighted by the GAO report - but went too far in calling for an unnecessary revision of DSHEA to mandate OTC Drug Controls on dietary supplements. Such revision is not necessary IF the FDA actually enforces using the substantive authority already granted by DSHEA.

The real problem may be that FDA's dietary supplement efforts are woefully under funded, and FDA may lack qualified staff with sufficient knowledge of dietary supplements and our industry. Industry has repeatedly requested additional FDA funding for dietary supplements, including Congressional testimony (mine included before the House Government Reform Committee). If the FDA were better funded (presumably and hopefully) they would be more effective at enforcing against unsafe products and untruthful claims.

The bottom line is that " *caveat emptor*" is a recommendation for ANY consumer with ANY business, as we have discovered even more widespread deception of senior consumers from much larger industries ranging from auto tires, insurance policies, auto repair, movie reviews, "low-fat" & "low-carb" foods, genetically modified foods, investment pyramids and, most egregiously, profitable "non-profit" corporations seeking donations. Several authoritative government agencies have publicly verified the physiological benefits of dietary supplements, including the Food and Drug Administration, the National Academy of Sciences, and the National Institute of Health. **Please do not confuse the unethical practices of a few with the majority of the industry that legitimately provides beneficial health products to health-conscious consumers.**

What can seniors do to guard against fraud in their choices of supplements? Here are some suggestions that your committee may want to recommend:

- > Ensure the supplier is registered with a local Better Business Bureau.
- > Ensure that the evidence supporting benefit claims is objective and scientific, **not** personal testimonials.
- > ensure the supplier is a member of a reputable national trade association that has a Code of Ethics that all members must comply with (such as the National Nutritional Foods Association).
- > ensure that the supplier has no legal actions or decisions against it by the local, state or national authorities
- > ensure that the supplier has Good Manufacturing Practices for Dietary Supplements in place and that they are being followed (hopefully certified by an independent certifier, such as through the program developed by the National Nutritional Foods Association)
- > And finally - if it sounds too good to be true - it probably is.

DSHEA does NOT need to be amended - just enforced by the FDA. There will be ongoing efforts in congress to re-visit and revise DSHEA -- so we recommend that your committee first hold government regulators accountable for enforcing the will of congress before giving them additional mandates.

Regards & Health

Karl Riedel
(kriedel@natulife.com)

(12/21/01/aging-senate committee testimony)

The Honorable John Breaux
United States Senate Special Committee on Aging

Testimony of David Seckman, Executive Director/CEO of the National Nutritional Foods Association, on dietary supplement use by senior citizens.

Founded in 1936, the national Nutritional Foods Association (NNFA) is a national, non-profit trade association dedicated to protecting and advancing the natural products industry for retailers, suppliers and distributors. We appreciate the opportunity to provide testimony before the Special Committee on Aging on use of dietary supplements by America's seniors. NNFA supports this Committee's efforts to encourage all necessary enforcement action in order to eliminate the "bad apples" from this industry. (Attachment A.)

Much of the testimony being presented during this hearing, as well as the U.S. General Accounting Office report on Health Products for Seniors, suggest that countless elderly Americans are being swindled while the agencies assigned to protect them remains hamstrung by a bad law. We vehemently disagree with the assertion.

While it certainly may be true that the FDA and FTC are both underfunded and understaffed, they are not powerless to adequately regulate supplements. (Attachment B) In fact, the former commissioner of FDA, Dr. Jane Hanney, has testified before the House Government Reform Committee that the Agency has adequate authority to regulate supplements under the Dietary Supplement Health and Education Act (DSHEA). (Attachment C)

Among the enforcement powers granted DSHEA, the FDA can obtain an injunction against the sale of dietary supplements that make false or unsubstantiated claims. FDA also has the authority to seize products determined to present an unreasonable or significant risk of injury or illness.

FTC has the authority to regulate the truthfulness of consumer advertising, including advertising for dietary supplements. Under the Federal Trade Commission Act, an advertiser has an obligation to have prior substantiation for advertising claims. This ordinarily means having a reasonable basis for claims. Unsubstantiated claims are considered unfair and deceptive practices, which can subject a company to significant monetary penalties.

The legitimate industry complies with the law by maintaining product safety substantiation and production safeguards to ensure consumers of wholesome, clean dietary supplements. NNFA's recently implemented Good Manufacturing Practices program is an excellent example of an industry taking responsibility for its own products.

Both the GAO report and testimony at the hearing acknowledges that there is no problem with the vast majority of dietary supplements on the market. The health of our nation's seniors would greatly benefit if this fact were more widely known.

Nutrient deficiencies increase with age. Jane Brody recently reported in the New York Times, that "[t]oo many older people may be accepting a cognitive and immunological decline as a normal part of aging, when it may reflect a deficiency in essential nutrients like vitamins and minerals. A simple one-a-day type supplement may be all that is needed to slow or even stem that decline..." (Attachment D)

Thank you for the opportunity to provide testimony on this important topic. Please do not hesitate to contact us with any questions or if you need additional information.

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Published Tuesday, September 11, 2001

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With pills, elderly get sold short, panel told

Billions being spent on supplements

BY TONY PUGH
Herald Washington Bureau

WASHINGTON -- Unscrupulous retailers take advantage of lax federal rules to bilk older Americans out of billions of dollars a year by selling them worthless dietary and nutritional supplements, experts told the Senate Special Committee on Aging on Monday.

U.S. consumers spend an estimated \$17 billion each year on dietary supplements, and seniors account for about 80 percent of those sales in retail stores, by direct mail and over the Internet, according to recent surveys.

Supplements can pose greater health risks to seniors, who are more likely to take prescription drugs and to have medical problems, both of which can be adversely affected by the products, according to a report from the General Accounting Office, the auditing arm of Congress.

Monday's hearing also focused on the \$200 million dietary-supplement empire of Almon Glenn Braswell, a California businessman who owns about 13 supplement companies and who has a home in Coconut Grove.

Braswell, who invoked his Fifth Amendment right against self-incrimination and refused to testify, was pardoned by former President Bill Clinton just before he left office last January for a 1983 conviction on charges of mail fraud, perjury and tax evasion.

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Some supplements, such as the herbs St. John's wort and Echinacea, can be effective in treating minor medical ailments, studies have shown, and only a few have been found to have harmful effects among healthy adults. But experts advise people to consult their doctors before taking any such product.

Advertisements for a variety of pills, tonics, balms, potions and gadgets claim the products can help halt memory loss and weight gain, ease the effects of menopause, boost energy and curb arthritis pain. Those claims are mostly false and simply exploit the hopes and fears of older Americans, said Dr. Joyce Lashof, professor emerita at the School of Public Health at the University of California at Berkeley.

"When you promise older people, either explicitly or implicitly, that by taking your product they will slow down the aging process, live longer, have more energy, have fewer wrinkles, remember more and perform better sexually, you have touched a raw nerve," Lashof testified.

Some supplements, such as kava, an herb believed to reduce stress, could worsen symptoms of Parkinson's disease, said Jane Heinrich, director of health care and public health issues for the GAO.

Even Echinacea, which is commonly used to fight colds and flu, and St. John's wort, an herb with mild sedative effects, pose a risk of bleeding and cardiovascular instability during surgery, Heinrich said.

David Seckman, executive director of the National Nutritional Foods Association, which represents dietary supplement manufacturers, said he supports any effort to get the "bad apples" out of the industry.

Braswell, the recipient of a Clinton pardon, is widely known for touting the healing powers of his supplements through a direct-mail newsletter, The Journal of Longevity. He served seven months of a three-year sentence for falsifying photos that promoted a hair-growth product.

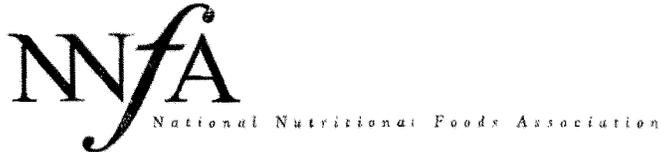
The pardon was controversial because the president's brother-in-law, Hugh Rodham, received \$400,000 for helping Braswell.

Under pressure from his sister, Sen. Hillary Rodham Clinton, D-N.Y., Rodham returned the money.

In testimony Monday, former employees of Braswell's accused him of knowingly issuing false claims about his products.

Under sworn testimony, Ron Tepper, editor of The Journal of Longevity, and Braswell both declined to comment on the advice of their attorney.

Attachment B

**Common Myths and Realities About Dietary Supplements**

MYTH: Dietary supplements are unregulated by the FDA.

Reality: Dietary supplements are regulated, although not in the way prescription or over the counter drugs are. Because dietary supplements are foods, and not drugs, the Food and Drug Administration (FDA) has the power to ensure that products on the market are both safe and accurately labeled. Before a product can be sold, a manufacturer must first notify the FDA of all intended label claims and ensure that they can be substantiated.

MYTH: The passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994 weakened the FDA's enforcement powers over the dietary supplement industry.

Reality: The passage of the DSHEA actually increased the FDA's enforcement powers over dietary supplements by establishing new labeling and potency standards. Violations of these standards are crimes. Under the DSHEA, the FDA has the power to:

- Refer for criminal action any company that sells a dietary supplement that is toxic or unsanitary [Section 402 (a)].
- Seize dietary supplements that pose an "unreasonable or significant risk of illness or injury" [Section 402 (f)].
- Stop a new dietary ingredient from being marketed if the FDA does not receive enough safety data in advance [Section 413].
- Stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard [Section 402 (f)].
- Obtain an injunction against the sale of a dietary supplement that has false or unsubstantiated claims [Section 403 (a), (6)].
- Require dietary supplements to meet strict manufacturing guidelines (Good Manufacturing Practices), including potency, cleanliness and stability [Section 402 (g)].

- more -

Dietary Supplements Myths vs. Realities
Page 2

In addition, there are industry self-regulatory efforts that supplement these governmental powers (see NNFA Leads the industry's Self Regulation) and the Federal Trade Commission has power over advertising and safety laws.

MYTH: Dietary supplements are unsafe.

Reality: According to a study published in the April 14, 1998 issue of *The Journal of the American Medical Association* (JAMA), adverse drug reactions, resulting from prescription and over-the-counter drugs, cause more than 100,000 deaths a year. Furthermore, the study estimates that 2.2 million people annually experience a serious adverse drug reaction.

In contrast, the FDA has on file approximately 2,500 "adverse event reports" (AERs), including 79 deaths, that *may* be related to dietary supplements. However, the FDA admits that these AERs may be flawed since there is "no certainty that an adverse event can be attributed to a particular product or ingredient." In addition, these AERs for supplements represent all reports to the FDA of adverse incidents allegedly connected to dietary supplements.

In addition, the February/March 1998 issue of *Nature's Impact* reports that dietary supplements are far safer to consume than foods, causing 1/60,000 as many deaths as foods each year. Consumers can check the safety of dietary supplements over the last two decades by comparing the incidence of deaths from all causes which are reported in either the *Journal of Emergency Medicine* or by the American Association of Poison Control Centers in Washington, D.C.

MYTH: There are no scientific studies supporting the efficacy of most dietary supplements.

Reality: Each year, numerous studies are published in major medical journals that support the use of dietary supplements for the treatment of specific conditions, prevention of diseases or for general nutritional enhancement. Such studies can be found in *The Journal of the American Medical Association*, *New England Journal of Medicine*, *American Journal of Cardiology*, *American Journal of Clinical Nutrition* and the *Journal of the National Cancer Institute*.

In addition, several leading research institutes and national associations such as John Hopkins University and the American Heart Association, have conducted and released studies on the benefits of dietary supplements.

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Attachment C

STATEMENT BY JANE E. HENNEY, M.D.
COMMISSIONER
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
MARCH 25, 1999

Excerpt

Mr. Chairman, I share the goal of making safe products available to consumers who want to make informed personal choices about using dietary supplements to improve their health. DSHEA was enacted to ensure access to those products. I also believe DSHEA provides FDA with the necessary legal authority to protect the public health. We will do our best to marshal the scientific information and expertise necessary to exercise that authority when the public health is threatened.

Attachment D

AUG 21, 2001

Nutrition a Key to Better Health for Elderly

By JANE E. BRODY

Attention, people over 65. Is your brain slowing down, your memory failing, your resistance to infection taking a nose dive? This is not an advertisement for a secret anti-aging formula, but a call to improve your nutrition.

Too many older people may be accepting a cognitive and immunological decline as a normal part of aging, when it may reflect a deficiency in essential nutrients like vitamins and minerals. A simple one-a-day type supplement may be all that is needed to slow or even stem that decline, recent studies show.

Surveys have shown that up to 40 percent of elderly people who live independently in affluent countries consume insufficient amounts of one or more essential nutrients or have deficient levels of these nutrients in their blood.

The reasons for these deficiencies include a limited income, difficulty getting to stores, chronic illnesses or medications that interfere with nutrients, problems with chewing or digesting, and poor appetite. Inactivity or illness can depress the appetite, as can a loss of taste, older people who eat alone or who are depressed can also lose interest in food.

Nutrient deficiencies appear to increase with age. A new study by Teresa A. Marshall and her colleagues at the University of Iowa looked at over 400 lowans /9 and older living independently in rural areas and found that 80 percent reported consuming inadequate amounts of four or more nutrients. In findings important to disease prevention, 75 percent of those people consumed too little folate, a B vitamin that helps prevent heart disease and stroke. And 83 percent did not get enough vitamin D and 63 percent got too little calcium, both essential to preserving bone and preventing osteoporosis and fractures.

Other nutrients commonly in short supply were vitamin E, magnesium, vitamin B6, vitamin C and zinc. Nutrient deficiencies were especially prominent among participants who relied on a limited number of foods.

In a report in the journal Nutrition last month, the authors recommended that older people be encouraged to increase the variety of foods they eat especially nutrient-rich fruits, vegetables and whole grains, and to take daily nutritional supplements.

"Supplement use allowed a small number of subjects to have adequate nutrient intakes," the authors wrote. "However, a substantial number of subjects who might have benefited from supplement use did not consume them."

8/23/01

Sharper Minds

In the newest report on better nutrition among the elderly, Dr. Ranjit Kumar Chandra, a pediatrician and immunologist at Memorial University of Newfoundland, demonstrated that a nutrient supplement with modest amounts of 18 vitamins, minerals and trace elements could improve cognitive function in apparently healthy people over 65. The study involved 86 people who were living independently and randomly assigned to take either the 18-nutrient supplement or a dummy pill for a year. The participants and the researcher did not know who was taking what until the study was finished.

As described in Dr. Chandra's report in Nutrition this month, those who took the supplement showed significant improvement in short-term memory, problem-solving ability, abstract thinking and attention. Even the participants who started out with adequate nutrition got some mental benefits from the daily nutrient supplement, although the greatest improvements occurred in people whose blood contained deficient amounts of one or more nutrients, Dr. Chandra said. No change occurred in long-term memory, which has long been known to be relatively immune to aging's effects.

Dr. Chandra said the cognitive benefits from improved nutrition could significantly improve the lives of the elderly. They would be better able to perform the activities of daily living and would presumably discover more joy. He emphasized that megadoses of nutrients were not necessary or desirable because high doses of certain nutrients could have serious negative effects. The supplement he suggests contains the recommended daily amounts or less of most vitamins and minerals and somewhat larger amounts of beta carotene and vitamin E.

How might nutrients improve brain function? One possibility is that taking a modest nutrient supplement daily can improve immune function. "An enhanced immune response in those receiving the nutrition supplement may be instrumental in preserving the anatomy and function of neurons and their appendages," he wrote in the new report.

Improving Immunity

Dr. Chandra suggested that by improving immunity, the supplement may prevent the accumulation of beta-amyloid, neurofibrillary tangles and other harmful deposits associated with serious neuronal damage and neuropsychiatric disorders like Alzheimer's disease. But it remains to be shown whether a nutrient supplement can delay or prevent the onset of dementia.

In a report nearly a decade ago, Dr. Chandra showed that the same supplement resulted in a significant improvement in standard immunological tests, including the number of natural killer cells and helper T-cells, the production of interleukin 2, and the antibody response to the influenza vaccine.

He also found that the supplement could restore a lagging immune response in six months, and sometimes as soon as three months. No improvement was found in those who took a dummy pill.

To be sure of the supplement's benefits, the researchers checked on the participants every two weeks to determine whether they had experienced an infectious illness or needed antibiotics. Infection-related illness occurred an average of 23 days in the year among those taking the supplement, while those taking the dummy pill averaged 48 days of infectious illness.

Dr. Chandra said that while it was most desirable to consume a nutritionally adequate diet, he was struck by the cost-effectiveness and simplicity of a nutritional supplement to prevent or delay illness and functional decline in

the elderly. Based on his findings, he has calculated that for every dollar spent on such a nutrient supplement, \$28 would be saved in health care costs.

The precise amounts of the nutrients in the supplement used in Dr. Chandra's studies were determined by how much of each nutrient had shown a maximum benefit to the immune system in his studies.

For comparison with the vitamin supplements sold to older adults, here are the contents of Dr. Chandra's supplement: 400 retinol equivalents (1,333 International Units) of vitamin A, 16 milligrams of beta carotene, 2.2 milligrams of thiamine, 1.5 milligrams of riboflavin, 16 milligrams of niacin, 3 milligrams of vitamin B6, 400 micrograms of folate, 4 micrograms of vitamin B12, 80 milligrams of vitamin C, 4 micrograms (160 I.U.'s) of vitamin D, 44 milligrams (44 I.U.'s) of vitamin E, 16 milligrams of iron, 14 milligrams of zinc, 1.4 milligrams of copper, 20 micrograms of selenium, 0.2 milligrams of iodine, 200 milligrams of calcium and 100 milligrams of magnesium.

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Tammy L. Born, D.O.
Gary H. Colter, D.O.
Arden B. Andersen, D.O., Ph.D.
Lisa C. Graham, Physician Assistant

September 13, 2001

U.S. Senate Special Committee on Aging
G32 Dirksen
Senate Office Building
Washington, D.C. 20510-6400

Attn: Patricia Hameister

Dear Ms. Hameister:

Thank you for reviewing this letter. I am a physician who practices complementary and alternative medicine in Grand Rapids, Michigan. We use as many natural products on patients as possible to avoid the expense and complications that may be associated with prescription medication. I completely agree that false claims and fraudulent advertising are serious offenses. However, I believe that adding additional regulations to natural products would seriously limit a person's right to choose natural products for their personal health care needs.

Please do not allow any further regulation of nutritional supplements by the FDA as it has been proven through many avenues that it is not the best mechanism for providing accurate data to the American public. Please work to maintain our freedom to choose the type of medical treatment we desire.

Sincerely,

A handwritten signature in cursive script that reads "Tammy L. Born".

Tammy L. Born, D.O.
4580 2nd St.
Caledonia, MI 49316

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totalhealth
FOR LONGEVITY

September 17, 2001

United States Senate Special Committee on Aging
G32 Dirksen Senate Office Building
Washington, D.C. 20510-6400

To whom it may concern:

As publishers of *totalhealth* for LONGEVITY magazine I am concerned that the results of the recent senate committee on aging hearing may have presented a biased view of anti-aging medicine.

Granted, as with any unique sector of our society, there are a plethora of "swindlers, hucksters and snake oil salesmen" who will attempt to prey on its special circumstances, needs and dreams.

However, there are also thousands of reputable companies and individuals involved in developing nutritional products, exercise programs, medical therapies and natural approaches to prolonging the onset of, arresting and reversing dementia. As well as a host of other valuable and viable positive, even miraculous tools for assuring the quality of the increased quantity of life we are experiencing at the onset of the 21st century.

I applaud you for your interest in protecting the welfare of our aging population. If you are interested in a list of individuals who are making significant contributions to the cause of healthy aging to testify at your next hearing, please contact me at 1-888-316-6051.

Regards,



Lyle Hurd
Editor/Publisher

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**Written Submission of Dan Burton (R-IN),
Chairman, Committee on Government Reform
to the Record of Senate Special Committee on Aging
Hearing of September 10, 2001 on Anti-Aging Products for Seniors**

As Chairman of the House Committee on Government Reform, I initiated oversight investigations looking at the role of complementary and alternative medicine in our health care system and the Food and Drug Administration's (FDA's) implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA). We have conducted numerous hearings over the last three years examining these issues.¹ We anticipate completing this investigation over the next 14 months and issuing reports of our findings next fall.

The title of the September 10 Senate hearing, "Swindlers, Hucksters and Snake Oil Salesmen: The Hype and Hope of Marketing Anti-Aging Products to Seniors," left many believing that the Senate Special Committee on Aging has discounted the benefit of any nutritional supplement for the aging population and condemned all manufacturers as crooks. I find this disturbing, especially at a time when it is increasingly recognized that Americans can improve their health status, prevent disease and chronic health conditions by paying attention to their lifestyle. By improving nutritional support and physical activity individuals can in fact have better health including healthier aging.

On August 8, HHS Secretary Tommy G. Thompson made the following announcement:

"At least 10 million Americans at high risk for type 2 diabetes can sharply lower their chances of getting the disease with diet and exercise, according to the findings of a major clinical trial. In view of the rapidly rising rates of obesity and diabetes in America, this good news couldn't come at a better time. So many of our health problems can be avoided through diet, exercise and making sure we take care of ourselves. By

¹Information on the House Committee on Government Reform's Health Care Hearings can be found at <http://www.house.gov/reform/healthcare/index.htm>

promoting healthy lifestyles, we can improve the quality of life for all Americans, and reduce health care costs dramatically.”²

The role of dietary supplements is even more important for the aging population given that many seniors are not able to obtain all of their daily vitamin and mineral requirements through food consumption alone.

There is no one in Congress that will tolerate the abuse of vulnerable populations including senior citizens. Whether it is products sold without substantiation for aging-related conditions, telephone scams for bogus charities, scams involving long-term care insurance, credit cards, home improvements, travel, or magazine subscriptions – intentionally misleading someone for financial gain is unacceptable and illegal. This is why we have empowered Federal regulatory agencies such as the Federal Trade Commission and the FDA with appropriate authorities to go after those individuals and companies who market illegal products or services or make illegitimate claims.

In 1994, Congress passed DSHEA by unanimous consent and with significant grass roots support. With the passage of the DSHEA Congress recognized the important role that vitamins, minerals, botanicals, and other dietary/nutritional substances can play in improving and maintaining health. Congress found that:

- *the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;*
- *there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis;*
- *consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;*
- *national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;*
- *although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers; and*
- *dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare.³*

² “Diet and Exercise Dramatically Delay Type 2 Diabetes - Diabetes Medication Metformin Also Effective” <http://www.hhs.gov/news/press/2001pres/20010808a.html>

³ Public Law No: 103-417

It is often misreported in the media that with the passage of DSHEA the FDA lost the ability to regulate supplements. The fact is that the FDA has seven points of authority to regulate dietary supplements. The FDA has the power to:

- Refer for criminal action any company that sells a dietary supplement that is toxic or unsanitary [Section 402(a)]
- Obtain an injunction against the sale of a dietary supplement that has false or unsubstantiated claims [Section 403(a),(r6)]
- Seize dietary supplements that pose an "unreasonable or significant risk of illness or injury" [Section 402(f)]
- Sue any company making a claim that a product cures or treats a disease [Section 201(g)]
- Stop a new dietary ingredient from being marketed if FDA does not receive enough safety data in advance [Section 413]
- Stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard [Section 402(f)]
- Require dietary supplements to meet strict manufacturing requirements (Good Manufacturing Practices), including potency, cleanliness and stability [Section 402(g)]

When asked about the FDA's power to regulate supplements, Dr. Jane Henney, then FDA Commissioner testified to the Committee on Government Reform in 1999 that the FDA had adequate authority to regulate dietary supplements. One issue of major importance is the full implementation of DSHEA, including most specifically the formation of Good Manufacturing Practices (GMPs) for dietary supplement manufacturers. Until GMPs are in place and the FDA becomes active in looking at enforcing GMPs, we will not have a full implementation of DSHEA. In the mean time, the FDA has the authority to enforce each of its authority including the current GMPs. Many of the concerns the public expresses about quality assurance are directly connected to the FDA's need to enforce GMPs. The FDA's written testimony provides information on a series of actions taken over the last decade but provides not a single example of scams against the elderly.

Additionally the Federal Trade Commission has jurisdiction on advertising claims for dietary supplements. The FTC published guidelines for manufacturers and has been very active in regulating these products.

Many of our nation's seniors are subjected to treatments in "conventional medicine" that are not necessary, cost more and are more dangerous than equally effective alternatives. This is of grave concern to me as well. Senior citizens are also oftentimes the victims of medical errors that result in tragedy and death. The over use of prescription drugs in nursing homes that cause impaired memory and confusion is an ongoing concern. Additionally, many physicians routinely prescribe high cost prescriptions drugs, oftentimes with significant side effects when there are lower cost options with fewer side effects available. Veterans Administration funded research found that Saw Palmetto was equally effective as a prescription drug for treating the symptoms of mild to moderate Benign Prostatic Hyperplasia (BPH). This condition, which affects an estimated

14,000,000 over the age of 50 in the United States. Treatment costs in the United States for BPH exceed two billion dollars a year and account for 1.7 million office visits each year.⁴ Saw Palmetto cost and side effects are significantly less than prescription drug alternatives.

Had the FDA not taken action to keep all red yeast products off the market, American seniors would have been able to choose a red yeast rice supplement instead of a prescription statin such as Bayocal. Earlier this year, the National Cholesterol Education Program - which is coordinated by the National Heart Lung and Blood Institute - recommended aggressive treatment of high cholesterol in diabetes and high blood pressure patients through the use of statins. On August 8, 2001, Bayer removed the statin drug Bayocal (cerivastatin) from the U.S. market because of reports of a severe muscle adverse reaction, rhabdomyolysis, which was sometimes fatal. On August 20, 2001, Public Citizen's Health Research Group urged the FDA to issue strong "black box" warnings on all HMG-CoA Reductase Inhibitors (statins) after researchers found that over the last 13 years the agency had received reports of 81 additional deaths from rhabdomyolysis among people taking statins. Besides the 31 fatalities involving cerivastatin, there were 81 other deaths from rhabdomyolysis involving statins from 1987, when the first one was introduced, through 2000. The statins on the market include lovastatin (Mevacor), pravastatin (Pravachol), simvastatin (Zocor), fluvastatin (Lescol) and atorvastatin (Lipitor). Cerivastatin had, by far, the largest number of reports of fatal and nonfatal rhabdomyolysis, although it held less than 10 percent of the market at the time it was withdrawn. Side effects for these drugs include: an allergic reaction (difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives; muscle aches, pain, or weakness; "flu-like" symptoms; decreased urine or rust-colored urine; blurred vision; or yellowing of your skin or eyes. Less severe side effects listed are: gas, bloating, nausea, stomach upset, heartburn, abdominal pain, constipation, or diarrhea; cough; headache; or insomnia.⁵

In a multi-center clinical trial of red yeast rice in subjects with elevated cholesterol - 18% were judged to have adverse reactions possibly or probably related to Red Yeast Rice treatment. The reported adverse events were headache, abdominal bloating, and gas. The trial, which took place at 12 U.S. sites confirmed that treatment with a traditional Chinese food, red yeast rice, was well tolerated and was effective in reducing TC, LD-c, TG and ratio of TC:HDL-c, and in increasing HDL-c in patients with hyperlipidemia. The cost of a red yeast rice supplement is only 20 percent of the prescription drug. This translates to approximately \$33.5 billion versus \$ 5.5 billion annually for the affected Medicare population. As we consider a prescription drug benefit for Medicare, we must think about these options and look for ways to reduce our dependence on expensive prescription drugs.

There is also significant government funded research showing the benefit in the senior population for such nutritional supplements as vitamins C and E, folic acid, coenzyme Q10, and Omega-3 fatty acids. The Office of Dietary Supplements has done a terrific job

⁴ VA Practice Matters, Vol 3 Issue 1, July 1998 http://www.va.gov/resdev/ps/pshsrd/PM_BPH.pdf

⁵ <http://www.citizen.org/hrg/PUBLICATIONS/1588.htm>

of providing accurate information and links to public and private resources on their Internet site.⁶

At a meeting of the American Society of Clinical Oncologists in the spring of this year, Dr. Ezekiel Emmanuel presented a study showing that doctors are prescribing chemotherapy to patients for cancers known not to be unresponsive. Using billing records of nearly 8,000 patients in the state of Massachusetts they found that 41 % of patients received chemotherapy in the final year of life, 33 % in the final six months, and 25% in the final three months. The researchers found that at six months, three months, and one month before death that chemotherapy was given with the same amount of frequency between the two groups. The research showed that for patients with cancers generally recognized as being unresponsive to chemotherapy (gallbladder, kidney, liver, pancreatic, and melanoma) in the last year of life, doctors prescribe treatments that cost \$38,000 when they know it is not going to help.⁷ Prescribing expensive drugs with serious side effects when there are lower cost, less dangerous options available and prescribing chemotherapy, which has significant risks associated with it and can cause a terrible loss of quality of life, when there is no evidence that it will benefit are serious scams within the medical community that need to be addressed.

I don't think we in government give Americans enough credit for being able to make their own medical and nutritional choices. Research shows that individuals who have made a determination to use CAM therapies are typically individuals who have at least some college education. I think we as a Government need to do a better job of enforcing existing laws and providing information about CAM and nutritional options.

One of the primary subjects of the September 10 hearing was Gero Vita International and the magazine owned and operated by businesses controlled by Glen Braswell. The provisions of DSHEA specifically state that manufacturers may not make claims to cure, treat, or mitigate disease. If Gero Vita International or any manufacturer is making any disease claim, the FDA has the authority to take action. Additionally if any manufacturer is making claims that they can not substantiate, the FTC has the authority to take regulatory action.

One bad apple does not, however, spoil the whole bushel basket. The entire supplement and alternative medicine industry should not be measured by Glen Braswell and Gero Vita International. The majority of supplement manufacturers are credible, honest businesses that seek to provide quality products and legal information to the consumer. Glen Braswell, convicted of mail fraud, perjury and fraud, who is under investigation for tax evasion and money laundering hired Hugh Rodham and succeeded in bypassing the normal procedures at the Justice Department to receive a pardon from former President William Clinton just hours before he left office.

Additionally, I would like to point out that we have learned that Dr. Timothy N. Gorski is not currently affiliated with the University of North Texas Health Science Center

⁶ The Office of Dietary Supplements URL: <http://ods.od.nih.gov>

⁷ Gottlieb, Scott; Chemotherapy may be overused at the end of life, BMJ Vol 322, page 1267 26 May 2001

(UNTHSC). Dr. Gorski lists on the first page of his testimony that he is an “Assistant Clinical Professor at UNTHSC. In his testimony he makes strong attacks regarding alternative medicine, including attacks on the credibility of research published after peer-review in the prestigious *New England Journal of Medicine*. Coming from someone with an academic appointment from UNTHSC, these attacks carry significantly more merit than someone who has made a career of attacking CAM practices. Calls from my staff on September 21 to the University of North Texas Health Sciences Center, including to the University President, uncovered that Dr. Gorski is not an employee or on faculty of that center. He is not now, nor has he been on faculty at least as far back as 1998.⁸ His intentional misuse of an academic affiliation should completely discount his testimony. A follow up investigation by UNTHSC uncovered that in 1991 Dr. Gorski had been granted a clinical appointment because he was on staff at a community hospital where UNTHSC sent several residents. In 1995 UNTHSC conducted an audit of these clinical appointments, sending letters requesting verification of credentials and licensing was sent to all community physicians. Dr. Gorski never responded and was dropped from the clinical appointment.

Dr. Gorski attacks the credibility of the Office of Alternative Medicine/National Center for Complementary and Alternative Medicine (NCCAM)⁹, which was created by Congress in order to address the unmet research needs in this field. He goes on to attack individuals, including Dr. Wayne Jonas the former Director of the Office of Alternative Medicine who was appointed to the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP). It should be noted for the record that Dr. Jonas, was recently honorably retired from the United States Army as a Lt. Colonel, after twenty years of service to our country. Dr. Jonas continues to serve our country on the White House Commission and offers a level of scientific expertise that few in the world can equal. Expertise that is based on thorough and honest review of existing theories, peer-reviewed scientific evidence, training in CAM therapies, exploration of research methodologies, and rigorous scientific research.

Dr. Gorski further states that the NCCAM “continues to be staffed and controlled by ideological advocates”. Dr. Stephen Strauss, the NCCAM Director is an expert in clinical research, he has stated in Congressional testimony and in media interviews that he is not an expert in or advocate of complementary medicine. He and his entire staff are committed to gathering information of existing research evidence in CAM, and funding and conducting rigorous research to expand the evidence base of CAM. The same is to be said of the staff of the WHCCAMP. They are highly qualified, dedicated, long-time Federal employees who have given their careers to public service. They do not deserve to be disparaged in that public service. The WHCCAMP was created by Congress to provide much needed advice on CAM. The Commission, which is comprised of

⁸ Based on staff telephone conversation with University of North Texas Health Sciences Center (UNTHSC) President, Dr. Ron Blanck (Retired Army Surgeon General) on Friday, September 21, 2001 and with the Office of Human Resources Management at both UNTHSC facilities and return call from Dr. Blanck on September 24.

⁹ Information on the National Center on Complementary and Alternative Medicine can be found at <http://www.nccam.nih.gov>

individuals knowledgeable in both conventional and complementary and alternative medicine, has been charged with addressing:

- Research on CAM practices and products.
- Delivery of and public access to CAM services.
- Dissemination of reliable information on CAM to health care providers and the general public, and
- Appropriate licensing, education, and training of CAM health care practitioners.

The Commission's recommendations on public policy and legislation are due to the President through the Secretary of Health and Human Services in March 2002.¹⁰

I am also concerned that the GAO's report did not include references to experts they consulted who provided "the rest of the story", i.e. products and treatments that could provide benefits to senior citizens. It has been reported to the Committee on Government Reform that individuals who the GAO contacted did provide such information. Their names and the positive information provided to GAO was left out of the report.

Conclusions

Given the concerns raised during this hearing, the long-standing Congressional request for the National Institutes of Health's various entities including NCCAM to conduct research and gather existing scientific data and make it known to the public is more important than ever.

In 1998, the Department of Health and Human Services announced a five year project, "The Healthy Aging Initiative" to identify the best ways to promote health and prevent physical decline among older Americans. To date, this project has focused entirely on clinical services provided under Medicare such as cancer screenings. This may be an appropriate avenue to coordinate a review of the existing science and traditions regarding aging-related nutrition, including supplementation in order to better understand the role of dietary supplements in healthy aging.

We have made tremendous advances in health care over the last century. Americans are more savvy than ever before and not easily duped by flashy advertising. Our seniors no more believe television advertising that suggests that arthritis patients will be able to ride skateboards with their grandchildren than they believe Chicken Little if he bought air time and said the sky was falling. Quality dietary supplements can and do offer benefits to the structure and function of the aging body when used wisely. We have laws that should be fully implemented and enforced. Americans deserve nothing less.

¹⁰ Information on the White House Commission on Complementary and Alternative Medicine Policy can be found at <http://www.whccamp.hhs.gov>

A Written Response to the Statement of the Honorable Congressman Dan Burton (R-IN),
Chairman, House Committee on Government Reform to the Record of the
Senate Special Committee on Aging Hearing on
“Swindlers, Hucksters and Snake Oil Salesmen: The Hype and Hope
of Marketing Anti-Aging Products to Seniors,”
September 10, 2001
United States Senate
Washington, DC

By Timothy N. Gorski MD FACOG

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INTRODUCTION

The Honorable Congressman Dan Burton’s forceful objections to the Senate Special Committee’s hearing and his accusations directed at me and my testimony are serious and deserve a response. I appreciate the opportunity of doing so, though it is without benefit of a paid research staff. In addition, I am under considerable pressure of time while caring for my patients in my full-time practice of Obstetrics and Gynecology as well as meeting my family obligations. Although I prefer to be brief, the nature of these objections limits that intention.

THE NATURE AND PURPOSE OF THE HEARING

To begin with, Chairman Breaux and the Senate Special Committee on Aging are to be commended, not condemned, for considering the very serious problem of fraud in the dietary supplement industry and, in particular, its impact on older Americans. This problem has received very little attention since the 1984 Pepper Report¹ and it is absolutely clear that current law and enforcement resources have been and remain insufficient to address it.

Senator Breaux made it very clear in his opening remarks that the focus of the hearing was on the “bad actors” in the multibillion dollar dietary supplement industry. The activities of Mr. A. Glenn Braswell were considered in detail and it was brought out that current penalties for fraud in this business are insufficient to stop or deter it. Mr. Braswell and Mr. Tepper, appearing under subpoena, repeatedly exercised their Fifth Amendment privileges. Additional witnesses, including myself, presented evidence, including many examples, showing that Mr. Braswell’s misbehavior is far from unique and must be considered in its context to be understood.

It was clearly and emphatically not the purpose of the hearing to indiscriminately discount the benefit of all vitamin, mineral or other supplementation of the diet or to condemn all

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.

manufacturers of such products. No evidence was presented that would argue for such a conclusion. Nor was the purpose of the hearing to take issue with well-established facts concerning the health benefits of diet, exercise, or the use of vitamin and mineral supplementation generally or in the management of specific health problems. On the contrary, evidence was presented by myself showing that perpetrators of fraud take advantage of the deliberate blurring of distinctions between the rational and the irrational engaged in by advocates of the latter.

It was also not the purpose of the hearing to consider the many ways in which the nation's medical care system as a whole might be improved, or even what improvement might consist of. But the Honorable Congressman Burton took the opportunity to assert that:

“Many of our nation's seniors are subjected to treatments in ‘conventional medicine’ that are not necessary, cost more and are more dangerous than equally effective alternatives.”

There are simply no facts to support this claim. As I pointed out in my testimony, there is widespread recognition and a wealth of examples to prove that the standards of medical science – falsely labeled “conventional,” and sometimes “traditional” or “orthodox” – are in continual flux in response to evidence. Treatments of any kind that are clearly shown to be superior have always quickly supplanted previous methods without need of legislative mandates. This is the essence of scientific progress.

Congressman Burton expresses outrage that I would question the conclusions of a report “published after peer-review in the prestigious *New England Journal of Medicine*.” Yet it is a fact that the findings of the article in question² have been systematically misrepresented by its lead author and by other advocates of irrational and aberrant methods including the NCCAM. The facts related to this deception have been documented in another peer-reviewed journal.³ This is the way of science. The literature is not sacred scripture, but dialogue in which facts are presented, considered, critiqued, and conclusions reached, rejected or modified. But this process should be governed by facts and reason and not by political, ideological or emotional considerations.

DSHEA

Several witnesses identified the 1994 DHSEA legislation, however well-intended it may have been at the time, as a principal contributor to the problem of fraud in the dietary supplement industry. This assessment has also been made by others,^{4,5,6,7,8} including former FDA Commissioner David Kessler⁹ and the editors of *The New England Journal of Medicine*.¹⁰

² Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, Deibanco TL. “Unconventional medicine in the United States. Prevalence, costs, and patterns of use.” *The New England Journal of Medicine* 1993 Jan 28;328(4):246-52.

³ Gorski T, “Does The Eisenberg Data Hold Up?” *Scientific Review of Alternative Medicine* 1999;3(2):62-69 available online at <http://www.hcrc.org/contrib/gorski/eisenb.html>

⁴ Talalay P, “The importance of using scientific principles in the development of medicinal agents from plants,” *Acad Med* 2001 Mar;76(3):238-47.

⁵ Nesheim MC, “What is the research base for the use of dietary supplements?” *Public Health Nutr* 1999 Mar;2(1):35-8.

As the FDA's own website advises consumers, "there is no provision under any law or regulation that FDA enforces that requires a firm to disclose to FDA or consumers the information they have about the safety or purported benefits of their dietary supplement products."¹¹ The FDA cannot take action against supplements that are worthless or merely suspected of being harmful, as it can – and has – in the case of both prescription and over-the-counter medications. Evidence presented at the hearing showed that the FDA has been unable to remove even dangerous supplements from the marketplace, not even ephedrine products which have injured thousands of people. When enforcement actions are taken, the FDA has no authority to inflict financial penalties, so that perpetrators of fraud bear no net financial cost from their predations. There is not even a requirement that the FDA be notified about the sale of a "dietary supplement" or of the identity and whereabouts of its manufacturer and promoters.

In essence, the provisions of DSHEA established an enormous and unprecedented "honor system" for substances promoted as having drug benefits. Evidence presented at the hearing – which represented merely a small sampling – showed that many in the industry are simply not honorable. Nor will the promulgation of good manufacturing practices adequately address the problem. So great has the problem become that polling data now show that "a majority of Americans surveyed supported the following: to require that the Food and Drug Administration review the safety of new dietary supplements prior to their sale; to provide increased authority to remove from sale those products shown to be unsafe; and to increase government regulation to ensure that advertising claims about the health benefits of dietary supplements are true."¹²

Evidence was presented at the hearing that the FTC has stepped up its enforcement actions in the regulatory vacuum created by DHSEA. This it has been able to do by relying on its authority to take action against advertising that lacks a competent scientific basis. But Congressman Burton would remove even this means of recourse against fraud in the dietary supplement industry. In the 106th Congress he introduced the so-called "Dietary Supplement Fairness in Labeling and Advertising Act," H.R. 3305, which would have amended the Federal Trade Commission Act in order to render the FTC as ineffectual as the FDA.¹³

I am very grateful that the Honorable Congressman Burton raised the matter of red yeast rice as an alternative to prescription "statin" drugs. This is yet another excellent example of how DSHEA has corrupted the law and, with it, the understanding of Americans with respect to products promoted as having health benefits. For on the one hand was the "drug" lovastatin, sold under the trade name Mevacor®, which the FDA requires be proven safe and effective for its

⁶ Mencimer S "Scorin' with Orrin: How the gentleman from Utah made it easier for kids to buy steroids, speed, and Spanish fly," *Washington Monthly* September 2001, available online at <http://www.washingtonmonthly.com/features/2001/0109.mencimer2.html>

⁷ Hulse R *Annals of Improbable Research* 1999 September/October; 5(5):21.

⁸ Utian WH "Is There an 'Alternate' Menopausal Management?" *Menopause Management* 1999 Sept/Oct page 6.

⁹ Kessler DA "Cancer and Herbs," editorial, *The New England Journal of Medicine* 2000 342(23):1742-3.

¹⁰ Angell M Kassirer JP *NEJM* 1999; 340:566.

¹¹ <http://vm.cfsan.fda.gov/~dms/qa-top.html>

¹² Blendon RJ, DesRoches CM, Benson JM, Brodie M, Altman DE "Americans' views on the use and regulation of dietary supplements," *Arch Intern Med* 2001 Mar 26;161(6):805-10.

¹³ The text of the bill is available by search at <http://thomas.loc.gov/home/thomas2.html>

intended purpose before marketing. On the other hand was the “dietary supplement” lovastatin, sold under the trade name Cholestin® (since reformulated), which was not subject to such strictures. Both contained the same active ingredient possessing the same pharmacologic activity and therefore the same potential for beneficial as well as adverse effects. If the “drug” is not safe without its use being prescribed and monitored by a physician, why should the “dietary supplement” be so considered? And if the “dietary supplement” is safe to use without medical supervision, why not the “drug” as well?

The same potential for confusion and contradiction exists whenever a substance is found to exist naturally somewhere in the universe and, at the same time, happens to be a prescription medication. Because of the fact that many medications are derived from animal or botanical sources, this situation can be expected to arise frequently. Another current example is that of vinpocetine, sold in Europe as a prescription drug to treat dementia at the same time it is promoted in the US – probably fraudulently¹⁴ – as a dietary supplement to improve memory and concentration. Congressman Burton laments the fact that the FDA eventually won its case in the matter of Cholestin®, but the fact is that if cerivastatin could be found in a plant extract, it could be marketed as a dietary supplement under DSHEA.

UNTHSC CLINICAL FACULTY APPOINTMENT

In addressing the Honorable Congressman Burton’s personal attack on me, I would like to begin by thanking his staff for discovering an oversight concerning my clinical faculty appointment to the University of North Texas Health Science Center (UNTHSC). Unfortunately, a proper investigation was not conducted with the result that the accusations of intentional misrepresentation or concealed wrongdoing of any kind is absolutely and utterly false, offensive and represents a grotesque smear of both myself and UNTHSC.

The facts are very simple. In late 1987 I joined the medical staff of the Dallas-Fort Worth Medical Center in Grand Prairie, Texas, a teaching hospital utilized by what was then the Texas College of Osteopathic Medicine, later renamed UNTHSC. As a consequence, and much to my satisfaction, I was thereafter continuously involved with the teaching and training of medical students and resident physicians of UNTHSC.

In 1991, without my having taken action of any kind, I was notified that I had been appointed to the assistant clinical faculty of the school’s department of Obstetrics and Gynecology. Though unasked for, I was gratified at this simple recognition of the many freely volunteered unpaid hours of effort that I devoted towards educating future physicians. Other members of the medical staff at the hospital were undoubtedly so recognized as well. But as to those details I have no information. In any case, I continued to have direct involvement with the medical education program at the hospital, including the evaluation of medical students and house staff performance until the hospital’s closure on November 7, 2000 as a result of federal budget cuts.

At no time did I receive any request from UNTHSC for any credentials verification, a function that was, in any case, carried out routinely by the hospital’s medical staff office. Had I received such a request I would have been glad to comply with it. It is outrageous for anyone to assert the contrary: that I could not or would not. It is perhaps even more concerning that it

¹⁴ Schardt D “Memory Pills – Mostly Forgettable” *Nutrition Action Healthletter* 2001 September pages 9-11.

would be assumed that an institution as outstanding and reputable as the UNTHSC would permit uncredentialed or unqualified individuals to teach and supervise its medical students and residents in the difficult, complex, and, at times, hazardous discipline of Obstetrics and Gynecology. I am justly proud of my association with UNTHSC and take spirited exception to its being unjustly slurred.

I am in receipt of a letter dated October 10, 2001, from Ronald R. Blanck, DO, President of UNTHSC, a copy of which I have forwarded to the US Senate Special Committee on Aging. Dr. Blanck stated:

“I have learned that we did appoint you as clinical faculty in 1991, and it was never rescinded. Although you were in an inactive status since 1995, your position as Clinical Assistant Professor in the Department of OB/GYN remains valid. You have received a letter from the Acting Chairman of the Department of OB/GYN, Dr. Gary Meyer, requesting additional information so we may update our files and continue your appointment. But, I repeat since you received no notification of termination, and in fact none was sent, your appointment at the health science center remains in force.”

I hope this lays to rest any and all doubts in this matter.

**OFFICE OF ALTERNATIVE MEDICINE (OAM) / NATIONAL CENTER FOR
COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM)**

I did not address the very different and much larger subject of the problems with the OAM/NCCAM in my testimony. My intention was only to put the subject of fraud in the dietary supplement industry into context and to highlight how far government policies of the last decade have departed from the findings of the 1984 Pepper report. But as Congressman Burton characterizes my criticisms of the OAM/NCCAM and the White House Commission on Alternative and Complementary Medicine Policy (WHCCAMP) as unfair or reckless attacks on careful and discerning scientists of world-class abilities and renown, it is necessary for me to cite additional facts to show that this is very far from the truth.

The OAM/NCCAM is widely considered “the brainchild of Iowa Senator Tom Harkin,”¹⁵ a creature of politics inspired by his personal experience with the use of bee pollen for hayfever symptoms. It was never established that there was any “unmet research need” to be met. Given the fact that funds available for medical research are limited, the most important consideration is to address the most pressing problems and to do so in a way that maximizes the likelihood of useful results. These principles have not been followed at the OAM/NCCAM. Numerous professional scientists, many of whom have earned legitimate stature for their work, have objected on just these grounds.¹⁶

The NCCAM is the only division of the NIH that is oriented toward a particular class of therapeutic methods, as vague and confused a concept as “CAM” may be. As such, it is the only center that is oriented primarily to the needs, desires and inclinations of practitioners – whether of acupuncture, homeopathy, “energy medicine” or some other belief system – instead of the

¹⁵ Satel S Taranto J “The Alternative Medicine Scam: Bogus Bee Pollen,” *The New Republic* 1996 January 8 page 24.

¹⁶ ScienceScope “Lobbying Blitz Attacks Alternative Medicine,” *Science* 1997 277:169.

needs, problems and circumstances of patients. Wallace Sampson, MD, Editor of the *Scientific Review of Alternative Medicine* and Clinical Professor of Medicine at Stanford University who taught a course there on "alternative medicine" for 22 years, has called the NCCAM "a full employment program for pseudoscientists and poor quality physicians."¹⁷ Funding decisions at the NCCAM reflect these assessments, as I will shortly show.

There is no doubt that the NIH did not welcome the imposition on it of the OAM in November of 1991. But the response among advocates of unproven, disproven and irrational medical claims and methods was euphoric. The first acting director of the office was Stephen C. Groft, D.Pharm, whose "friendliness towards the initiative was palpable" according to one enthusiastic advocate.¹⁸ But the peculiar political pedigree of the OAM soon led to problems when this advocate and others on the OAM's Ad Hoc Advisory Committee "were never consulted" about the appointment of its first director, Joseph Jacobs MD. To them he seemed "too conventional in his medical orientation" and, worse, had no proven track record of practicing or promoting aberrant methods.¹⁹

Within a year of his appointment, Dr. Jacobs was called before a special review hearing by Senator Harkin. At this meeting on June 24, 1993, Senator Harkin's friend Berkley Bedell spoke for unhappy advocates, complaining that all the OAM had to do was to conduct "field studies" consisting of compiling anecdotal reports. "When it was Jacobs' turn to testify," according to a report in *Science* magazine, Senator Harkin "raked him over the coals" and made it clear that the purpose of OAM was to "investigate and validate" irrational and aberrant therapies. Jacobs was quoted as saying that he considered these marching orders "very naïve" as well as "professionally insulting." The article observed that CAM advocates were "eager to have the imprimatur of an NIH review" but "may not want the rigor." Dr. Jacobs responded by saying that "As a taxpayer, I wouldn't trust what comes out of my office under a system like that."²⁰

After announcing his resignation but before actually leaving, Dr. Jacobs was faced with an additional demand in January of 1994 to put four "alternative medicine" activists, hand-picked by Senator Harkin, on an OAM advisory panel. According to one account the lawmaker threatened to hold up the entire NIH budget until the individuals were added.²¹ These were:

- Berkley Bedell, former Iowa Congressman and multimillionaire fishing tackle manufacturer, claimed that the quack cancer remedy "714X" cured his prostate cancer and that a whey treatment devised by a Minnesota farmer cured his Lyme disease.²² A friend of Senator Harkin, it was Mr. Bedell who first prevailed on the Senator to try bee pollen.
- Ralph Moss was fired as assistant director of Public Affairs at Memorial Sloan-Kettering Cancer Center for failing "to properly discharge his most basic job responsibilities."²³ He

¹⁷ Sampson, WI, personal communication.

¹⁸ Moss RW "The Cancer Industry: The Classic Expose on the Cancer Establishment," 1996 Equinox Press posted at <http://www.ralphmoss.com/caind3.html>

¹⁹ Ibid.

²⁰ Marshall E "The Politics of Alternative Medicine," *Science* 1994 265:2000-2002.

²¹ "NIH OAM Director Resigns; Herbert Calls For Investigation Of Appointees," *NCAHF News* 1994 Sept/Oct available online at <http://www.ncahf.org/nl/1994/9-10.html>

²² Jarvis WT "Berkley Bedell" available online at <http://www.ncahf.org/articles/a-b/bedell.html>

²³ "NIH OAM Director Resigns; Herbert Calls For Investigation Of Appointees," *NCAHF Newsletter* 1994 17(5) Sept/Oct available online at <http://www.ncahf.org/nl/1994/9-10.html>

subsequently wrote *The Moss Reports*, *The Cancer Chronicles* and several books that attack science-based medicine and extol unproven cancer treatments including those of Stanislaw Burzynski and others. He is still on the Cancer Advisory Panel of the NCCAM and has said that “There is nothing inherently ‘ludicrous’ about guided imagery, yoga, massage, homeopathy and therapeutic touch” in curing serious disease.²⁴

- Gar Hildebrand is the president of the Gerson Research Organization (GRO) in San Diego which promotes the irrational “Gerson Method” of cancer treatment. GRO runs a Tijuana cancer clinic at which patients have been charged \$9000 for a two week course of unproven care while Mr. Hildebrand lectures them, emphasizing his ties to the NIH.²⁵ Mr. Hildebrand says that women with ovarian cancer should not receive chemotherapy but should instead “detoxify the body” with dietary measures including “oodles of plant chemicals.” Once this is done, he says, “these patients’ immune systems become intelligent again. They stop making excess stupid white cells, and create more lymphocytes interested in more types of challenges.”²⁶ Hildebrand also promotes coffee enemas, hyperbaric oxygen and other nonsensical treatments for cancer.
- Frank Wiewel is the head of People Against Cancer (PAC), formerly the Immunoaugmentative Therapy Patients Association. PAC is a referral organization for cancer patients that promotes irrational treatments including the discredited “Immunoaugmentative Therapy” devised by zoologist Lawrence Burton, PhD. PAC also promotes the ideas of Hulda Clark and other notorious cancer quacks.²⁷ The organization’s website states that “you are never told the truth about cancer,”²⁸ a detestable falsehood designed to drive a wedge between frightened and desperate cancer victims and their doctors in order to exploit the sick.

Wayne Jonas MD assumed leadership at the OAM in July of 1995, almost a year after the departure of Dr. Jacobs. Dr. Jonas is a homeopath, a believer in a discredited 18th Century mystical prescientific theory of medicine that asserts the truth of preposterous “laws.” One of these, “The Law of Similars,” from which homeopathy takes its name, asserts that substances that cause certain symptoms are effective in treating those same symptoms. Another, “The Law of Infinitesimals,” states that diluting a substance makes it more potent. Thus, homeopathic “medicine” consists of substances diluted to fantastic proportions, to the point where no molecules of the substance remain.

Dr. Jonas was enamored of homeopathy as a medical student at the Bowman Gray School of Medicine in North Carolina. After suggesting that a patient with severe pneumonia be treated with homeopathy, his supervisors asked him to repeat his rotation in medicine. But even as a medical student Dr. Jonas was impervious to reason. As OAM Director he told an interviewer

²⁴ Ralph W. Moss, Ph.D., Brooklyn, N.Y. posted at <http://www.ralphmoss.com/nytimes1.html>; 10/1/2001

²⁵ “Notes From Ann’s Diary – A Talk Given in 1996” at <http://store.yahoo.com/annicappleseedproject/andiarofthers.html>

²⁶ <http://www.garynull.com/Documents/ReproductiveCancers.htm>

²⁷ Ross B “People Against Cancer: An Open letter to anyone dealing with cancer from the son of a cancer victim.” June 29, 1998 available online at <http://www.hcrc.org/contrib/ross/pac.html>

²⁸ http://www.peopleagainstcancer.com/cancer_truth.htm

that “Just as the discovery of infectious agents revolutionized our ability to care for many diseases at the turn of the century, the discovery of what happens when a homeopathic preparation is made and how it impacts the body might revolutionize our understanding of chemistry, biology and medicine.”²⁹

Dr Jonas co-authored a book on homeopathy in which he makes it clear that he is certain of its effectiveness but is only doubtful about its mechanism. The pattern of nonexistent molecules “must be stored in some way in the diluted water/alcohol mixture” he wrote, suggesting that all manner of occult energies, imaginary “biophotons” or New Age quantum effects could be involved.³⁰ Of late, Dr. Jonas has become frustrated with homeopathy research, perhaps because of the obvious truth in one medical scientist’s observation that such research is nothing more than “a game of chance between two placebos.”³¹ Dr. Jonas has suggested that validating homeopathy “may require a theory that incorporates subjective variables,”³² which is to say, how the thoughts of patients, doctors, and perhaps their next-door neighbors might influence the effects of a homeopathic remedy. This is in line with mystical beliefs in “nonlocal effects” caused by “intentionality,” or, in other words, psychic powers.

This is also entirely consistent with Dr. Jonas’ new position on the Scientific Advisory Committee of the paranormalism-oriented Institute for Noetic Sciences (IONS). According to IONS, Dr. Jonas “envisions the development of protocols using gene-array procedures to examine possible genetic expression arising from CAM signals in distant healing.” He considers it wrongheaded and obsolete that “the current view of the body is grounded in molecular biology.” He prefers to think that “bodily parts [can] communicate over long distances almost instantaneously” by means of “nonlocal characteristics in the biological process, with widely separated parts interacting in ways that don’t have obvious physical carriers.”³³

In June of 2001 Dr. Jonas was on the Program Committee of a conference in San Diego touting the reality of UFO’s, paranormalism, Qigong, Orgone Energy and other pseudoscientific claims.³⁴ His preoccupation with aberrant methods appears to be thoroughly ideological if not religious. At one of the hearings of the WHCCAMP, of which he is an appointed member, he stated: “... a number of groups are now getting into this field from the orthodox community, because there has been some money available. How can we go about sorting through which ones are truly going to capture the spirit of whole person health or how many are looking really at the bottom line, which is getting redder and redder by the year?”³⁵

Dr. Jonas left the OAM at the end of 1998 some two months after its conversion to the NCCAM. By that time many eminent and accomplished scientists had called for its defunding

²⁹ Stix, Gary “Profile: Wayne B. Jonas,” *Scientific American* 1996 October available online at <http://www.sciam.com/1096issue/1096profile.html>

³⁰ Jonas, Wayne B and Jacobs, Jennifer, *Healing With Homeopathy: the Complete Guide*, Warner Books 1995.

³¹ Vandembroucke JP “Homoeopathy Trials: Going Nowhere,” *Lancet* 1997; 350:824.

³² Jonas WB “The Homeopathy Debate,” *J Altern Complement Med* 2000 Jun;6(3):213-5.

³³ http://www.noetic.org/Ions/publications/55frontiers_jonas.htm

³⁴ <http://www.scientificexploration.org/meetings/20th.html>

³⁵ At a hearing on Monday, December 4, 2000 (Afternoon Session) Hubert H. Humphrey Building, Room 800 200 Independence Avenue, SW Washington, D.C., posted at http://www.whccamp.hhs.gov/meetings/transcript_12_4_00_afternoon.html

including former presidential science advisor D. Allan Bromley and others.³⁶³⁷³⁸ Especially shameful was the allocation about that time of \$1.4 million to the work of Nicholas Gonzalez and his bizarre coffee enema and psychic hair analysis cancer treatments. Even Barrie Cassileth, PhD, Chief of the Integrative Medicine Service at Sloan-Kettering Cancer Center, called Gonzalez' claims and methods "voodoo magic ... silly ... Not scientific. Worse than not scientific. This is pure ridiculousness."³⁹

When Stephen Strauss MD became director of the NCCAM in October of 1999, many supposed that matters could hardly get any worse. Indeed, Dr. Straus' reputation was such that some dared to hope for improvement. But the new director quickly began defending the funding devoted to the work of Dr. Gonzalez.⁴⁰

It is true that under Dr. Strauss the NCCAM has also undertaken large-scale multi-center research trials on Saint John's Wort, Ginkgo and glucosamine, the results of which will likely be trustworthy. Sadly, these are unlikely to be clinically useful for reasons that I pointed out in my testimony at the September 10 hearing. Indeed, after almost ten years and hundreds of millions of taxpayer dollars spent, nothing has yet come out of the OAM/NCCAM that has been shown to be clinically important. Even a definitive study to determine the effectiveness of the bee pollen that Senator Tom Harkin believes cured his hayfever has not been undertaken.

But Dr. Strauss' leadership at the NCCAM is disturbing for other reasons. There is clear evidence either that he lacks scientific judgement or that ideological advocates remain firmly in control at the NCCAM. It may be a contributing factor that, as a virologist, he has no expertise in evaluating aberrant and irrational medical methods. Among dozens of smaller NCCAM research grants, for example, have been many that are wasteful, inappropriate and utterly bizarre. In 2000, for example, three grants were awarded for obvious paranormalism research into "psychic powers," euphemistically called "distant healing" or "transfer of neural energy" from one person to another:

- 1-R01-AT-485-1 Distant Healing Efforts for AIDS by Nurses and 'Healers' Targ, Elisabeth⁴¹ F., California Pacific Medical Center -Pacific Campus. This is a three year grant awarded on July 1, 2000 totaling nearly \$663,000.⁴²
- 1-R01-AT-644-1 Efficacy of Distant Healing in Glioblastoma Treatment Targ, Elisabeth F., California Pacific Medical Center-Pacific Campus. This is a four-year grant totaling nearly \$823,000.⁴³
- 1-R21-AT-287-1 Transfer of Neural Energy Between Human Subjects Standish, Leanna J. Bastyr University. (Dollar figures unknown)

³⁶ ScienceScope: "Lobbying Blitz Attacks Alternative Medicine," *Science* 1997; 277:169.

³⁷ Goodenough, Ursula and Park, Robert L. "Buying Snake Oil with Tax Dollars," *The New York Times* January 3, 1996, pg. A15.

³⁸ Donlan, Thomas G. "Official Malpractice," *Barron's* March 24, 1997 page 70.

³⁹ ABC News 20/20 program "Controversial Cancer Treatment," June 16, 2000 available online at http://more.abcnews.go.com/onair/2020/2020_000616_cancer_feature.html

⁴⁰ <http://nccam.nih.gov/ne/occam-testimony.html>

⁴¹ This is the correct spelling of Dr. Targ's first name. It is misspelled "Elizabeth" on the NCCAM website at http://nccam.nih.gov/research/grants/rfb/combined_fv00.htm

⁴² Grant Cost Spreadsheets obtained from NCCAM by an FOIA request in late 2000.

⁴³ Ibid.

Elisabeth Targ MD, who with the first two of these grant awards scooped up nearly \$1.5 million of taxpayer dollars, is head of the Complementary Medicine Research Institute of California Pacifica Medical Center in San Francisco. She is a third generation psychic believer continuing a long tradition of pursuing absurd and discredited paranormal claims. This is a tradition distinguished chiefly by fraud and self-deception.⁴⁴ Her father, Russell Targ, earned notoriety in the 1970's for bilking the U.S. Department of Defense on promises that "remote viewers" could be trained to provide on-site details of Russian military facilities by visiting them "psychically." According to her father, Elisabeth was trained on a psychic power teaching machine as a young girl and was able to predict the winners of horse races and presidential elections.⁴⁶ Distinguished science writer Martin Gardner recently provided additional details about the Targs, their eccentric beliefs and NCCAM funding of them.⁴⁷

Janet Quinn, RN PhD, a Therapeutic Touch (TT) practitioner and a former student of TT's founder Dolores Krieger, is a paid consultant to Dr. Targ on the AIDS work and is recruiting additional TT practitioners to act as a "control group" against the main group of psi-powered "healers." \$500 honorariums are being paid to perform this "work" with a total of \$20,834 allocated for it through the February 28th, 2001 budget period. TT is a mystical "healing" method, the premise of which was falsified by an elementary school science project.⁴⁸ The most recent exploits of its founder, Dolores Krieger, are of "doing healing at distance" of those killed in the September 11 attacks on the World Trade Center, "calling upon the help of the angels of compassion ... to help the person through the terror of dying so suddenly and so horribly. ... working together with whatever beneficent forces I think of or who present themselves at this time."⁴⁹

Understandably worried about the reaction of more sensible people to her NCCAM-funded studies, Dr. Targ has announced her determination to either get positive results or leave the door open to wasting more of the taxpayers' dollars on her work with psychic powers. At a parapsychology conference entitled "Subtle Energies and Uncharted Realms of the Mind," at the New Age oriented Esalen Institute in July 2000, it was reported that:

"Targ discussed the difficulties of doing a clinical research study on distant healing. Since the mainstream medical community is highly skeptical of Targ's research, she must be meticulous at every step in the process. In addition, she must also guard against showing a

⁴⁴ Cromer, Alan, "Pathological Science: An Update," chapter in Kendrick Frazier, *Encounters With the Paranormal*, Prometheus Press, Amherst, NY, 1998

⁴⁵ Gilovich, Thomas, "Belief In ESP," chapter 10 in *How We Know What Isn't So*, Free Press, New York 1991.

⁴⁶ Targ R Harary K, *The Mind Race: Understanding and Using Psychic Abilities*, New York, NY: Villard Books, 1984; 96-99.

⁴⁷ Gardner, Martin, "Distant Healing and Elisabeth Targ", *Skeptical Inquirer*, March/April 2001; 12-14. Available online at <http://www.csicop.org/si/2001-03/fringe-watcher.html>

⁴⁸ Rosa L, Rosa E, Sarner L, Barrett S. "A Close Look At Therapeutic Touch," *JAMA* 1998 Apr 1;279(13):1005-10.

⁴⁹ <http://www.therapeutic-touch.org/Crisis/boardsuggestions.htm>

negative result, because the mainstream will take those results and attempt to discredit what Targ is trying to show.”⁵⁰

Current NCCAM advisor Marilyn Schlitz, PhD, and former NCCAM advisor Beverly Rubik, as well as Dr. Targ’s father Russell were among the other featured speakers at the event.⁵¹

Dr. Strauss is fully aware of and supportive of these grants to Dr. Targ. In his annual director’s report given at a February 5, 2001 NCCAM Advisory Committee meeting, Dr. Strauss said:

“Dr. Targ at the California Pacific Medical Center is studying distance healing for glioblastoma, trying to move this research forward from small trials. The study has 150 patients in a double blind RCT in which healers pray for patient recovery. Endpoints include symptoms and functional status.”⁵²

The third grant was awarded to one of the NCCAM’s own advisory board members, Leanna J. Standish: 1-R21-AT-287-1, Transfer of Neural Energy Between Human Subjects, Bastyr University. Bastyr University is an official NCCAM research center. Its website indicates that Dr. Standish, who is the school’s research co-director, is joined in her psychic investigations by fellow NCCAM advisor Marilyn Schlitz PhD.⁵³

Dr. Schlitz is also on the board of IONS and directs its research programs.⁵⁴ With IONS Fellow Dr. Targ, Dr. Schlitz has been conducting her own psi research at California Pacific Medical Center.⁵⁵ In addition, Dr. Schlitz is herself an astral voyager “remote viewer” who was praised by Russell Targ for having “achieved the greatest statistical significance of any remote-viewing experiment so far conducted” in exploring tourist sites in Rome from her home in Detroit MI.⁵⁶

Standish, a “naturopathic doctor,” is, in turn, listed as a co-researcher with Dr. Targ on grant #1-R01-AT-485-1. Another NCCAM advisor, Michael F. Cantwell MD, works with Dr. Targ as lead physician in the Health and Healing Clinic at California Pacific Medical Center. Dr. Cantwell was to be the Principal Investigator for a proposed study of Russian psychics healing children with Cerebral Palsy sponsored by the Monterey Institute for the Study of Alternative Healing Arts which the United Cerebral Palsy Research and Educational Foundation declined to fund.⁵⁷

These activities, and doubtless others obscured with more pedestrian titles, fly in the face of an exhaustive study of parapsychology by the National Research Council (NRC) conducted in the late 1980’s and early 1990’s. The NRC concluded that there is “no scientific justification

⁵⁰ <http://www.esalenctr.org/display/confpage.cfm?confid=8&pageid=74&pgtype=1>

⁵¹ <http://www.esalenctr.org/display/conference.cfm?ID=8>

⁵² NCCAM Meeting Minutes, February 6, 2001 available online at http://nccam.nih.gov/an/advisory/naccam/minutes_new/minutes_0201.html

⁵³ <http://www.bastyr.edu/research/projects>

⁵⁴ <http://www.ions.org/ions/about/board.asp>

⁵⁵ <http://www.cpmc.org/services/ihh/about/cmriprojects.html>

⁵⁶ Russell Targ and Keith Harary, *The Mind Race: Understanding and Using Psychic Abilities*, New York, NY: Villard Books, 1984; 44.

⁵⁷ <http://www.whps.com/misaha/cantwell.html>

from research conducted over a period of 130 years for the existence of parapsychological phenomena.”⁵⁸ Although clearly supported by Dr. Strauss, it is only fair to say that the NCCAM’s interest in parapsychological research had begun earlier. These forays into mysticism disguised as science were suggested in a report issued by the OAM’s Mind-Body Panel when it was cochaired by paranormalist Larry Dossey MD, Jungian “transpersonal psychologist” Jeanne Achterberg and James S. Gordon MD who is now Chair of the White House Commission on Complementary and Alternative Medicine Policy. This report falsely asserted that:

“There exist many published reports of experiments in which persons were able to influence a variety of cellular and other biological systems through mental means. The target systems for these investigations have included bacteria, yeast, fungi, mobile algae, plants, protozoa, larvae, insects, chicks, mice, rats, gerbils, cats, and dogs, as well as cellular preparations (blood cells, neurons, cancer cells) and enzyme activities. In human “target persons,” eye movements, muscular movements, electrodermal activity, plethysmographic activity, respiration, and brain rhythms have been affected through direct mental influence.”⁵⁹

All of this alleged evidence was considered and rejected by the NRC’s review. Yet it is continually pointed to by dishonest promoters of paranormalism.

But it may very well be that Dr. Strauss, in his heart of hearts, would agree that these and many other NCCAM-funded activities are absurd and unscientific. It may very well be that, as one journalist wrote last year:

“[P]rinciples aside, Straus also has to follow the mandate of Congress - and some of its, well, less-than-scientific members. NCCAM is stuck funding a 5-year, \$1.4 million trial of an unusual protocol designed to treat terminal pancreatic cancer by physician Nicolas Gonzalez. The so-called Gonzalez Protocol – a hodgepodge of pancreatic enzymes, coffee enemas, and up to 150 dietary supplements a day – caught the attention of Representative Dan Burton (R-IN), who in 1998 encouraged the National Cancer Institute (NCI) to study it. Even though Straus considers the evidence just an ‘aggregate of interesting anecdotes,’ he defends the trial – albeit lukewarmly. ‘I’m more comfortable and find it easier to approach and fund things that already make a lot more sense to me,’ he admits. ‘But the mandate here is ... to be willing to take more risks for things that are novel.’”⁶⁰

Yet the sad fact remains that these “things that are novel,” especially when they are given the imprimatur of the NIH, ultimately put the public at risk for the kinds of harm that I outlined in my testimony on September 10. Perhaps the most egregious example is that of Dr. Gonzalez, who had already been found guilty of medical malpractice and ordered to pay more than \$2 million in 1997. Another case was then underway involving a death in which Dr. Gonzalez was ultimately found guilty again – in April of 2000 – and ordered to pay \$282,000 to the husband of

⁵⁸ Druckman, Daniel, and Bjork, Robert A., eds., 1991. In the Mind’s Eye: Enhancing Human Performance. Washington, DC; National Academy Press, cited in Hunt, Morton, *The Story of Psychology*, 1993 Doubleday, New York NY, page 632.

⁵⁹ Available online at <http://www.naturalhealthvillage.com/reports/rpt2oam/mindbody.htm>

⁶⁰ Stokstad, Erik *Science* June 2, 2000; 288:1568.

a woman who died under his care.⁶¹ Yet at the urging of Congressman Burton, the NCCAM ignored these considerations and made the preposterous decision that there was good reason to suppose that Gonzalez's methods had merit. Indeed, it is exceedingly puzzling that Congressman Burton trusts American citizens to make their own medical choices when he cannot trust the professional judgments of NIH and NCI research scientists.

WHITE HOUSE COMMISSION ON ALTERNATIVE AND COMPLEMENTARY MEDICINE POLICY (WHCCAMP)

The situation with respect to the WHCCAMP is even worse. Established by President Clinton on March 7th of 2000 by Executive Order 13147 and subsequently amended, the group is charged with providing a report "on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine." The commission's report is due in March of 2002, but there is little doubt that it will recommend expanded federal spending and other policy initiatives to foster irrational and aberrant methods.

The WHCCAMP Chair is James S. Gordon, MD, a Georgetown University psychiatrist who has said that he found "a whole other system of medicine operating under completely different laws" in the 1960's when he began studying traditional Chinese medicine. Then, while receiving his training in psychiatry, Dr. Gordon said, he decided that schizophrenia and other disorders "did not seem like diseases to me [but] instead like different ways of being." It was at this time that he became a student of the radical British psychiatrist R. D. Laing whose "Insanity is Sanity" philosophy achieved great popularity in the 1960s drug counterculture.⁶² Dr. Gordon appears to have become enamored of these ideas at the very time that Kingsley Hall, Laing's London "therapeutic community" in which the mentally ill and their therapists lived together and – among other things – indulged in LSD, was forced to close under a cloud of scandal and public complaint.⁶³ His thinking distorted by long-term LSD use,⁶⁴ Laing himself went on to become involved in "Primal Scream" and "rebirthing psychodrama"⁶⁵ of the kind that killed a young girl in Colorado in May of 2000 and sent two therapists to jail.⁶⁶

Dr. Gordon was a follower of the late Bhagwan Shree Rajneesh, the Indian mystic who amassed wealth and influence enough to take over the small town of Antelope, Oregon in the 1980's before being deported by the authorities for fraud. Dr. Gordon wrote a sympathetic book about the cult, *The Golden Guru*, in which he offered excuses for the Bhagwan's erratic behavior and the violence connected with the cult. Dr. Gordon also describes his own "rebirthing"

⁶¹ Maull, Samuel "Coffee Enema Doctor Sentenced," Associated Press, April 20, 2000.

⁶² Interview with Barry Chowka published in *Nutrition Science News*, September, 1996
<http://www.naturalhealthvillage.com/newsletter/15july00/interview.htm>

⁶³ Burston, Daniel, *The Wing of Madness: The Life and Work of R. D. Laing*, Cambridge, Mass; Harvard University Press; 1996: 79-92

⁶⁴ *Ibid*, pp. 51-61

⁶⁵ *Ibid*, pp. 125-131

⁶⁶ Articles on this rebirthing death are located at <http://denver.rockymountainnews.com/candace/>

experience at the hands of one of the Bhagwan's therapists.⁶⁷ In 1984, some followers of the Bhagwan cult were involved in deliberate poisonings of hundreds of people in Oregon.⁶⁸

In recent years, Dr. Gordon has been a collaborator of parapsychologists and Jungian mystics within the Transpersonal Psychology movement.⁶⁹ He has also become a leading advocate of alien abduction therapy and research, serving on the Scientific Advisory Board of

⁶⁷ Gordon, James S., *The Golden Guru*, Lexington, Mass; The Stephen Greene Press; 1987.

Notable passages from *The Golden Guru*:

- a) Dr. Gordon describes his own "rebirthing" in Chapter 3 "Surrender to Bhagwan." pp 86-89. At the hands of a naked female therapist, Dr. Gordon recounted "a replay of my descent through the birth canal" leaving him "flailing on the mat, squalling like a newborn," feeling "gratitude and love, not so general now as in groups, but focused on Rajneesh, on his generosity."
- b) On pages 84-86, Dr. Gordon defends the use of violent psychotherapies short of killing, which did happen at the Rajneesh's commune in India. He writes that he is "not against fighting in groups" and that the Rajneesh's followers "believed that the violent confrontations – even their own bad bruises and broken limbs – had been a small and necessary price to pay for the freedom they now felt from past traumas and inhibitions, for the perspective they had gained on their own sadism and masochism."
- c) On page 114, Dr. Gordon defends the Rajneesh's collection of 93 Rolls Royces at the Oregon commune. "In displaying his wealth so conspicuously, in ignoring accusations of selfishness," writes Dr. Gordon, "Rajneesh was mocking the preconceptions of his New World audience, who – particularly the Christians – tended to associate spirituality with poverty, modesty, charity."
- d) On page 148, Dr. Gordon defends the Rajneesh's recruitment and exploitation of the homeless and mentally ill, saying that the guru's "program, in spite of its inequities and exploitativeness, does seem a great improvement over what these men have been offered in city and state mental hospitals and shelters. Those who stay are functioning, useful members of a loving community. They seem to have a real opportunity to change."
- e) In his concluding paragraphs on page 245, Dr. Gordon writes exults in Rajneesh's "vision of a loving, cooperative community dedicated to the creation of new men and women living in harmony with their own nature and the natural world. ... For me, it is not finally a question of agreeing or disagreeing with Rajneesh, of praising or condemning him or his sannyasins. It is, rather, a matter of learning from him and them, of appreciating his remarkable talents and gifts and recognizing his perverse uses of them, of seeing myself in him and his sannyasins, of using his extraordinary story and strange, as yet unfinished journey as a mirror for my own."

⁶⁸ Torok TJ, Tauxe RV, Wise RP, Livengood JR, Sokolow R, Mauvais S, Birkness KA, Skeels MR, Horan JM, Foster LR., "A large community outbreak of salmonellosis caused by intentional contamination of restaurant salad bars." *JAMA* 1997 Aug 6;278(5):389-95.

⁶⁹ He is listed as a plenary speaker at a 1999 "Life After Death" conference of parapsychologists and mystics at <http://www.pathwaysminneapolis.org/lifedeath.html>. He has also appeared at conferences of followers of the noted "orgone energy" pseudo-psychologist Wilhelm Reich <http://members.aol.com/mannionabc/> and has advocated that resources be devoted to researching "orgone accumulators."

the Program for Extraordinary Experience Research (PEER), an organization established explicitly by Harvard psychiatrist John Mack, MD, to research alien abductions.⁷⁰

Inexplicably, Dr. Gordon also involved himself in the Oklahoma bombing trial of Terry Nichols. As a psychiatrist for the defense, he submitted a letter to the court stating that Nichols was not violent and should not receive a long prison term. Dr. Gordon's opinion was apparently based entirely on letters received from Nichols.⁷¹

Dr. Gordon is a fellow of the John E. Fetzer Institute, which funded the dishonest 1993 report published in *The New England Journal of Medicine* by David Eisenberg and others that claimed that a third of Americans were using "alternative" methods by including such categories as relaxation, imagery, massage, commercial weight loss and self-help groups. One of Gordon's many books, *Manifesto For A New Medicine*, is in the millenarian genre of others that predict the transformation of medical care along New Age lines.

In 1994, Dr. Gordon was appointed the very first chairman of the Office of Alternative Medicine's Program Advisory Council and was a co-director of OAM's Mind-Body Panel. Through his Center for Mind-Body Medicine, which has also been funded by the Fetzer Institute, Dr. Gordon has organized a series of Comprehensive Cancer Care Conferences that have gathered together dozens of questionable practitioners as an effective lobbying force for aberrant cancer care.⁷²

Dr. Gordon has previous experience as a Presidential advisor, having directed a nationwide study of alternative mental health services for President Carter's Commission on Mental Health in the 1970s. In his brief 1978 report, in addition to noncontroversial mental health programs such as rape support and runaway programs, Gordon recommends the spiritual midwifery practices of "The Farm," a psychedelic commune, reiterates his support for R. D. Laing's and Carl Jung's theory of psychosis as creativity (R. D. Laing is directly quoted referring to schizophrenia as "a voyage into self of a potentially revolutionary nature") and offers praise for the then budding holistic medicine industry.⁷³

Other members of the White House Commission include Dr. Jonas, whose exploits have already been considered and:

- George M. Bernier, Jr. MD is the only prominent academic on the Commission. He is the former Dean of Medicine at the University of Pittsburgh, left that position in 1995 to accept the positions of Dean and Vice President for academic affairs at the University of Texas Medical Branch in Galveston, Texas. He currently is the Vice President of Education at

⁷⁰ Dr. John Mack's PEER website can be viewed at <http://www.peer-mack.org/learnmore.html>

⁷¹ Defense expert: "Nichols had no outrage over Waco;" Denver Post Online, June 3, 1998, <http://63.147.65.175/bomb/bomb0603.htm>; Also, "Judge to Sentence Nichols for Oklahoma bombing", CNN June 4, 1998

⁷² The Quackwatch website lists Gordon's book on these conferences, *Comprehensive Cancer Care* (James S. Gordon, MD, and Sharon Curtin, 2000) on its list of non-recommended Cancer information books at <http://www.quackwatch.com/00AboutQuackwatch/altseek.html>

⁷³ *Alternative Services: A Special Study (Final Report to The President's Commission on Mental Health of the Special Study on Alternative Mental Health Services, James S. Gordon, Director)*, in Task Panel Reports Submitted to the President's Commission on Mental Health, President's Commission on Mental Health, Volume II, Appendix. 1978.

UTMB.

Since his arrival, UTMB's program in Alternative and Integrative Healthcare has blossomed, offering mystical and paranormal healing techniques including Therapeutic Touch and recommending to the public the mystical writings of Deepak Chopra, Andrew Weil, Larry Dossey and Carolyn Myss.⁷⁴ The program is directed by Victor S. Sierpina, MD, a nationally prominent CAM activist⁷⁵ and includes a faculty member, Mary Anne Hanley, RN, who is a former student of Theosophist mystic Dolores Krieger, the founder of TT.⁷⁶

Dr. Bernier was instrumental in establishing a "Spirituality in Clinical Care" course of study for medical and nursing students funded by the National Institute for Healthcare Research (NIHR), an evangelical Christian group associated with the John Templeton Foundation.⁷⁷ The course bibliography features not only the writings of NIHR head David B. Larson but also *Healing Words* by Larry Dossey MD,⁷⁸ in which it is claimed that paranormal effects have been demonstrated on bacteria, sweetpeas and mice as well as humans.

- Effie Poy Yew Chow, PhD, is an acupuncturist, "Qigong Grandmaster" and founder of the East-West Academy of Healing Arts in San Francisco.⁷⁹ Her PhD is in Education. She has connections with the NCCAM going back to the OAM when she was appointed to its first Ad Hoc Advisory Committee.⁸⁰

"Qi" is the traditional Chinese counterpart to psychic "life energy," the "flow" of which is said to be modified by acupuncture and which advocates claim can be "absorbed" and "emitted." Chow claims to cure illness and boost the psychic powers of individuals by transmitting "qi" to them by telephone.⁸¹ She employs typical stage magic tricks to "prove" the existence of "qi" energy.

At the Commission's September 8, 2000 meeting in San Francisco, she said that "what we're here for" is "recommending policies to making a big change in the system."⁸² Transcripts of the Commission's work show that she has a long relationship with fellow Commissioner David Bresler and with its chair Dr. Gordon.⁸³

- "Dr." David Bresler is also an acupuncturist. Like Chow, he is not a physician but holds a PhD. He is credited by the White House with being "one of the first contemporary American scientists to study and research acupuncture, guided imagery, and other mind/body approaches." But the only two published clinical trials of which he is a co-author involve acupuncture, one of which showed no benefit in asthma. Another article purported to show

⁷⁴ <http://atc.utmb.edu/altmed/books.htm>

⁷⁵ <http://atc.utmb.edu/altmed/>

⁷⁶ <http://atc.utmb.edu/altmed/faculty.htm>

⁷⁷ <http://atc.utmb.edu/altmed/spirit-acknowledge.htm>

⁷⁸ <http://atc.utmb.edu/altmed/spirit-bibliogr.htm>

⁷⁹ <http://www.eastwestqi.com/html/home.html>

⁸⁰ http://www.eastwestqi.com/html/dr_chow.html

⁸¹ <http://members.aol.com/eastwestqi/clinic.htm>

⁸² http://www.whccamp.hhs.gov/meetings/transcript_9_8_00_s1_2.html

⁸³ http://www.whccamp.hhs.gov/meetings/transcript_12_4_00_morning.html

scientifically that the whole human body is mapped out on the ear.⁸⁴

Guided imagery is based on almost as fanciful a notion, namely, that imagining physical changes in the body can effect those changes. Thus, cancer patients are taught to imagine their tumors being destroyed. Yet there is no published evidence – *zero* – in support of guided imagery affording more than psychological benefits for any condition, or that such effects are superior to those offered by other interventions. Nevertheless, Bresler founded the Academy of Guided Imagery (AGI)⁸⁵ in 1989 which now sells 150-hour “certification” training programs at \$3495 each. Among other things, such training involves “dialoguing with symptoms.” Another practice is to call up an “inner advisor,” a kind of spirit guide that may take the form of an animal.

AGI promotes audio tapes to the general public. One for “Arthritis and Lupus,” for example, is “[d]esigned to help reduce rheumatoid joint inflammation, soreness, excess fluid; replace eroded bone and joint tissue; help calm overactive, misguided immune cells.” Another, for diabetic patients, is “[d]esigned to encourage insulin sensitivity at the cellular level; help the body metabolize food in a steady, balanced way; help repair damage to organs and tissue.” Still another, for victims of atherosclerosis, is alleged “to help the body restore weary heart tissue; improve cholesterol and blood pressure; dissolve arterial plaque; [and] maintain healthy arteries.” There is no evidence that AGI’s tapes exert such miraculous effects.

Bresler is a credulous believer in other nonsense as well. To an Iranian faith-healer, one Ostad Hadi Parvarandeh who claimed to be in touch with the “collective consciousness” of the universe, Bresler wrote: “Ostad, I have been quite amazed by the progress shown by several of my patients who have seen you, and feel that it is time to launch some serious scientific studies to carefully document whatever is happening.”⁸⁶

- Xiao Ming Tian is a Beijing-trained physician-acupuncturist who runs the Academy of Acupuncture and Chinese Medicine at his Wildwood Acupuncture Center in Bethesda. There he offers acupuncture, acupressure, Chinese herbal remedies, and Qi-Gong “treatments,” qi-gong being the vitalistic “energy” medicine of the prescientific Orient.⁸⁷ Tian has been a consultant to the NIH and was involved in producing the NIH Consensus Statement on Acupuncture that deliberately excluded critics of the method. The biographical information on Tian released by the White House indicates that he received government funding for “many research projects on the use of Chinese herbal medicine and dietary supplements,” none of which appears to have resulted in published work available by search on PUBMED. According to the White House press release, Tian is also “President of the American Association of Chinese Medicine,” as well as “Honorary Director of the China Association of Traditional Chinese Medicine and Vice President of The International Academy of Medical Qigong, both in Beijing, China.”
- Veronica Gutierrez is a chiropractor from Lake Stevens, Washington. She is extremely active in the World Chiropractic Alliance (WCA), sitting on its Board of Directors, serving

⁸⁴ Oleson TD, Kroening RJ, Bresler DE “An experimental evaluation of auricular diagnosis: the somatotopic mapping or musculoskeletal pain at ear acupuncture points.” *Pain* 1980 Apr;8(2):217-29

⁸⁵ http://www.healthy.net/agi/index_netscape.html

⁸⁶ <http://www.iranonline.com/Ostad/Opinion.html>

⁸⁷ <http://www.chinesherbmedicine.com/intro.html>

as its Director of Programs in Public Policy, and chairing its Health Care Reform Committee and its Council on Women's Health.⁸⁸

The WCA is an organization of "straight" chiropractors whose allegiance is to the original doctrine of disease causation taught by chiropractic's founder, D.D. Palmer, that spinal "subluxations" interfere with the "flow" of supernatural "innate intelligence" and can only be corrected by chiropractic "adjustments." The WCA promotes chiropractic as the ideal form of medical care for infants and children as well as for adults. It opposes routine immunizations⁸⁹ while dismissing medical science – as "alternative medicine" guru Andrew Weil MD does – as good only for "trauma care and crisis management." In fact, Gutierrez herself fumes that, "If anyone still believes medical science reigns supreme, they now must say 'The Emperor wears no clothes.'"⁹⁰

Ms. Gutierrez is also connected with the Council for Chiropractic Practice (CCP). The CCP advocates home births, chiropractic manipulation of infants for the prevention of SIDS, of children for pediatric ear infections, and lifelong "adjustments" for an alleged epidemic of "subluxations" for everyone. The CCP also claims that EEG's, surface EMG's, and thermography, as well as other unproven methods can demonstrate chiropractic "subluxations."⁹¹

Ms. Gutierrez's presence on the commission is the result of lobbying by the WCA,⁹² which boasts of growing political influence and maintains a presence in Washington D.C. for the purpose of exerting political influence.⁹³ Indeed, immediately upon Gutierrez's appointment to the commission, the WCA began mobilizing its members to testify at its meetings.⁹⁴

- Donald W. Warren is a dentist from Clinton, Arkansas who treats temporomandibular joint dysfunction and other ailments with "dental cranial osteopathy." In addition, he practices "contact reflex analysis," which is claimed to be a method of "analyzing the body's structural, physical, and nutritional needs." This is done by pressing on various mystical points on the body while pushing and pulling on the patient's arm (or other body part). Alterations in muscle strength – the "reflexes" – are claimed to "quickly and accurately uncover the root" of any health problem.

Details concerning this astonishingly irrational form of medical quackery, including the locations of the "Master Allergy Reflexes," the "Metabolic Reflex," the "Yeast Reflex," the "Hemoglobin Reflex," and additional "reflexes" especially relevant for the flu season, can be found at <http://www.crahealth.org> (click on "CRA and Syndromes"). On this same website can be found Dr. Warren lengthy statement of enthusiastic belief in CRA as well as the healing powers of "God, chiropractic, CRA-based nutrition, dentistry and osteopathy."⁹⁵

Dr. Warren's personal convictions concerning this curious application of stage magic are forthright, if delusional: "In my 16 years of practicing as a dentist, I have never known any

⁸⁸ <http://www.worldchiropracticalliance.org>

⁸⁹ <http://www.worldchiropracticalliance.org/tcj/2000/oct/oct2000twarner.htm>

⁹⁰ <http://www.worldchiropracticalliance.org/tcj/1998/feb/feb1998b.htm>

⁹¹ <http://www.chiropage.com>

⁹² <http://www.worldchiropracticalliance.org/media/gutierrez.htm>

⁹³ <http://www.worldchiropracticalliance.org/tcj/2000/oct/oct2000a.htm>

⁹⁴ <http://www.worldchiropracticalliance.org/tcj/2001/jan/jan2001g.htm>

⁹⁵ http://www.crahealth.org/news/2000-12-dr_warren.htm

method of analysis, technique, treatment or nutritional presentation so helpful, so exact, so satisfying, and have such a high level of quality as Contact Reflex Analysis.”⁹⁶

- Linnea Larson is a Social Worker who is Associate Director of an “Integrative Medicine” department of West Suburban Health Care in Oak Park, IL. She also practices Eye Movement Desensitization and Reprocessing (EMDR) as well as other irrational forms of “mind-body” therapy.⁹⁷ Serious problems exist with respect to EMDR and its lack of validation.⁹⁸

Larson was among the faculty listed at a program in Santa Fe in October of 2000 entitled “Integrating Culture and Complementary Medicine: Challenges to the Biomedical Paradigm.”⁹⁹ This conference assailed the scientific biopsychosocial model of medicine from the perspective of postmodern cultural relativism. Another notable speaker was Victor Sierpina MD, the head of the University of Texas Medical Branch’s alternative medicine program which has been nurtured by fellow commissioner George M. Bernier MD.

- Joseph E. Pizzorno, Jr, is an “ND” Doctor of Naturopathy, a naturopathic midwife and the founding president of Bastyr University, a naturopathic school that was chosen by the National Center of Complementary and Alternative Medicine (NCCAM) to be a Center for Alternative Medicine Research. He continues to act as an advisor to the school.

Mr. Pizzorno is on the “Management Team” of The Dove Health Alliance,¹⁰⁰ the mission of which is “to discover, validate, and disseminate the principles and practices of energy medicine on personal, societal and environmental levels.”¹⁰¹

Mr. Pizzorno promotes a variety of unproven and irrational claims as fact. For example, he asserts that “The hypothesis that gluten is a causative factor in the development of schizophrenia is substantiated by epidemiological, clinical and experimental studies.”¹⁰² He believes that food allergies cause multiple sclerosis.¹⁰³ He says the dandelion is useful for the “sluggish, congested, toxic liver.”¹⁰⁴ He promotes kava for “stress.”¹⁰⁵ And, like Deepak Chopra, he is a proponent of the mystico-herbal practice of Ayurveda.¹⁰⁶

Mr. Pizzorno also believes in the bizarre “blood type diet” advocated by fellow naturopathic “doctor” Peter D’Adamo, a Bastyr graduate. Pizzorno calls it “The Medical Breakthrough For The Ages,” saying that it will change the practice of medicine for centuries to come and lauds D’Adamo as “an outstanding example of the best Bastyr has to offer.”¹⁰⁷

⁹⁶ <http://members.tripod.com/drothdc/cra.htm>

⁹⁷ http://www.wshmc.org/www.wshmc.org/fam_prac/bios.html

⁹⁸ Lilienfeld SO “EMDR Treatments: Less Than Meets the Eye?” available online at <http://www.hcrc.org/contrib/lilienf/emdr.html>

⁹⁹ <http://www.absame.org/Mt00schd.htm>

¹⁰⁰ <http://www.dovehealthalliance.com/management.htm>

¹⁰¹ <http://www.dovehealthalliance.com/vision.htm>

¹⁰² <http://maranao.com/health/h5-causesofschizophrenia.htm>

¹⁰³ <http://www.pychealth.com/multiplesclerosis.html>

¹⁰⁴

<http://www.goldentemple.com/clients/kiit/gt/Ingredients.nsf/3ecdf4775883fdd2872568f6006f1684/1527387d302fa8568725695800786a1b!OpenDocument>

¹⁰⁵ <http://www.healthsalon.com/articles/anxiety.htm>

¹⁰⁶ <http://www.ayurvedaonline.com/advisors.html>

¹⁰⁷ <http://www.rationalradio.com/e006.html>

- Joseph J. Fins, MD is Director of Medical Ethics at the Cornell campus of New York Presbyterian Hospital and holds academic positions at the Weill Medical College of Cornell University. He appears to be one of only three Commission members who have not clearly established reputations as ideological advocates for irrational claims and practices. His primary interests to date have been in palliative and hospice care for the dying.¹⁰⁸
In his comments during meetings of the commission, Dr. Fins has betrayed more serious prejudices, saying that he was “really struck by this notion of ancestral medicine.” He also seems unaware of the fact that concern for the family and spiritual dimensions of patients is well within the biopsychosocial model of scientific medicine in speaking of the “failings of allopathic medical education.”¹⁰⁹
- George DeVries runs at least three different companies. American Specialty Health and Wellness sells supplements over the Internet. American Specialty Health Plans¹¹⁰ and American Specialty Networks “provide chiropractic and acupuncture managed-care services.” *Acupuncture Today* calls him the “president of one of the largest acupuncture HMOs in the nation”¹¹¹ DeVries’ efforts seem to be devoted primarily to getting employers and insurance companies, and, it would now appear, taxpayers, to pay for unproven methods.
- Sister Charlotte Rose Kerr is an acupuncturist who is said to “integrate” theology into her methods. This might be assumed to be Catholicism but she has taught and practiced at the Tai Sophia Institute in Columbia, Maryland since 1977 at which Qi Gong, homeopathy, food supplementation, shiatzu and “zero balancing” are offered.¹¹² Links from the Tai Sophia website include IONS, the Esalen Institute, and the Omega Institute for Holistic Studies, another New Age organization. An announcement praising Sister Kerr’s appointment to commission is posted on the Tai Sophia website¹¹³ in which it is stated that “Dr. James S. Gordon, Director of the Center for Mind/Body Medicine in Washington, D.C., [is] a long-time friend of the Tai Sophia Institute.”
At the Commission’s Draft Interim Report meeting on July 3rd of 2001, Sister Kerr said: “... we believe the body/mind has the right and power to heal itself. ... healing is being in right relationship with self, others, community and the cosmos.”¹¹⁴
- Tieraona Low Dog, MD, practices “herbal medicine” in New Mexico and teaches others to do the same. In fact, she offers a \$1500 correspondence course and advocates the use of herbs for a wide variety of serious illnesses affecting all major organ systems as well as for childbirth and breast-feeding. Prospective students are assured that they will have “a thorough working knowledge” of how to practice medicine using herbal products upon completing the instruction.¹¹⁵ Dr. Low Dog endorses black cohosh for the treatment of menopause and echinacea for colds and is an advisor to many herbal and alternative medicine organizations and publications. She is on the faculty of the Rosenthal Center at Columbia University directed by Fredi Kronenberg PhD. According to Quackwatch, the center could

¹⁰⁸ <http://www.med.cornell.edu/gradschool/fac/fins.html>

¹⁰⁹ http://www.whccamp.hhs.gov/meetings/transcript_01_23_01_part2.html

¹¹⁰ <http://www.americanspecialtyhp.com/>

¹¹¹ <http://www.acupuncturetoday.com/archives/2000/oct/10clinton.html>

¹¹² <http://www.tai.edu/index.html>

¹¹³ http://www.tai.edu/press_releases.html#whouse

¹¹⁴ http://www.whccamp.hhs.gov/meetings/transcript_070201v2p1.html

¹¹⁵ <http://www.fihm.com/>

accurately represent the information it offers to the public as follows: “Our information merely regurgitates proponent viewpoints. We don't criticize senseless methods because (a) that would not be politically correct; (b) some of our allies would get upset with us; and (c) maybe our Center would get less grant money.”¹¹⁶

- Dean Ornish, MD earned his reputation with his work on the management of atherosclerosis with extremely low fat vegetarian diets. But like predecessor Nathan Pritikin, Ornish's recommendations are not suitable for most people. The few small studies claimed to prove the worth of his work have also been questioned on scientific grounds. Dr. Richard Pasternak, director of preventive cardiology at the Massachusetts General Hospital in Boston, has said that “There's virtually no science” in them.¹¹⁷ Dr. Robert Eckel, Professor of Medicine at the University of Colorado Health Sciences Center in Denver and chairman of the nutrition committee of the American Heart Association also expressed serious doubts, as did Dr. Frank Sacks, a nutrition professor at Harvard Medical School and the Harvard School of Public Health. Dr. Sacks, in trying to replicate Dr. Ornish's results with a grant from the NIH, found that it was difficult to recruit patients and few could stick with the program.¹¹⁸ Fortunately, Ornish's program has been superseded by more effective forms of managing elevated blood cholesterol and the discovery of other treatable risk factors.

Like Dr. Gordon, Dr. Ornish began as a devotee of an Indian guru, Sri Swami Satchidananda. He became involved with the Swami after dropping out of Rice University in 1972 in a state of suicidal depression. It was apparently during this time that he formed his beliefs about the importance of a vegetarian diet with no added salt, sugar or fat and no caffeine combined with meditation, yoga and exercise.

Dr. Ornish has enthusiastically endorsed many irresponsible unscientific works by others including Larry Dossey's *Healing Words*,¹¹⁹ and psychic Judith Orloff's *Second Sight*.¹²⁰ Dr. Gordon's own Center for Mind-Body Medicine features an endorsement by Ornish as well.¹²¹

- William Fair, MD is former Chief of Urology Services at Sloan Kettering Cancer Center in New York City. He is a disciple of Dr. Ornish to whom he turned to help with colon cancer in the mid-1990's. Dr. Fair now credits dietary measures for his own cure and claims that similar approaches are effective with prostate cancer. At the first meeting of the Commission he stated that “I honestly think we need to change medicine. ... I think we need to bring these complementary and alternative medicine techniques into the practice of every doctor.”¹²²

Dr. Fair is currently chairman of the clinical advisory board of Health, LLC, through which he and his son promote alternative medicine.¹²³ He has also worked closely with the commission chair, Dr. Gordon, in putting on a series of conferences promoting alternative

¹¹⁶ <http://www.quackwatch.com/12Web/rosenthal.html>

¹¹⁷ Kolata, Gina “At Dinner With Dean Ornish – A Promoter of Programs To Foster Heart Health,” *The New York Times* December 29, 1998 available online at <http://members.aol.com/annullas/newstory/nytimes.htm>

¹¹⁸ Ibid.

¹¹⁹ <http://www.insight-books.com/new/0062502522.html>

¹²⁰ <http://www.twbookmark.com/books/20/0446673358/>

¹²¹ <http://www.cmbm.org/>

¹²² http://www.whccamp.hhs.gov/meetings/transcript_000713_content.html

¹²³ <http://newsun.com/fair.html>

medicine for cancer¹²⁴ and is on the board of Gordon's Center for Mind-Body Medicine. Drs. Fair and Gordon also sit on the editorial board of Larry Dossey's *Alternative Therapies in Health and Medicine* which regularly features articles on paranormal healing as well as bioenergetics and shamanism.

- Thomas Chappell is a businessman with a degree from Harvard Divinity School. He runs Tom's of Maine, a dietary supplement company¹²⁵ as well as a management consulting firm in Colorado called the Saltwater Institute.¹²⁶ His supplement company makes typical unsubstantiated claims to promote its products such as that Ginseng "revitalizes an active life-style" and that Echinacea "supports the immune system."¹²⁷
- Conchita M. Paz, MD, of Las Cruces, NM is a family practitioner who appears to be interested in cultural issues in medicine. She is a member of the National Hispanic Medical Association .
- Buford Rolin has been the Health Administrator of the Poarch Band of Creek Indians since 1984. He is also a member of the Alabama Public Health Advisory Board and former chairman of the National Indian Health Board (NIHB). Mr. Rolin's primary interest has understandably been with the medically undeserved communities of native Americans. But the NIHB has endorsed Indian Health Service funding for "traditional healing," apparently in the belief that this form of "holistic" care is a more realistic expectation for native Americans.¹²⁸ Mr. Rolin has voiced similar opinions.¹²⁹
- Julia R. Scott, RN, is the President of the National Black Women's Health Project, has been active on behalf of the Children's Defense Fund and has served as an NIH consultant on African-American health issues.

The appointment of the last three members of the commission appears to be a cynical attempt to enlist the support of racial minorities in the cause of legitimizing irrational and aberrant medical claims and practices. This should be seen in the context of the ideological beliefs of other commission members, including its Chair, in the notion that science is little more than a tool of cultural domination and oppression. It is a shameful attempt to dissuade groups that are in the greatest need of accessible and equitable medical treatment to be satisfied, instead, with something less than the standards of science and reason. That this recurrent theme in the "alternative medicine" movement could appeal to a cynical interest in cost-saving at the expense of the lives and health of the nation's elderly is particularly worrisome.¹³⁰ Former Colorado Governor Richard Lamm's assertion that Americans have "a duty to die and get out of the way with all of our machines and artificial hearts and everything else like that" is not one with which all Americans disagree.¹³¹

¹²⁴ <http://www.cmbm.org/conferences/ccc98/transcripts/fair.html>

¹²⁵ <http://www.tomsofmaine.com/>

¹²⁶ <http://www.saltwater.org>

¹²⁷ <http://208.5.178.253/products/wellnsextract.htm>

¹²⁸ [http://www.nihb.org/home/profiles.htm#Traditional Medicine](http://www.nihb.org/home/profiles.htm#Traditional%20Medicine)

¹²⁹ <http://www.rehabpub.com/departments/42001/2.asp>

¹³⁰ "Would 'Alternative Medicine' Save Health Care \$\$\$?" *NCAHF Newsletter* 1993 May/June 16(3):1 available online at <http://www.ncahf.org/nl/1993/5-6.html>

¹³¹ <http://www-hsc.usc.edu/~mbernst/ethics.dutytodie.html>

Completely absent from the WHCCAMP are any individuals whose concern is primarily for sound science, evidence-based medicine, and the protection of the public from health fraud. It is all the more surprising given the ready availability of many individuals who have established reputations as scholars of the subject of unproven, disproven and irrational methods often subsumed under the heading of “alternative” and “complementary” medicine.

That the commission was created for the purpose of advocacy is also shown by the fact that its Executive Director and Secretary are also ideological proponents of “alternative medicine.” The former is Stephen C. Groft, who began as the acting director of OAM at its inception. The commission’s Executive Secretary, Michele Chang, is a massage therapist who has worked for Senator Paul Harkin and says that she “help[ed] with the conception of this Commission.” At the WHCCAMP’s first meeting she expressed her belief that there is a “need to consider hearing from people who are practicing CAM modalities in secret” but who “are afraid that they are going to be closed down once the authorities become involved.”¹³²

CONCLUSION

The objections of the Honorable Congressman Burton to the nature and substance of the September 10 hearing of the Senate Special Committee on Aging are misplaced, misinformed, and unfair. All of those who spoke at the hearing, with the exception of Mr. Braswell and Mr. Tepper, were plainly interested in drawing the distinction between health-related claims that are based in facts and reason and those that clearly are not. This is the very same standard that was applied in the 1984 Pepper Report and from which current government policies have strayed dangerously. Not only are there serious problems with DSHEA but these problems exist in a context of political institutions such as the NCCAM and the WHCCAMP that are at best tolerant of quackery and at worst tend to directly or indirectly promote it. The controversy over these and related issues is not fundamentally one between personalities or philosophies but between reason and unreason in the sphere of the marketplace for health-related products and services.

I wish to acknowledge and thank consumer activist E. Patrick Curry, for his collaboration on previous presentation of some of the material included in this response.¹³³

¹³² http://www.whccamp.hhs.gov/meetings/transcript_000713_content.html

¹³³ Gorski T, Curry EP, “White House Commission Stacked Against Science,” *Scientific Review of Alternative Medicine* 2001;5(1):7-8.



UNIVERSITY of NORTH TEXAS
HEALTHSCIENCE CENTER at Fort Worth
★
Education, Research, Patient Care and Services

September 28, 2001

Timothy Gorski, M.D.
1001 N. Waldrop, Ste 815
Arlington, TX 76012

Dear Dr. Gorski:

Recently it has come to the attention of the administration of the UNT Health Science Center at Fort Worth that you have referenced that you are a member of the clinical faculty of the school. Review of our records has determined that your faculty status expired in 1995. I am sure that you are unaware of this and would like to remedy the situation.

We would welcome your reapplication to the clinical faculty of our institution and to do so you may contact the credentialing department at 817/735-2396 to request your application packet.

Regards,

Gary A. Meyer, DO, FACOG
Acting Chairman, Department of OB/GYN
UNT Health Science Center at Fort Worth

GAM/ss

3500 Camp Bowie Boulevard
Fort Worth, Texas 76107-2699



TEXAS COLLEGE OF OSTEOPATHIC MEDICINE

August 20, 1991

Timothy Gorski, M.D.
2705 Hospital Boulevard, Suite 107
Grand Prairie, TX 75051

Dear Dr. Gorski:

The Vice President for Academic Affairs and Dean, as well as the Associate Dean for Primary Care Medicine and the Chairman of the TCOM department of OB/Gyn have recommended that you be appointed as Clinical Assistant Professor in the Department of OB/Gyn of the Texas College of Osteopathic Medicine effective August 19, 1991.

Since this is a non-paid position and is not considered to be official employment at Texas College of Osteopathic Medicine, you are not included under the College's malpractice insurance and are not subject to provisions of the state indemnification law.

We appreciate your good work in helping to ensure our students will get the best medical education possible.

Sincerely,

David M. Richards, D.O.
President

DMR/tr

cc: Benjamin L. Cohen, D.O., Vice President for Academic Affairs and Dean
John Peckham, D.O., Associate Dean for Primary Care Medicine
Robert Adams, D.O., Chairman, Department of OB/Gyn

OFFICE OF THE PRESIDENT

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September 25, 2001

Senator John BreauX, Chairman
 Senate Special Committee on Aging
 G31 Dirksen Senate Office Building
 Washington, D.C. 20510-6400

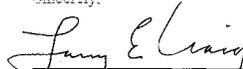
Dear Mr. Chairman:

It has come to my attention that Dr. Timothy N. Gorski, a witness at the Senate Special Committee on Aging's September 10, 2001 hearing on anti-aging products, may have misrepresented his credentials. Specifically, in his written testimony, Dr. Gorski claimed to be an Assistant Clinical Professor at the University of North Texas Health Science Center (UNTHSC). Dr. Gorski is not currently a member of the UNTHSC faculty, and the University does not appear to have approved his testimony. Since Dr. Gorski was not sworn in, as were witnesses on the two previous panels, his misstatement does not constitute perjury, but may be a false statement governed by 18 U.S.C. §1001.

At the very least, the record of the September 10, 2001 hearing should be corrected to accurately reflect the credentials of Dr. Gorski. Additionally, should you decide to refer this matter to a U.S. Attorney, I will join with you in a bipartisan referral.

Thank you for your consideration of this matter.

Sincerely,


 Larry E. Craig, Ranking Member
 Senate Special Committee on Aging

JOHN BREAUX, LOUISIANA, CHAIRMAN
 HARRY REID, NEVADA
 HERB KOHL, WISCONSIN
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 JOHN ENSIGN, NEVADA
 CHUCK HAGEL, NEBRASKA

October 15, 2001

The Honorable Larry Craig
 Ranking Member
 Special Committee on Aging
 628 Hart Senate Office Building
 Washington, D.C. 20510-6400

Dear Senator Craig:

I recently received your letter dated September 25, 2001. In your letter, you raised serious concerns about Dr. Timothy N. Gorski, a witness at the Committee's September 10th hearing and a witness you and I jointly invited to participate in the hearing.

Although I agree that witnesses should accurately represent their credentials before Congress, I do not share your position that Dr. Gorski may have made a false statement in violation of 18 U.S.C. § 1001, subjecting him to a fine or imprisonment of up to five years, or both. To violate 18 U.S.C. § 1001, Dr. Gorski would have to "knowingly and willfully" make a "materially false, fictitious, or fraudulent statement or representation." The facts of this matter simply do not support such a finding.

Rather, the facts indicate that Dr. Gorski provided gratuitous teaching and training of medical students and resident physicians at the Texas College of Osteopathic Medicine upon unsolicited appointment in 1991. He continued teaching in that capacity after 1995, even when the facility was renamed the University of North Texas Health Science Center. Dr. Gorski was unaware the official appointment lapsed into inactive status in 1995. Due to the multiple inquiries to the hospital about Dr. Gorski's veracity after the Committee's hearing, the University's Acting Chairman of the Department of OB/GYN invited Dr. Gorski to reapply to correct this administrative error on September 28, 2001. Last week, I provided you with copies of the August 20, 1991 appointment of Dr. Gorski and this September 28, 2001 letter from the University and will include these documents in the hearing record. Today, I am attaching a copy of the October 10, 2001, letter just received from the University, clarifying that Dr. Gorski was, in fact, only in an inactive status.

I think it is unfortunate that a man of Dr. Gorski's stature and character should be questioned in this manner. I appreciate his willingness to volunteer his time and to assist the

Committee in considering this important and complex review of companies and individuals who would mislead the nation's senior citizens about anti-aging supplements. Although technically Dr. Gorski was inactive as an associate clinical professor when he included the fact in his biography, there is no dispute that he continued to provide the teaching services to the University after 1995 and that the University welcomes his continued services and association. Accordingly, there is no basis to correct the record to reflect that he served in this capacity from 1991-1995. Moreover, I see no basis for referring this matter to the United States Attorney or in concluding that this was anything more than an administrative oversight.

Thank you for bringing this matter to my attention. I hope this satisfactorily addresses your concerns.

Sincerely,


John Breaux
Chairman

03T-10-2001 WED 05:47 PM FROM:

FAX:

PAGE 1

Oct-10-01 09:59am From:UNTHSC Administration

817 735 2488

T-478 P.001/001 F-281



UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER at Fort Worth

Education, Research,
Patient Care and Service

October 10, 2001

Office of the President
3500 Camp Bowie Boulevard
Fort Worth, Texas 76107-2699

Timothy N. Gorski, M.D., F.A.C.O.G.
1001 North Waldrop Dr. Suite 815
Arlington, Texas 76012

Dear Dr. Gorski:

Thank you for your letter concerning your faculty appointment at the University of North Texas Health Science Center. I have learned that we did appoint you as clinical faculty in 1991, and it was never rescinded. Although you were in an inactive status since 1995, your position as Clinical Assistant Professor in the Department of OB/GYN remains valid. You have received a letter from the Acting Chairman of the Department of OB/GYN, Dr. Gary Meyer, requesting additional information so we may update our files and continue your appointment. But, I repeat since you received no notification of termination, and in fact none was sent, your appointment at the health science center remains in force. I hope this clarifies matters for you.

Thank you for your help with our students and support of the health science center.

Sincerely,

Ronald F. Blanck, D.O.
President

RRB/sd

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UNITED STATES OF AMERICA

**Before The
Special Committee on Aging
United States Senate**

**Swinders, Hucksters and Snake Oil Salesmen:
The Hype and Hope of Marketing
Anti-Aging Products to Seniors**

September 10, 2001

**Testimony of Michael McGuffin
President
American Herbal Products Association**

My name is Michael McGuffin. I am President of the American Herbal Products Association ("AHPA"). AHPA was founded in 1983 by a group of companies active in the trade in botanicals. AHPA is now the national trade association and voice of the herbal products industry, comprised of domestic and foreign companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal dietary supplement products. AHPA serves its members by promoting the responsible commerce of products that contain herbs and that are used to enhance health and quality of life.

Thank you for the opportunity to present AHPA's position on Swindlers, Hucksters and Snake Oil Salesmen. Our position is simple – there is no legitimate place in our industry for individuals and companies that flaunt and ignore the law. We applaud this Committee putting the spotlight on those who behave outrageously and who prey on the elderly and the infirm. We have expressed these same views when the Federal Trade Commission has announced actions against other miscreants who pollute our streams of commerce. As Senator Breaux stated in the hearing, "the vast majority of manufacturers and marketers of dietary supplements are reputable and law abiding." AHPA represents responsible commerce in herbal dietary supplements.

FTC. At the hearing, you heard that the Federal Trade Commission has used the same authority it has had since 1938 to protect consumers from dietary supplement swindlers and hucksters. And the FTC and its staff have done an admirable job of pursuing such companies and their officers. Every year the FTC opens cases and

closes case with substantial penalties and consumer redress and AHPA supports that effort. The Commission enforces its 63 year old law the old fashioned way, by bringing cases and pursuing those case to closure in the public interest.

FDA. AHPA is concerned about the responses the Committee received from John Taylor, from the Food and Drug Administration's Office of Enforcement. In response to questions, he expressed concerns about the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), the seven year old law that regulates dietary supplements. The concerns he identified included that manufacturers are not required to register with FDA, so that the agency finds it "difficult to identify all of the sources" of dietary supplement products; that adverse event reporting is voluntary; and the fact that, in Taylor's view, DSHEA's placement of the burden of proof on FDA to prove its case "makes it much more challenging to bring enforcement action" against supplement companies. In our view, Mr. Taylor has no basis for concern.

First, DSHEA's mandate that the government bears the burden of proof to show that an ingredient is adulterated or misbranded is not novel, challenging, or disabling. The FTC has no objection to proving its cases – why should FDA object to doing so? Our judicial system does not declare the accused guilty and then require the accused to prove innocence. The failure and the challenge, we submit, is one of will. The FDA has stopped being an enforcement agency. The number of cases it has brought has fallen drastically in the past twenty years. Meeting a burden of proof in court is not extraordinarily difficult or unique. It is done in federal courts on a daily basis. FDA has simply stopped bringing cases and has forgotten how to do so. There is a challenge in meeting a burden of proof if you have never gone to court to do it. Simply stated, it is

AHPA's position that FDA's lack of enforcement encourages the lawbreakers of the country to engage in their nefarious practices.

Second, we were surprised by Mr. Taylor's statement that FDA finds it difficult to identify all sources of dietary supplement products. Here again, Mr. Taylor ignores the fact that the Federal Food, Drug, and Cosmetic Act has required since 1938 that dietary supplement product labels bear the name and address of the manufacturer or distributor. Moreover, FDA's Center for Food Safety and Applied Nutrition, Division of Enforcement and Programs, has stated it can provide FDA personnel "with a printout listing the known dietary supplement manufacturers in each district." FDA Compliance Policy Program 7321.008, p. 6 (2/17/00) (attached hereto). And if product labels and FDA's own records do not locate a company, FDA should use its law enforcement tools to do so. Moreover, many states, like California and Texas, require all food manufacturers, including dietary supplement companies, to be registered or licensed by the State. Where there is a will, there is a way. But FDA can't enforce the law if it does not try to do so. And FDA has not asked AHPA or other trade associations to provide manufacturer and distributor information.

Third, we were not surprised by Mr. Taylor's concern that adverse event reporting for dietary supplements is voluntary. We are not surprised because this is the refrain we hear from an FDA that cannot now process and simply make public the voluntarily submitted adverse event reports it has received. This failure has gone on now for a number of years. Our industry has and will support the repair and functioning of the FDA's dietary supplement adverse event reporting system. However, there

should be no consideration of a mandatory system until FDA has shown that it can make the present system function.

cGMP. AHPA is concerned about the perception that dietary supplements are unregulated. This is simply wrong. It has become a refrain of those who do not understand that DSHEA regulates dietary supplements and that FDA, the custodian of this law, simply has no will to effectuate its mandate. Current Good Manufacturing Practice regulations for dietary supplements present a case study of FDA's failure to effectuate DSHEA.

The Federal regulations that govern food and supplement manufacturing are referred to as Current Good Manufacturing Practices (cGMP), and they are established by FDA to control the manufacture of all foods. There are similar regulations for drugs and devices. These cGMPs establish basic guidelines to assure that goods are manufactured under sanitary conditions that result in properly identified products that are not contaminated or adulterated, and that are fit for consumption. Section 9 of DSHEA gave FDA specific authority to promulgate cGMPs for dietary supplements.

The cGMP for foods is published in Title 21, *Code of Federal Regulations*, Part 110 (21 CFR Part 110). Because the task of implementing DSHEA was substantial, draft cGMPs for dietary supplements were cooperatively developed by several industry trade associations and submitted to FDA in late 1996, one year after DSHEA became law. They were modeled after the cGMP for foods and published by FDA in the *Federal Register* in February, 1997 as the "Industry Draft" in an Advanced Notice of Proposed Rulemaking. Since that publication, FDA has received comments on this Industry Draft

and expended resources on developing proposed cGMP regulations. FDA has also stated that it intends to issue these proposed regulations, but these have been under review by the White House Office of Management and Budget since March of this year.

Present Food cGMPs and Labeling Regulations. Until such time as cGMPs for dietary supplements are proposed and made final, however, manufacturers of dietary supplements are bound by the cGMPs for foods. It is important to know that every food and supplement manufacturer in the United States is subject to inspection and may not refuse inspection. This requirement is described in Section 374 of Title 21, *United States Code*, as follows: "... officers or employees duly designated by the Secretary [of Health and Human Services], upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein."

The US Food and Drug Administration also has authority over the labeling and manufacture of dietary supplements, and they do use this authority. Warning Letters have been sent to companies where FDA has analyzed products and found them to be out of conformity with their labeling. And the FDA has told distributors that "As a

repacker and distributor of dietary supplements, you are responsible for ensuring not only that the products you repack and/or distribute are safe for human consumption, but that they are also labeled in accordance with current labeling regulations." But FDA has not followed up on those companies that are persistent non-compliers.

The labeling requirements for supplements are found in Title 21 of the *Code of Federal Regulations*, in several sections in Part 101. They are so detailed that FDA has had to create simplified versions to explain to industry how to comply. FDA also requires that manufacturers label their products with all information that is material to consumers of their goods. In the final rules for the regulation of allowable claims for dietary supplements, published by FDA in January 2000, the agency reiterated this point:

"... the agency notes that dietary supplement labeling, like the labeling of all other FDA-regulated products, is required to include all information that is material in light of consequences that may result from the use of the product or representations made about it (see sections 403(a)(1) and 201(n) of the act)."

These final FDA labeling regulations specify what claims are allowed to be made for dietary supplements. These are set forth in 21 CFR 101.93.

Dietary Supplement Advocate. What dietary supplement consumers and the regulated dietary supplement industry lack at FDA is a voice. Dr. Janet Woodcock is the Director of FDA's Center for Drug Evaluation and Research. Dr. Kathryn Zoon

heads up the agency's Center for Biologics Evaluation and Research, and Dr. Stephen Sundlof holds that position at the Center for Veterinary Medicine. While I have not had the opportunity to interview any of these or others of FDA's Center Directors, I do not believe that I go too far out on a limb in assuming that each of them is a responsible advocate for the products under their regulatory aegis. Dr. Woodcock almost certainly believes that timely approval and access to drugs is important to Americans. Dr. Zoon very likely holds that vaccines benefit the public health. Dr Sundlof likely supports the use of veterinary drugs and medical feeds, both for our pets and our food-producing animals. I will go further in my speculation and presume that the products regulated by each of these and each of the other Centers at FDA are held in similar regard by most if not all of the senior and mid-level management, so that deputy and associate Directors and Directors of the various offices within each Center also consider the drugs, vaccines and other biologics, veterinary drugs, etc. to have value for Americans.

Dietary supplements are regulated primarily by FDA's Center for Food Safety and Applied Nutrition (CFSAN) and specifically by the Office of Nutritional Products, Labeling and Dietary Supplements at CFSAN. I mean no disrespect to either Mr. Joseph Levitt or Dr. Christine Lewis, the Center and Office Directors respectively, when I state that neither of these dedicated and qualified individuals has the same or even similar high regard for dietary supplements that the management of other Centers have for their regulated product categories. Neither is there anyone else at any level of management at CFSAN that I have come in contact with who has ever expressed any indication that they believe that dietary supplements have even a potential contribution

to make to the health of Americans. In fact, there is a general perception that CFSAN not only is absent any sense or expression of the value of supplements, but in fact believes that the primary impacts of supplement usage on Americans are negative. Accordingly, we have come to have the view that CFSAN has abdicated its responsibility to enforce the laws regarding dietary supplements and to establish important regulatory parameters such as current Good Manufacturing Practice regulations.

Let me be clear. FDA's disrespect of dietary supplements hurts consumers and industry alike because there is no will to enforce DSHEA in the interests of either consumers or the industry. FDA's attitude appears to be that this is not a law it asked for, and therefore it is not a law it intends to enforce.

This situation needs to be corrected. One way to do so would be to create a position that I will tentatively identify as a "dietary supplement advocate" at CFSAN. This position should be filled by someone who has a background in training and experience that provides them with knowledge of the health benefits that supplements offer to our culture. In addition, from the perspective of AHPA and its members, this person should have specific knowledge and experience in the area of botanicals.

Beginning after the passage in 1938 of the Federal Food, Drug, and Cosmetic Act, the FDA, often with the support of so-called "organized medicine" and with no objection from the pharmaceutical industry, devoted substantial enforcement resources against vitamin and mineral products. This effort culminated in a 14-year long regulatory proceeding that ended in the early 1970's where FDA sought to impose

substantial regulations on such products. Congress responded with the Proxmire Amendments which basically told FDA to cease their unwarranted scrutiny of vitamin and mineral supplements. And FDA's continuing hostility to the industry led to the enactment of the DSHEA – passed unanimously by both houses of Congress and signed into law without reservation. If we are to ever arrive at a peaceful coexistence with FDA, we will need to know that someone at that agency has some basic respect for the goods that are marketed by our members. And consumers need to know that FDA will proceed against the miscreants who have no place in the industry. That will not happen until there is an advocate because, again there is no will to do so now.

As the Committee is aware, most government regulation is sought by industry as a way to create and ensure a level playing field matrix for more certainty of investment in products and marketing. DSHEA created that matrix for dietary supplements. But the law might as well not be there if FDA will not enforce it. Because FDA does not enforce this law, consumers are losing confidence in the dietary supplement industry. This is not surprising, you would fly less frequently if the Federal Aviation Administration stopped inspecting the airlines.

AHPA. AHPA has taken a leadership role over the 17 years since we were founded in encouraging our members to provide material information to consumers. That is why AHPA's members have voluntarily agreed to use very specific labeling on products that contain certain herbal ingredients, such as chaparral, comfrey, ephedra, and kava. That is why we published the *Botanical Safety Handbook* in 1997, and why

our members have agreed to voluntarily utilize the pregnancy and nursing cautions that are contained therein.

DSHEA was enacted in 1994. FDA has taken some but not all the regulatory steps necessary to implement this law. FDA needs to be encouraged by this Committee to move forward on implementing the law not only through the promulgation of cGMP regulations but through enforcement of the law and existing regulations as well.

<p>U.S. Food Drug Administration Center for Food Safety Applied Nutrition</p> <p>Food Compliance Program</p>

Food Composition, Standards, Labeling And
Economics
Dietary Supplements--Import And Domestic
Issued February 17, 2000

7321.008

CHAPTER 21 - FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS

DIETARY SUPPLEMENTS--IMPORT AND DOMESTIC
FOODS (FY *00/01*)

UPON RECEIPT

9/30/01

PAC 21008

Industry Code 54

21R829 (for all involving
nutritional health fraud
issues)

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

FIELD REPORTING REQUIREMENTS

*

The following items will be forwarded, within the timeframes noted, to CFSAN/Dietary Supplement Monitor at the address listed below.

Within 30 days after completion of each inspection, forward:

<http://vm.cfsan.fda.gov/~comm/cp21008.html>

9/21/01

- a copy of the complete EIR;
- all labels collected according to instructions in Part III;
- a completed Attachment G; and
- the questionnaire on BSE (Attachment B).

Send the above information to:

Brenda K. Aloï
Dietary Supplement Monitor (HFS-636)
Food and Drug Administration
200 C Street, S.W., Rm. 5113
Washington, D.C. 20204
Phone (202) 205-8168
FAX (202) 205-9670

PART I BACKGROUND

General

The definition of a dietary supplement that is encompassed in this program was

expanded by the Dietary Supplement Health and Education Act of 1994 (DSHEA) which was enacted on October 25, 1994.

The DSHEA amended the Federal Food, Drug, and Cosmetic Act (the Act) to significantly alter the way the Food and Drug Administration (FDA) regulates dietary supplements. This legislation necessitated that the Agency undertake limited rulemaking to fully implement some of the provisions of the Act.

The DSHEA established a new regulatory definition for "dietary supplement." A "dietary supplement" is a product (other than tobacco), intended to supplement the diet, that contains one or more dietary ingredients. The dietary ingredients include vitamins, minerals, herbs or other botanicals, amino acids and dietary substances for use by man to supplement the diet by increasing the total dietary intake. This includes concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredients. Dietary supplements are intended for ingestion in capsule, powder, softgel, gelcap, tablet or liquid form, or if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet. Dietary supplements must be labeled as such.

The DSHEA gives the Agency the authority to promulgate good manufacturing practice (GMP) regulations for the dietary supplement industry. No GMP regulations for dietary supplements have been promulgated to date.

The DSHEA establishes a framework for regulating the safety of dietary supplements. Dietary ingredients in, or intended for use in, dietary supplements are excluded from the definition of a "food additive."

*Therefore, deeming a substance to be an unapproved food additive is not an appropriate reason for recommending enforcement action against a dietary supplement. However, other ingredients in dietary

supplements, that are not dietary ingredients within the meaning of section 201(ff)(1) of the act (e.g., colors, flavors, technical additives, etc.), are still subject to the food additive provisions of the act. An unapproved food additive charge may be appropriate for these ingredients.*

The DSHEA defines a "new dietary ingredient" as a dietary ingredient that was not marketed in the United States (U.S.) before October 15, 1994, and establishes circumstances under which such ingredients can be safely used in dietary supplements. The DSHEA places the burden on FDA to prove that a dietary supplement product presents a significant or unreasonable risk of illness or injury under the labeled conditions of use or that it contains a substance that may render it injurious to health (under section 402(a)(1) of the act) before it can be removed from the marketplace.

*Labeling

The DSHEA provided the FDA with specific authority to require nutrition labeling on most dietary supplements regulated by the Agency, established requirements for the identification of dietary supplement products, and ingredient labeling. Regulations implementing the DSHEA labeling provisions were issued on September 23, 1997 and became effective on March 23, 1999.

All dietary supplement products (with the exception of exempt products) labeled after March 23, 1999, are subject to the DSHEA regulations. Exemptions from the nutrition labeling regulations include dietary supplement products manufactured by firms that meet the small business exemptions provided under the regulations, e.g., low volume products, and products shipped in bulk. (See Attachment D)

Note: In the September 23, 1997 FEDERAL REGISTER (62 FR 49839), FDA announced that it was revoking Compliance Policy Guide 7121.04 - "Vitamin Products for Human Use" in order to eliminate inconsistencies with the new labeling requirements. FDA previously announced in the April 19, 1995 FEDERAL REGISTER (60 FR 19597) that it had withdrawn Compliance Policy Guides 7117.04 - "Botanical Products for Use As Food" and 7118.01 - "Dietary Supplements - Misbranding and Nutritionally Insignificant Ingredients."

Firms that believe they are entitled to an exemption for low-volume dietary supplement products for small businesses must file a notice claiming the exemption and provide the information necessary to verify their exempt status to CFSAN/Office of Food Labeling (OFL). The home district for the firm receives a copy of the firm's notice and OFL's acknowledgement. OFL will make the list of products qualifying for this exemption available to FDA and State personnel on FDA's Website at WWW.FDA.GOV. This site will also contain a listing of firms that have filed and received approval for alternative approaches for compliance under 21 CFR 101.36(f)(2).

FDA published a final rule in the January 15, 1997 Federal Register (62 FR 2218) requiring, in part, that dietary supplement products in solid oral dosage form that contain added iron bear a warning statement. The effective date of the dietary supplement nutrition labeling regulations, March 23, 1999, also applies to the enforcement of this requirement. Furthermore, if the added iron is in an amount of 30 milligrams (mg) or more the product must be packaged in unit-dose packaging. The unit-dose packaging rule became effective July 15, 1997. The rule provided a temporary exemption to the unit-dose packaging requirement for products that contained carbonyl iron as the iron source; the temporary exemption expired January 15, 1998 and the requirement for unit-dose packaging for carbonyl iron-containing products became effective July 15, 1998.

Compliance with the nutrition labeling requirements and other mandatory labeling requirements for dietary supplements will be determined through field exams and sample collections that will be limited

to the following areas:

- (1) Non-exempt products that fail to bear a "Supplement Facts" panel on the label.
- (2) Products that fail to bear an appropriate statement of identity on the principal display panel.
- (3) Products that bear health claims or nutrient content claims that have not been authorized by FDA, or that are not appropriately based on an authoritative statement as provided in section 403 (r) (2) (6) or section 403 (r) (3) (c) of the FD&C Act.
- (4) Products that bear authorized approved health claims or nutrient content claims that do not qualify for making the claims.
- (5) Products that bear nutrition labeling ("Supplement Facts" panel) with significant format deviations.
- (6) Products in solid oral dosage form containing 30 mg. or more of iron that fail to be packaged in unit dose packaging.
- (7) Products with added iron that fail to bear the mandatory warning statement.
- (8) Products that fail to bear other mandatory label information.

Enforcement actions are not contemplated at this time against products bearing structure/function claims that do not also include the required disclaimer. Enforcement actions also are not contemplated against products that bear structure/function claims for which manufacturers have not submitted the required 30-day notifications. The reasons for this enforcement policy are explained in detail in the preamble to the final rule (Part IV. Implementation Plan) published in the Federal Register on January 6, 2000 (65 FR Page 1044).

The Agency will consider, on a case-by-case basis, enforcement actions against products that bear egregious disease claims or that may be unsubstantiated and false or misleading. Investigators should review claims made for dietary supplements in labels and labeling. Products that bear inappropriate disease claims or that appear to bear egregiously false or misleading claims should be referred to the Center for evaluation.

The preamble to the final rule provides important background and rationale for the Agency's policies related to the structure/function and disease claims issue. In addition to the preamble discussion, the agency intends to issue a guidance document to provide additional information regarding structure/function and disease claims. The guidance document would complement, rather than substitute for, the final rule.

Because of reports of serious adverse events associated with chronic long-term use of dietary supplements containing stimulant laxative ingredients, the Center continues to have concerns about these products. Following consideration of the safety of stimulant laxative ingredients by FDA's Food Advisory Committee, and meetings with members of the industry, the Agency deferred consideration of rulemaking to require warning statements on these products if industry would voluntarily use the warning notice required by California on labels for these products nationwide. The California warning statement became effective March 1, 1998.

During the field exams outlined above, investigators are asked to collect additional information on any products containing stimulant laxative ingredients (Refer to Attachment F).

*

Coverage of Bovine-Derived Ingredients

By letter dated May 9, 1996 (ATTACHMENT C), FDA recommended that firms that manufacture or import dietary supplements and their ingredients containing specific bovine tissues, including extracts or substances derived from such tissues, take whatever steps are necessary to assure that such ingredients do not come from cattle born, raised, or slaughtered in countries where bovine spongiform encephalopathy (BSE) exists. BSE is a fatal transmissible spongiform encephalopathy similar to Creutzfeldt-Jakob disease in humans. BSE continues to be prevalent in Great Britain (including Northern Ireland and the Falklands), France, Switzerland, Republic of Ireland, Oman, and Portugal. (Refer to Import Alert #17-04 for the current list of BSE-countries.) The Agency believes that immediate and concrete steps should be taken by manufacturers to reduce the potential risk of human exposure to, or transmission of, the agent which causes BSE in cattle.

The Agency believes that manufacturers and importers of dietary supplements and their ingredients should have planned, systematic procedures in place to provide assurances to themselves and to consumers that bovine-derived tissues do not come from cattle in countries where BSE occurs. *An example of one such procedure would be the receipt of a certificate from the supplier that certifies that the bovine-derived tissue came from a herd that is BSE-free.* Inspections under this compliance program will include completion of the questionnaire (ATTACHMENT D) to determine whether the firm being inspected is aware of the Agency's concerns about the transmission of BSE as outlined in the May 9, 1996 letter, and whether the firm has procedures in place to provide assurance that bovine-derived tissues do not come from countries where BSE exists.

NOTE: The list of tissues contained in the Agency's 5/9/96 letter has been expanded (ATTACHMENT A) to include additional bovine tissue or tissue-derived ingredients with a suspected risk of infectivity. The tissues and tissue derived-ingredients marked with asterisks are considered to present the highest risk of infectivity (hereinafter referred to as "high risk tissues").

Import Coverage

*

Note: Numerous import alerts and bulletins pertaining to dietary supplement ingredients have been withdrawn since the inception of DSHEA. Districts must refer to FIARS for an up-to-date index of applicable import alerts and bulletins. Districts should contact the Division of Import Operations and Policy (DIOP), HFC-170, to determine the current status of an applicable import alert or bulletin.*

PART II IMPLEMENTATION

OBJECTIVE

The objectives of the program are as follows.

- To conduct inspections under 21 CFR Part 110 (General Current Good Manufacturing Practices for Foods) at domestic manufacturers of dietary supplements of vitamins, minerals, proteins, herbs and

similar nutritional substances.

- To gather information during these inspections on dietary supplements in the marketplace containing selected dietary ingredients (as identified in Part III).
- To collect and analyze a limited number of domestic and domestic-import samples of dietary supplements of vitamins, minerals, and proteins to compare label declarations to the nutritional composition of the product.

*

- To conduct field exams to determine compliance with the nutrition labeling ("Supplement Facts") and other labeling requirements that are now in effect for all non-exempt dietary supplement products.*

INTERACTION WITH OTHER PROGRAMS

Include coverage of this program during inspections conducted under CDER's Drug Process Inspection Compliance Program when it is determined that the firm manufactures both drugs and dietary supplements. Use the appropriate CFSAN and CDER Program Assignment Codes (PACS) when reporting time for these inspections.

PROGRAM MANAGEMENT INSTRUCTIONS

To use the planned resources effectively, the Center has established priorities for selecting firms to be inspected and dietary supplements to be collected for analysis.

CFSAN's Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) and the Division of Enforcement and Programs may be contacting selected districts during the year to arrange for OSN personnel to accompany field investigators during routine inspections conducted under this program. A first hand knowledge of the firms comprising this industry and the manufacturing practices employed by these firms will be invaluable to OSN headquarters personnel during the rulemaking regarding dietary supplements.

A. Planning Instructions

As a guide to the districts in selecting firms to be inspected, the Division of Enforcement and Programs can provide each district with a print-out listing the known dietary supplement manufacturers in each district. Contact Brenda K. Aloï, CFSAN/DOEP at (202) 205-8168 if you would like the print-out for your district.

B. Select firms for inspection in the following order of priority:

1. Firms producing both dietary supplements such as botanicals (e.g., ginseng, yohimbe), animal and plant extracts (e.g., garlic extracts and inert glandulars), fats and lipid substances (e.g., oil of evening primrose, fish oils, essential fatty acids) and also producing dietary supplements such as vitamins, minerals, and proteins;
2. Firms producing dietary supplements such as botanicals (e.g., ginseng, yohimbe), animal and plant extracts (e.g., garlic extracts and inert glandulars), fats and lipid substances (e.g., oil of evening

primrose, fish oils, essential fatty acids) but not producing any dietary supplements of vitamins, minerals, or proteins; and

3. Firms producing only vitamin, mineral, or protein supplements.

* The above prioritization scheme, because of its focus on firms manufacturing "non-traditional" products, may not result in sufficient products that meet the threshold for sample collection and analyses under the program, i.e., products with vitamins, minerals, proteins at (#) of the D.V. Districts should attempt to meet their workplan obligation for sample collections by collecting appropriate samples from other establishment types visited for purposes of conducting field exams (see C below).

C. Field Exams

In order to meet Workplan obligations, field exams may be conducted:

During the inspections planned and conducted at manufacturers, provided the firm applies the finished product label;

At firms that pack products into different containers, provided they are not bulk containers; or

At warehouses or distributors of finished products.

Note: No inspections at the above establishment types, other than at manufacturers, are planned or necessary to perform the field exams and sample collections which are planned separately in ORA's Workplan.

D. Label Exams for Import Products

Districts must refer to the FDA Website at WWW.FDA.GOV for a list of small businesses that are exempt from "Supplement Facts" labeling before conducting label examinations. All products manufactured by those firms meeting the requirements for exemption are exempt from DSHEA labeling requirements.

Products subject to detention without physical examination due to supplement facts labeling violations will be listed in Import Alert

54-09, "Products Subject to Automatic Detention Due to DSHEA Labeling Violations," which is accessible in FIARS.

*

PART III INSPECTIONAL

A. Inspection

1. a) If the firm appears to be following drug CGMPs in the manufacturing of their dietary supplement products, note in the EIR, *and still conduct a CGMP inspections under Part 110 at each firm scheduled for inspection*.

b) If inspectional evidence discloses insanitary conditions, issue an FDA 483 to the firm. In addition to

samples collected to document the insanitary conditions, if the investigator observes any of the conditions outlined below, collect an official physical sample, and all available evidence documenting the suspected deficiencies and submit as exhibits with the EIR. Include documentation of interstate commerce.

- Review several records of analyses, when available, for any product having nutrients declared as being present (#) of the Reference Daily Intake (RDI) or Daily Reference Value (DRV). Compare the results with label declarations. If the firm has not had nutrient analyses performed on its own products, determine the firm's method for assuring the accuracy of the nutrient declarations on the product label.
- Determine if vitamins used for enrichment are stored in a cool place and protected from light. Improper storage as well as age of the vitamin enrichment material may result in a loss of potency.
- Determine if the firm's QA procedures ensure that the balances used for weighing enrichment materials are calibrated and are of a sensitivity which is adequate for the amounts being weighed.
- Review quality control procedures, especially any relating to control of mechanisms regulating continuous addition of nutrients to a processing line.
- If elemental iron (such as reduced iron, carbonyl iron, or electrolytic iron) is added for enrichment (rather than a compounded form of iron, such as ferrous sulfate), determine if the firm's processing lines contain magnets for removal of foreign objects.

If the elemental iron is added before the product reaches the magnets, the magnets may remove the iron from the product.

- If available, review the firm's records of nutrient analyses performed on raw materials used for enrichment; finished product; and shelf life nutrient stability of the product.

2. Coverage of Bovine Tissue and Tissue-Derived Ingredients

The questionnaire (Attachment B) was developed to determine the following at each firm inspected:

- a) Whether the firm manufactures or imports products containing bovine tissue or tissue-derived materials;
- b) Whether the firm has procedures in place to ensure that it does not receive tissues from cattle from BSE-countries; and
- c) The origin of all bovine tissue or tissue-derived ingredients used by the firm and the products containing them.

Upon completion, a copy of the questionnaire (Attachment B) must be mailed or faxed to the Dietary Supplement Monitor at the address listed on Page 1 of this compliance program.

As indicated in c) above, the origin of all bovine tissues and tissue-derived ingredients used by the firm and products containing them will be collected on Attachment B.

Additional documentation on bovine tissue or tissue-derived ingredient usage for possible regulatory

follow-up is required only when a firm is manufacturing or importing dietary supplement products or their ingredients using high risk tissues or tissue-derived ingredients from a BSE country. High risk tissues or tissue-derived ingredients are identified by asterisks on Attachment A.

Investigators must refer to Import Alert #17-04 prior to conducting inspections to obtain the most recent list of BSE countries.

Document the following for possible regulatory consideration by CFSAN/DOEP/Case Processing Branch:

- the high risk tissue or tissue-derived ingredients being used;
- the finished products containing them;
- the specific country of origin of the high risk tissue; and
- the name and address of the importer or other responsible party.

3. Collection of Product Labels and Completion of Attachment G

The Center has concerns about the ingredients listed below. The labels and/or information requested on Attachment G is necessary for the Center to determine the conditions of use of the products containing the ingredients and the levels of the ingredients. The information will allow the Center to adequately evaluate the possible health risks, if any, presented by the products and formulate appropriate policies for addressing the risks. At this time, no regulatory/enforcement actions are planned or anticipated for products containing these ingredients.

a) For each separate product manufactured by the firm that contains one or more of the following added ingredients, collect an original (or quality copy) of the label.

*

<u>Common Name</u>	<u>Latin Binomial Name</u>
aconitum aconite root, monkshood, friar's cap, helmet flower, soldier's cap, wolfsbane)	<i>Aconitum spp.</i>
aristolochia	<i>Aristolochia spp.</i>
(None)	<i>Akebia spp.</i>
androstenedione	nor-androstenedione
androstenediol	nor-androstenediol
bitter orange or sour orange	Citrus aurantium

"bovine complexes" non-specific origin	
chaparral (creosote bush, greasewood hediondilla, tarweed, sonora gum)	<i>Larrea</i> spp.
chromium (picolinate or polynicotinate)	
comfrey (ass ear, backwort, blackwort, boneset bruisewort, briswort, consound, galloc, gum plant, healing- herb, knitbone, russion comfrey, slippery root)	<i>Symphytum officinale</i> L., <i>Symphytum asperum</i> Lepechin, <i>Symphytum tuberosum</i> L., <i>Symphytum x uplandicum</i> Nyman
<i>dehydroepian- dosterone (DHEA)</i>	
dogbane (indian hemp)	<i>Apocynum</i> spp.
ephedra (epitonin, joint fir, Ma huang, Mexican tea, miner's tea, mormon tea, Pakistana ephedra, popotilo, sea grape, squaw tea, desert tea, teamster's tea, yellow horse, yellow astringent)	<i>Ephedra</i> spp.
fangchi fang ji	
folate (folic acid)	≥ 5 mg/day
fluoride	≥ 10 mg/day for adults; ≥ 2 mg/day or children under 8 yrs. Of age
garcinia (cambogia, gamboge, gambogia)	<i>Garcinia hanburyi</i> Hook.
germander (Woodsage)	<i>Teucrium</i> spp.
germanium	
guarana	

(Brazilian cocoa, zoom)	<i>Paullinia cupana</i> H.B.&K. Kunth, <i>Paullinia sorbilis</i> (L.) Mart.
5-hydroxy-L-tryptophan	
kava kava	<i>Piper methysticum</i>
L-Tryptophan	(only purified amino acid) (See Import Alert #54-04 for importation of L-Tryptophan)
melatonin	
mu dong	
mu tong	
mu tung	
niacin (nicotinic acid and nicotinamide)	≥ 50 mg/day
selenium	≥ 1.0 mg per day
St. John's Wort	<i>Hypericum perforatum</i>
<i>Stephania</i>	<i>Stephania spp.</i>
(Chinese cucumber, <i>Tricosanthes spp.</i>	<i>Tricosanthes spp.</i>
Chinese snake gourd, compound Q, gua-lou, tian-hya-fea)	
vitamin A	≥ 25,000 IU/day
vitamin D	≥ 2,400 IU/day (60 micrograms/day) for adults; > 1800 IU/day (45 micrograms/day) for infants under 1 yr.)
vitamin B6	≥ 200 mg/day
yerba maté (Paraguay tea, St. Bartholomew's tea, Jesuit's tea)	<i>Ilex paraguensis</i> A. St. Hill, <i>Ilex paraguariensis</i> D. Don Maté
yohimbe	<i>Pausinystalia yohimba</i> <i>Rauwolfia spp.</i> <i>Strophularia spp.</i> <i>Tribulus terrestris</i>

*

NOTE: For purposes of collecting the labels, any product that represents: a different product form (tablet, capsule, extract); strength (500 mg, 400 mg); formulation (different ingredients or different levels of ingredients); or a different brand name for the product constitutes a different product.

For firms that are packaging the same product under multiple brand names, select a representative label and provide an *estimate of the different brand names under which the product is sold*.

b) In addition to the product label, for any product containing one or more of the above added ingredients whose label does not list the ingredient/levels, Attachment G should also be completed, attached to the EIR, and submitted to CFSAN.

In determining whether to include a product containing one of the nutrients listed above with a level, e.g., niacin >500 mg/per day, on Attachment G, calculate the recommended per day consumption as strength (or level of nutrient in multi-ingredient products) x amount consumed per day.

Since the above ingredients and their levels may not be listed on product labels, whenever possible their presence must be documented through review of product formulation or through discussions with firm management in order to complete Attachment G.

Although the FD&C Act does not specifically require management to furnish formula information except for prescription drugs, restricted devices, and infant formula, this information should be requested. Management may provide the qualitative formula but refuse the quantitative formula. If formula information is refused, attempt to reconstruct formula by observing: a) product in production, 2) batch cards or formula sheets, and 3) raw materials and their location. Record refusals should be noted on the FDA 481(a) and discussed in the narrative of the EIR.

Investigators must use their judgement, based on the firm's level of cooperation, in determining whether to pursue the levels of other ingredients present in the product. These other ingredients are important as they may be involved in synergistic reactions, however, priority should be given to obtaining information on the selected ingredients noted above.

*

B. Field Exams and Import Label Exams

Products shipped in bulk form, not distributed to consumers in such form, and used in the manufacture of other dietary supplements are not subject to "Supplement Facts" labeling.

Investigators must review the firm jacket prior to conducting inspections to determine if the firm and/or any of its products are exempt from nutrition labeling. Also utilize the information available on the FDA Website at WWW.FDA.GOV. *Investigators must verify the firm's status with firm management after issuing the FDA 482, but prior to conducting any field exams.*

Do not conduct field exams in firms that are exempt from compliance.

Investigators conducting import entry reviews must also refer to the

FDA Website for a list of exempt importers and brokers before conducting label examinations.

NOTE: A nutrient content claim or health claim on a dietary supplement label generally negates the exempt status of the product and triggers the requirement for supplement facts labeling.

Specific questions about the exempt status of a domestic firm, importer, or broker should be directed to Angela Pope, CFSAN/Office of Nutritional Products, Labeling and Dietary Supplements (HFS-812),

(202) 205-4561.

NOTE BEFORE CONDUCTING FIELD EXAMS AND LABEL EXAMS:

Areas of Emphasis Nos. 6 and 7 below concern certain new labeling and packaging requirements for iron-containing dietary supplements. Enforcement actions will be based on the failure of products to be properly packaged or labeled as outlined below. However, the Agency must have a means to determine the level of industry compliance with the requirements, i.e., how many total products are subject to the requirements. At this time, we are requesting that investigators assist us in accumulating this baseline data by identifying and tabulating all products that are subject to the requirements as outlined under areas of emphasis 6 and 7. Specifically, how many products are in solid oral dosage form and contain 30 milligrams or more of iron and how many products contain any amount of added iron.

This information must be reported separately in the EIR as a percentage statement, for example: "Firm manufactures or distributes XXX total products containing 30 mg. or more of iron, of which XX products (or XX%) are packed in unit-dose packaging." or "Firm manufactures or distributes XXX total products containing added iron, of which XX products (or XX%) bear the required warning statement."

Although not included as a label violation in the **Areas of Emphasis** below, investigators are asked to look for any dietary supplements containing stimulant laxative ingredients. Attachment F consists of a list of laxative stimulant ingredients. For each firm manufacturing or distributing products containing one or more of these ingredients report the following items separately in the EIR:

- (a) the identity of each product containing stimulant laxative ingredients;
- (b) the identity of the above products bearing a warning statement identical or similar to the State of California statement (refer to Attachment F; and
- (c) the identity of stimulant laxative ingredient(s) contained in the above products including the common name and Latin binomial name used on the label.

Labels may be submitted in lieu of reporting the information in the EIR.

See hardcopy reporting instructions below.

Review the label of 2-3 non-exempt products labeled on or after

March 23, 1999.

The following label violations will be the focus of the field exams and label reviews (Refer to Attachment E for additional guidance and examples of these violations).

Areas of Emphasis

1. Products that fail to bear nutrition labeling, i.e., the absence of "Supplement Facts" on the label, and the product is not covered by an exemption.
2. Products that fail to bear an appropriate statement of identity on the principal display panel, i.e., use of the term "dietary supplement" or some variation of " supplement."

3. Products that bear health claims or nutrient content claims that have not been authorized by FDA regulation, or are not authorized on the basis of an authoritative statement as provided in section 403(r)(2)(G) or section 403(r)(3)(C) of the FD&C Act.

4. Products that bear authorized health claims or nutrient content claims that do not qualify for making the claims.

5. Products that bear nutrition ("Supplement Facts") labeling with significant format deviations.

6. Products distributed in solid oral dosage form containing 30 mg. or more of iron but fail to be packaged in unit-dose packaging.

7. Products with added iron that fail to bear the required warning statement.

8. Products that fail to bear other mandatory label information.

*

C. Import Investigations

Refer to the guidance contained in Import Alert #17-04 for detention without physical examination of bulk shipments of high risk bovine tissue from BSE countries. Be alert for such shipments during import entry review. *A certificate, or other acceptable proof, from the supplier that the herd from which the tissue was obtained is BSE-free may be required before the shipment is released."

D. Sample Collection

Collect a compliance sample with interstate documentation if warranted based on inspectional observations as outlined above in A.1.

Documentary samples collected under Area of Emphasis Nos. 1, 2, 3, 5, 6, 7 and 8 will generally consist of the label only; no physical sample is required.

NOTE: When the configuration of the container makes it difficult to determine the total amount of label space available to bear labeling it will be necessary to collect the actual container along with the label. Collect one (1) product container along with the four (4) original product labels.

1. Compliance Samples

a) Areas of Emphasis Nos. 1, 2, 3, 5, 6, 7 and 8

(i) Collect a sample of any product that appears, on the basis of the field exam or label exam to be

violative under one of more of the above Areas of Emphasis.

Import lots sampled for a violation under one of the above areas must be held pending compliance review.

(ii) The sample will consist of four (4) original labels (and one product container, if warranted) for the product being sampled. This is a documentary sample only; no physical sample is required. Prepare a Collection Report (C/R) for each potentially violative product label collected and mark as "Documentary" in the **Sample Type** field.

(iii) Indicate "Compliance" in the **Basis** field of the C/R. Under **Reason for Collection** indicate "Label Review Only."

(iv) Send the sample to your compliance branch for label review, sample classification, and regulatory consideration.

b) Area of Emphasis No. 4

In order to make authorized health claims or nutrient content claims, products must meet certain nutritional requirements. For example, to make a claim "High", "Rich in", or "Excellent Source of", the product must contain (#) or more of the Daily Value (DV) of the described vitamin, mineral, dietary fiber or potassium per reference amount.

Investigators should refer to charts on nutrient content claims and health claims included as part of the July 29, 1999 "Dietary Supplement Training Course" manual to determine if the amount of the nutrient listed on the nutrition label qualifies the product to make the claim. Analysis may be necessary to verify the level of the nutrient and a physical sample must be collected.

(ii) Collect a compliance sample of any product that appears to be violative under Area of Emphasis No. 4.

(ii) Because of the analytical time required to document a violation in this area, sample imported lots as follows:

After reviewing the entry documents for a shipment, DO NOT issue a May Proceed Notice or Sampling Notice immediately. Leave the entry in OASIS and conduct a field exam to determine whether the product meets the criteria for sampling. If the product appears to be violative under Area of Emphasis No. 4, collect the sample. After returning to the district office, issue the May Proceed Notice. Enter the sample into FACTS as a DI sample. Refer to the OASIS Help Site for additional instructions on collecting these DI samples.

(iii)*The sample will consist of 24 consumer size retail packages, 2 packages from each of 12 randomly selected shipping cases or 10 percent of the number of packages in the same inspection lot (collected in duplicate), whichever is smaller.

(iv) This sample size includes the 702(b) portion. Number the subsamples as 1a, 1b, 2a, 2b, etc., to separate the units for analysis from units that comprise the 702(b) portion. *

(v) Prepare a Collection Report (C/R) for each sample collected and mark as "Official" in the **Sample Type** field.

(vi) Indicate "Compliance" in the **Basis** field of the C/R. Under **Reason for Collection** indicate "For insert Nutrient(s) forming the basis for the claim analysis."

2. Surveillance Samples

- a) Collect for routine nutrient analysis only those vitamin, mineral, and protein supplements or combination vitamin/mineral supplements which have at least one nutrient declared on the label (#) of the Daily Reference Intake (RDI) or Reference Daily Value (DRV).
- b) If inspections do not generate sufficient samples to meet district workplan obligations domestic and domestic-import surveillance samples may be collected at the retail level. Limit sampling to products which have been manufactured within the collecting district so that follow-up compliance sampling with interstate documentation may be conducted, if necessary.
- c) In selecting samples for collection, consider factors which might result in lower nutrient quality, such as age of product (sample oldest lot) and effect of light on some nutrients (sample product in transparent packages when appropriate).
- d) Do not sample products that are expired or are within six months of their expiration dates. This will allow sufficient time for analysis and regulatory consideration should the sample be found violative.
- e) Do not collect dietary supplements of herbals, botanicals, animal extracts, etc. for nutrient analysis **unless** the product also contains a protein, vitamin, or mineral with a label declaration of (#) of the RDI or DRV. Refer to Attachment H for a list of nutrients and their established RDI or DRV levels.
- f) Each sample must represent a single manufacturing lot code. Do not commingle lots within a sample.
- g) Except in cases involving a serious adverse event or an imminent health hazard, do not routinely collect samples in follow-up to consumer complaints without first calling Dr. Lori Love, CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements (202) 205-4198.

E. Sample Size

1. Surveillance Samples: Collect 3 units (each unit must contain a minimum of 12 servings) of the product. For example, 3-2 lb tins; 3-100 tablet bottles; 3-30 capsule packets; 3-12 bar packages. The sample must represent a single lot code. Contact Atlanta Center for Nutrient Analysis (ACNA) at (404) 253-1181 if necessary for additional guidance on sample size.

*

2. Compliance Samples: Collect in duplicate--twelve (12) or 10% of the number of packages available in the same inspection lot whichever is smaller. Do not commingle codes.

*

F. Shipment of Samples for Nutrient Analysis

Ship all samples to:

<http://vm.cfsan.fda.gov/~comm/cp21008.html>

9/21/01

DHHS/PHS/Southeast Regional Laboratory
HFRSE680
Atlanta Center for Nutrient Analysis (ACNA)
60 Eighth Street, N.E.
Atlanta, GA 30309
(404) 253-1181

NOTE: Notify ACNA by phone when compliance samples are collected and provide all shipping information so that arrangements can be made to expedite sample analysis.

Fully explain the reason(s) for collection on the Collection Report (C/R). For compliance samples, this would include a brief description of the inspectional observation(s) which resulted in collection, e.g., improper enrichment procedures, improper storage of raw material. *For samples collected for health claim or nutrient content claim analysis, i.e., Area of Emphasis No 4, indicate the suspect nutrient forming the basis for the health claim or nutrient content claim*. Send a copy of the C/R to ACNA along with the sample.

NOTE: For compliance samples, make certain that the C/Rs are flagged "COMPLIANCE SAMPLE ANALYZE UPON RECEIPT."

Compliance samples should be shipped to ACNA using *overnight delivery service*.

*

G. Documentary Samples for Label Review

All documentary samples collected in support of violations under Areas of Emphasis 1, 2, 3, 5, 6, 7, or 8, should be forwarded to the district's compliance branch for a label review and sample classification. Label reviews must be reported into FACTS and each sample that undergoes a label review must be classified.

*

H. Hardcopy Reporting to CFSAN

The following items will be forwarded, within the timeframes noted, to CFSAN/Dietary Supplement Monitor at the address listed below.

*Within 30 days after completion of each inspection, forward:

- a copy of the complete EIR;
- all labels collected in accordance with instructions in Part III, including product labels that contain ingredients of concern and labels of products containing stimulant laxative ingredients (see Attachment F).
- a completed Attachment G, if applicable; and
- the questionnaire on BSE (Attachment B).

Send the above information to:

Brenda K. Aloï

Food and Drug Administration/CFSAN
Dietary Supplement Monitor (HFS-636)
200 C Street, S.W., Rm. 5113
Washington, D.C. 20204
Phone (202) 205-8168
FAX (202) 205-9670

PART IV ANALYTICAL

Analyzing Laboratory

Atlanta Center for Nutrient Analysis (ACNA), HFRSE680.

A. Analysis

* 1. Label Review

The label of each sample will be reviewed for compliance with 21 CFR 101.9, 101.36 and other applicable labeling requirements.

For the reviewer's convenience, a model review format is provided as Attachment I. Use Attachment I for recording observations only DO NOT submit to the Center.

*

2. Nutrient Analyses

a) Do not perform nutrient analyses on samples containing more than one manufacturing lot code. Notify the collecting district to re-sample if this occurs.

*

b) For compliance samples collected for nutrient analysis in support of an unqualified health claim or nutrient content claim, analyze only for the suspect nutrient. Otherwise:

*

Select for analysis ONLY those nutrients that are declared as being present (#) of the RDI or DRV.

- With the above criteria in mind, select a maximum of four (4) nutrients per product, giving first priority to the following nutrients: Vitamin A/Beta Carotene, Selenium, Folic Acid, Pantothenic Acid, or Vitamin C.
- For any remaining analysis, select those nutrients declared at the highest percentages of the RDI or DRV (#). In the case of "ties", randomly select from among the "ties" nutrients for the last selection.

c) Perform analyses for the selected ingredients as follows:

Compliance Samples--Prepare a composite by taking equal portions from each subsample. Use either the "a" or the "b" subsamples. For tablets, capsules, or caplets take a minimum of 2 units per subsample. For other dosage forms, use equal measured amounts from each subsample. The composite should contain an amount of analyte sufficient to perform several determinations. A separate composite shall be prepared by the check analyst for all check analyses. Retain the remaining sub-samples as the 702(b) portion.

Surveillance Samples--Sample portion for original analysis should be taken from a single subsample. For tablets, capsules, or bars, composite a minimum of 12 servings, e.g. 12 tablets, capsules, bars, etc. provided that the serving size is 1 tablet, capsule, bar, etc.. For liquids or powders, take an appropriately sized (equal to 12 servings) analytical portion from a well-mixed subsample. Another subsample unit will be used for the check analysis if necessary. Additional subsample units will remain intact.

Analyze the composite by methods contained in the AOAC, USP or National Formulary, as applicable and appropriate. Use of methods contained in one of these compendials must take precedence over use of other methods. If AOAC, USP, or National Formulary methods are not available, then use of an appropriate validated method from the scientific literature or from in-house work is appropriate. Agency policy mandates that compendial methods must be considered before non-compendial methods are considered.

d) All methods used whether compendial or non-compendial, must be validated through the use of recovery and reproducibility studies, use of positive and negative controls, use of Standard Reference Material, when available or in-house quality assurance/quality control materials, etc.

Use of in-house quality assurance/quality control samples is suitable for QA/QC purposes only when adequate documentation of the origin, age, handling (storage procedures), composition, frequency of analysis and results of analysis, etc. is readily available.

e) For nutrients labeled as USP, the appropriate USP analytical method shall be used for analysis.

f) Randomly select vitamin or mineral supplements, labeled as meeting USP requirements, for dissolution/disintegration testing using current USP methodology. Priority should be given to calcium supplements then folate/folic acid supplements, and then other appropriate supplements. This testing is not mandatory and the laboratory should use its discretion in determining when and how many samples to select for dissolution/disintegration testing within the constraints of the available resources.

g) Perform a check analysis on any apparently violative sample (Refer to Part V). The check analysis should be performed by a second analyst using an official AOAC method, a USP method where designated, or one approved by the Center.

CAUTION: Do not allow the sample to "age" as many nutrients deteriorate and some minerals precipitate with time. Vitamins A and C break down when improperly handled. Begin original analysis and check analysis (if necessary) as soon after compositing as possible.

h) When requested by the Center to support compliance actions, analyze samples labeled with a dietary fiber content using AOAC, 16th Ed., Ch. 45, Section 45.4.07 (985.29), 32.1.16 (991.42), 32.1.17 (991.43), or 45.4.08 (993.19) whichever is appropriate.

i) Contacts for questions on methodology, levels, significance of findings, are as follows:

Dr. Jeanne Rader CFSAN/ONPLDS/Division of Research and Applied Technology at (202) 205-5375 for all questions except those related to metals/minerals.

Metals/Minerals--William Mindak or Steven Capar CFSAN/OPDFB at (202) 205-4740.

B. Analytical Reporting

ACNA will report all samples classified as violative based on nutrient analyses to the compliance branch of the collecting district for appropriate regulatory follow-up.

Report all analytical results into FACTS using Problem Area Flag "NIF" (Infant Formula). *The use of PAF "NIF" is necessary so that the following additional analytical information, not captured in PAF "NIS" will be entered*:

- a) the complete product name, including brand name, in the product description field;
- b) the use by date; and
- c) the lot or other batch identification number.

PART V REGULATORY/ADMINISTRATIVE FOLLOWUP

Upon notification by ACNA of potentially actionable samples, the following guidance should be used in assessing the significance of the analytical results and in recommending an appropriate regulatory action to CFSAN/DOEP.

*

Note: Warning Letters and seizure recommendations should not include labeling deviations that are not of regulatory significance.

A. Label Violations

District compliance branches must refer to Attachment E for additional guidance and examples of each of the violations listed below. Refer to Attachment J for standard language to be included in Warning Letters.

DOMESTIC PRODUCTS

1. Areas of Emphasis Nos. 1, 6, and 7

a. Districts may issue Warning Letters directly to firms whose product(s):

- fail to bear nutrition labeling and are not exempt; or
- are in solid oral dosage form containing 30 mg or more of iron but are not packaged in unit-dose packaging; or

- contain added iron or iron salts but do not bear a warning statement.
- b. This direct reference authority applies only to products whose labels are violative in one or more of the above areas, but are not violative in any other area of emphasis or in other mandatory labeling information. Regulatory recommendations against product labels that are also found violative in one of the other areas of emphasis noted below must be handled as indicated below.
- c. The Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) must be included on the distribution list for these letters. A copy of these direct reference Warning Letters must be immediately faxed to CFSAN/DOEP/Case Processing Branch at (202) 260-0133.
2. Areas of Emphasis 2, 3, 4, 5, 8
- a. Districts should prepare Warning Letter recommendations against firms whose product(s):
- fail to bear an appropriate statement of identity on the principal display panel, i.e., use of the term "dietary supplement" or some variation of "supplement;" or
 - bear health claims or nutrient content claims that have not been authorized by FDA regulation; or are not authorized based on an authoritative statement as provided in section 403(r)(2)(G) or 403(r)(3)(C) of the FD&C Act; or
 - bear authorized health claims or nutrient content claims but nutrient analyses has determined that the product does not qualify for making the claim; or
 - bear nutrition labeling ("Supplement Facts" panel) with significant format deviations; or
 - fail to bear other mandatory labeling information.
- b. Regulatory recommendations for Areas of Emphasis 2, 3, 4, 5 and 8 must be submitted to CFSAN/DOEP/Case Processing Branch (HFS-607) for review and concurrence prior to issuance. Include three (3) original product labels and, if appropriate, the product container with each recommendations.
- c. Generally, for violations in Area of Emphasis No. 4, the recommendation would be accompanied by supporting analytical results, however, there may be instances where a violation in this area may be supportable based solely on label review without related analytical results. This type of violation would be an exception and would apply to egregious violations.

IMPORTED PRODUCTS

- a. When an import sample is determined to be violative in Areas of Emphasis Nos. 1, 2, 3, 5, 6, 7, or 8, districts should detain the entry. In addition, the district must submit a recommendation for Detention without Physical Examination (Automatic Detention) to ORA/DIOP (HFC-170). Follow the criteria stated in RPM Chapter 9, Item 6 to place a firm/product on Import Alert 54-09 - Products Subject to Automatic Detention for DSHEA Labeling Violations.
- b. An **ORIGINAL** of the label **MUST** be included in the package submitted to the ORA/DIOP for review.

B. Nutrient Analysis

1. Conditions of Regulatory Concern

- The analysis supports the fact that the product does not qualify to make the health claim or nutrient content claim contained on the product label.

*

- Regulations require that for class 1 (added) nutrients such as vitamins, minerals, protein, dietary fiber, or potassium, the nutrient content of the composite must be at least equal to the value for that nutrient declared on the label.

(&)

*

(&)

Regulatory actions will normally not be considered for products with deficiencies of declared nutrients if such nutrients are present in insignificant amounts. For purposes of this program, these nutrients include protein, vitamins, minerals and fiber. In general, we consider less than 25% of the DV per reference amount to be not of regulatory significance.

2. Applicable Charges for Regulatory Actions

* The appropriate charge(s) for the above types of violation would be:

- 403(a)(1) (false and misleading labeling) for products that do not qualify for a health claim or nutrient content claim on the product label; and
- 403(a)(1) (false and misleading labeling) and also 402(b)(1) (adulteration; valuable constituent has been in whole or in part omitted...) for products that contain less than (#) of declared of any class 1 added vitamin, mineral, or protein. These are the charges to be included in all regulatory actions involving nutrient deficiencies recommended under this program.

*

3. Recommendations for Regulatory Follow-up

Follow the guidance below in recommending regulatory follow-up:

a) Compliance Samples

- If the sample was collected exactly as required in 21 CFR 101.36(f)(1) and a seizable size lot is available, recommend a seizure.
- If the sample does not fully comply with the requirements of 21 CFR 101.36(f)(1) or if a seizable size lot is not available, recommend issuance of a Warning Letter.

b) Surveillance Samples

Warning Letter recommendations should be prepared and forwarded for actionable surveillance samples.

Submit recommendations for domestic samples to CFSAN/OFP/Case Processing Branch (HFS-607) for review and clearance prior to issuance. Each recommendation must include a copy of the collection report, an original product label, all analyst worksheets, and other pertinent information, such as documentation of method performance for all "Non-Official" methods utilized.

c) Domestic-Import Samples

For actionable domestic-import samples, submit a recommendation for a new import alert for Detention without Physical Examination (Automatic Detention) to ORA/DIOP (HFC-170). Subsequent shipments of the same product offered for entry into any FDA district port should be handled in accordance with the guidance provided in this new import alert.

Each recommendation must include a copy of the collection report, an original product label (or quality copy), all analyst worksheets, and other pertinent information, such as documentation of method performance for all "Non-Official" methods utilized.

*

C. Product Labels Collected under Part III

The "ingredients of concern" listed in Part III that are subject to collection of the product label or completion of Attachment G are of particular interest to the Center because of possible safety issues. The information from the labels and Attachment G will assist the Center in defining our concerns, however, no regulatory actions are anticipated at this time for these products.

If safety concerns for these ingredients become evident, the Center will provide guidance as appropriate through the issuance of special assignments.

The information on products containing stimulant laxative ingredients will be used to determine whether industry is voluntarily including appropriate label warnings for the use of these products. The Agency has deferred additional rulemaking on this issuance to allow industry to provide this warning voluntarily.

*

D. Regulatory Actions Based on Consumer Complaints

Districts should not submit recommendations for enforcement actions based on follow-up to consumer complaints without first contacting the appropriate branch in CFSAN/DOEP for guidance.

A copy of all consumer complaints involving dietary supplements must be sent to CFSAN, Office of Field Programs, Division of Enforcement and Programs in accordance with Chapter 9 of the Investigations Operations Manual.

With the exception of serious adverse events or imminent health hazard complaints, for which the district would normally be expected to conduct immediate follow-up, the Office of Nutritional Products,

Labeling and Dietary Supplements and the Office of Field Programs will use the information reported in consumer complaints to determine whether follow-up either with the consumer or with the responsible firm is appropriate.

E. Guidance for Products Containing High Risk Bovine Tissue or

Tissue-Derived Ingredients from BSE-Countries

If it is determined that the firm is obtaining and using high risk tissue or tissue-derived ingredients (ingredients marked with asterisks on Attachment A) from BSE-countries, contact CFSAN/DOEP/Case Processing Branch (HFS-607) to discuss the facts involved and the appropriate follow-up.

Updated information on BSE-countries must be obtained from I.A. #17-04.

The absence of adequate procedures to preclude use of bovine tissue from known BSE-countries, is not by itself a sufficient basis for a regulatory recommendation.

Per instructions contained in Import Alert #17-04, shipments of bulk high risk tissues from BSE countries should be detained without physical examination unless or until the importer provides documentation that establishes that the tissue came from BSE-free cattle

PART VI ATTACHMENTS AND CONTACTS

ATTACHMENTS

Attachment A - Bovine Tissue and Bovine-Derived Ingredients

Attachment B - Questionnaire on Bovine Tissue and Bovine-Derived Ingredients

Attachment C - May 9, 1996 Letter to Manufacturers and Importers

Attachment D - Exemptions from Nutrition ("Supplement Facts") Labeling

Attachment E - Guidance and Examples on Areas of Emphasis for Dietary Supplements

Attachment F - Dietary Supplements Containing Stimulant/Laxative Ingredients

Attachment G - Reporting Form for Products Containing Selected Ingredients

Attachment H - Table of Essential Nutrients and their RDI and DRV Levels

Attachment I - Model Nutrition Labeling ("Supplement Facts") Review Format

Attachment J - Standard Language for Warning Letters

CONTACTS

1. Method Inquiries

FDA/CFSAN Food Compliance Program: Food Composition, Standards, Labeling and l... Page 25 of 41

Dr. Jeanne Rader CFSAN/ONPLDS/Division of Research and Applied Technology at (202) 205-5375 for all questions except those related to metals/minerals.

Metals/Minerals--William Mindak or Steven Capar CFSAN/OPDFB at (202) 205-4740.

George Salem, ORA/Division of Field Science, HFC141 at (301) 827-1031.

2. Inspectional Inquiries

Barbara Marcelletti, ORA/Division of Emergency and Investigational Operations, HFC132 at (301) 827-5635.

Domestic-Import and Import Sampling--Fredda Shere-Valenti or Linda Wisniowski ORA/DIOP, HFC-170 at (301) 443-6553.

3. Program Contact

Brenda K. Aloji, CFSAN/OFP/Division of Enforcement and Programs, HFS-636 at (202) 205-8168, Fax (202) 205-9670.

4. Regulatory Contact

Domestic Products - *Sheila Bayne-Lisby* or John Thomas, CFSAN/OFP/DOEP/Case Processing Branch, (202) 205-5235.

Domestic-Import and Import Products - Brian Landesberg, CFSAN/OFP/DOEP/Import Branch, HFS-606, at (202) 205-5247.

*

5. Low Volume/Small Business Exemption Questions

Angela Pope, CFSAN/ONPLDS, HFS-812, (202) 205-4561.

6. Regulatory Policy Questions

Robert J. Moore, CFSAN/ONPLDS, HFS-811, (202) 205-5372.

*

7. BSE Policy Inquiries

Questions concerning BSE policy should be directed to Dr. Elisa Elliot, CFSAN, HFS-615 at (202) 205-4018.

PART VII CENTER RESPONSIBILITY

During the course of this program the Director, Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS), will identify deficiencies that may limit regulatory action. The ONPLDS will review ACNA's analytical results and evaluate the accomplishments under this Compliance Program,

and will prepare an annual written evaluation of this program and submit it to the Director, Division of Enforcement and Programs, HFS-605, by April 1 of the following fiscal year.

BOVINE TISSUE AND TISSUE-DERIVED INGREDIENTS

MATERIALS WITH SUSPECTED RISK OF INFECTIVITY

Adrenal gland**
 Basal ganglia/basal ganglion
 Bone marrow**
 Brain**
 Brain extract**
 Ceramide B-lactoside
 Ceramide dihexoside
 Cerebellum
 Cerebroside (sulfate)
 Cerebrospinal fluid**
 Cranial nerves**
 Collagen (soluble)
 Colon (proximal and distal)**
 Digalactosylceramide
 Diglycosylceramides (cytosides)
 Disialoganglioside
 Dura mater**
 Elastin (source: oxen neck ligaments)
 Eye**
 Galactocerebroside
 Galactosylcerebroside (sulfate ester)
 Ganglioside
 Glucosylcerebroside
 Glycerophospholipid
 Glycosaminoglycan
 Glycosphingolipid
 Glycosylceramide
 Hypothalamus**
 Ileum**
 Intercellular Lipids (ICL's)
 Lactocerebroside
 Lactosylceramide
 Liposomes
 Liver (including liver powder)
 Lung
 Lymph nodes**
 Mammary tissues
 Monoglycosylceramide (cerebroside)
 Monosialoganglioside
 N-Nervonoyl cerebroside
 N-Oleoyl cerebroside
 N-Palmitoyl cerebroside
 Nasal mucosa**
 Olfactory bulb or gland**

"Orchic" extracts
 Ovaries
 Pancreas (including pancreatin)
 Phospholipids
 Pineal gland**
 Pituitary gland**
 Placenta**
 Rowamyelin
 Sciatic nerve
 Sphingosine phosphatide
 Sphingomyelin
 Sphingolipid
 Spinal cord**
 Spleen**
 Suprarenal gland**
 Tetraglycosylceramide
 Thyroid
 Thymus gland (sweet-bread)
 Tonsil**
 Triglycosylceramide
 Trinitrophenylaminolauroylglucocerebroside
 Trinitrophenylaminolauroylgalactocerebroside
 Trisialoganglioside

**Considered high risk for infectivity. If any of these tissues are obtained from known BSE countries, refer to Part III of the compliance program for additional information to be obtained for possible regulatory follow-up.

QUESTIONNAIRE ON BOVINE TISSUE AND TISSUE-DERIVED INGREDIENTS PART A--To be Completed in Each Firm Inspected		
Inspecting District:	Date of Inspection:	
Firm Name and Address	Central File Number:	
Does the firm manufacture or import products containing bovine tissue or tissue-derived materials? Yes ___ No ___		
If the answer is no, do not complete the remainder of questionnaire. Give firm management a copy of the Agency's 5/6/96 letter (Attachment C) for future reference and include the questionnaire along with the EIR to be submitted to CFSAN as instructed below.		
PART B--To be Completed in Firms Using Bovine-Derived Material		
	YES	NO
1. Is the firm aware of the Agency's 5/6/96 letter to dietary supplement firms?		

If the answer is no provide firm management with a copy of the Agency's 5/6/96 letter (Attachment C).		
2. Has the firm put in place procedures to ensure that it does not receive tissues from cattle horn, raised or slaughtered in any of the countries listed below?		
3. Do the procedures include a mechanism to identify all countries where the animals used were born, raised or slaughtered?		
4. Does the firm have a means of identifying the origin of each lot of bovine-derived material and further identifying products made with these materials?		
5. Does the firm have a means of tracing the disposition of imported products which contain bovine-derived material?		
<p>Indicate the origin(s) of the bovine tissue or tissue-derived ingredients used by the firm. Domestic Import</p> <p>If import origin, list below the country(ies) of origin.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Note: Investigators must refer to I.A. #17-04 for an up-to-date list of BSE-countries. If one of the countries listed on I.A. 17-04 is the country of origin, refer to Part III of the compliance program (7321.008) for guidance on documentation for possible regulatory follow-up.</p>		

QUESTIONNAIRE ON BOVINE TISSUE AND TISSUE-DERIVED INGREDIENTS	
PART C--To be Completed in Firms Using Bovine-Derived Material	
<p>List in the space below all products manufactured or imported by the firm that contain a bovine-derived ingredient (see Attachment A). If the bovine-derived ingredient is listed on the finished product, the label may be submitted to CFSAN as instructed below along with Parts A and B of this questionnaire in lieu of completing Part C.</p> <p>To the extent possible, determine the name of any products (including brand name(s)) in which the firm uses any of the bovine-derived material listed on Attachment A of this program. Provide the brand name of the product and the specific bovine-derived material it contains.</p>	
Product Name (Including Any Brand Name(s) Used)	Specific Bovine-Derived Material in Product

Include this questionnaire along with the labels as appropriate and submit along with the completed EIR to: CFSAN/DietarySupplement Monitor, HFS-636, Rm. 5113, 200 C Street, S.W., Washington, D.C. 20204

May 9, 1996

TO MANUFACTURERS AND IMPORTERS OF DIETARY SUPPLEMENTS AND DIETARY SUPPLEMENT INGREDIENTS:

As the media have widely reported, the British government announced on March 20, 1996, that new information had been gathered about bovine spongiform encephalopathy (BSE) in cattle that suggests a possible relationship between BSE and ten cases of a newly identified form of Creutzfeldt-Jakob disease (CJD), a similar fatal transmissible spongiform encephalopathy (TSE) in humans. To serve our mutual interest in protecting public health, the Food and Drug Administration (FDA) believes it is prudent to reiterate concerns we have previously expressed on this issue.

BSE is a transmissible neurologic disorder of cattle and is prevalent in certain parts of the world. This neurological disease is one of a number of transmissible spongiform encephalopathies (TSE) known and is similar to other TSEs such as scrapie in sheep and CJD in humans. BSE has never been diagnosed in cattle in the United States. It is believed that the spread of BSE in cattle in some countries, particularly Great Britain, was caused by the feeding of infected cattle and sheep tissues to cattle. While transmission of the causative agent of BSE to humans has not been definitively documented to date, inter-species transfer has been demonstrated (e.g., mice can be infected by exposure to infected bovine tissues). Recent developments in Great Britain raise serious questions regarding potential hazards of the consumption of animal tissues containing the causative agent of BSE.

Although there is still no definitive evidence that the consumption of bovine tissues that contain the transmissible agent for BSE cause CJD in humans, FDA is concerned that appropriate measures to eliminate the use of bovine tissues from BSE-countries be instituted industry-wide.

We strongly recommend that firms manufacturing or importing dietary supplements which contain specific bovine tissues (see appendix A), including extracts or substances derived from such tissues, take whatever steps are necessary to assure themselves and the public that such ingredients do not come from cattle born, raised, or slaughtered in countries where BSE exists. FDA believes that immediate and concrete steps should be taken by manufacturers to reduce the potential risk of human exposure to the infectious agent which causes BSE in cattle.

The list of countries where BSE is known to exist is maintained by the U.S. Department of Agriculture

(USDA) and codified in Title 9, Code of Federal Regulations, Part 94.18.

The following is the current list:

USDA LIST OF COUNTRIES WHERE BSE EXISTS (Current as of May 1996)

Great Britain (including Northern Ireland and the Falklands)
Switzerland
France
Republic of Ireland
Oman
Portugal

A range of research projects into the exact nature of both the BSE agent and other TSE agents is ongoing. Available scientific information indicates that these agents are extremely resistant to inactivation by normal disinfection or sterilization procedures.

A number of dietary supplement products use bovine-derived tissues or extracts of such tissues as ingredients. These ingredients include, for example, specific tissues and organs or their extracts (e.g., liver powder, "orchic" extracts, ovaries, eye tissue, mammary tissue), glandular powders or extracts (e.g., adrenal gland, thyroid gland), or specific substances extracted from glands or tissues (e.g., melatonin extracted from the pineal gland).

At a future date, we will contact you with guidance on how best to provide assurance that your products do not contain potentially BSE-infected materials.

We appreciate your attention to and cooperation in this matter. If you need more information, please contact Dr. Elisa Elliot by telephone at (202) 205-5140.

Sincerely yours,

/s/

Michael A. Friedman, M.D.

Deputy Commissioner for Operations

Enclosure

Appendix A

List of Tissues with Suspected Infectivity¹

Category I (High infectivity)

- brain
- spinal cord

Category II (Medium infectivity)

- ileum
- lymph nodes
- proximal colon
- spleen
- tonsil
- dura mater
- pineal gland
- placenta
- cerebrospinal fluid
- pituitary gland
- adrenal gland

Category III (Low infectivity)

- distal colon
- nasal mucosa
- sciatic nerve
- bone marrow
- liver
- lung
- thymus gland

List taken from Report of a WHO Consultation on Public Health Issues Related to Animal and Human Spongiform Encephalopathies, World Health Organization, Office of International Epizootics, Geneva, Switzerland, November 12-14, 1991.

¹The absence of a specific tissue, organ, or gland from this list does not mean that such tissue, organ, or gland cannot contain the infectious agent responsible for BSE. It only means that there was not adequate information available at the time to assign the tissue, organ, or gland to a specific category.

EXEMPTIONS FROM NUTRITION ("SUPPLEMENT FACTS") LABELING

A dietary supplement is not required to have a "Supplement Facts" panel if it is:

- Offered for sale by a small business that has not more than \$50,000 gross sales per year from food sales or no more than \$500,000 from total sales in accordance with section 101.36(h)(1);
- A low-volume product (i.e., less than 100,000 units sold annually) sold by a firm with less than 100 full-time equivalent employees in accordance with section 101.36(h)(2); or

c. Shipped in bulk form, not distributed to consumers in such form, and used in the manufacture of other dietary supplements in accordance with section 101.36(h)(3).

NOTE: The exemptions for small businesses and low-volume products are available only to products whose labels bear no claims or other nutrition information.

GUIDANCE AND EXAMPLES ON THE AREAS OF EMPHASIS FOR DIETARY SUPPLEMENTS

1. Products that fail to bear nutrition labeling, i.e., the absence of a "Supplement Facts" panel on the label, and are not covered by an exemption.

Exempt products include those meeting the small business provisions; or bulk dietary supplements for further manufacturing.

NOTE: A nutrient declaration, nutrient content claim or health claim on a dietary supplement label generally negates the small business exempt status of the product and triggers the requirement for nutrition labeling.

2. Products that fail to bear an appropriate statement of identity on the principal display panel, i.e., use of the term "dietary supplement" or some variation of "___ supplement."

a. Appropriate Statements of Identity

- Vitamin C Supplement
- Multivitamin Supplement
- Herbal Supplement with Vitamins

b. Inappropriate Statements of Identity

- Food Supplement
- Energy Bar

3. Products that bear health claims or nutrient content claims that have not been authorized by FDA regulation, or are not authorized on the basis of an authoritative statement as provided in section 403(r)(2)(G) or section 403(r)(3)(C) of the FD&C Act.

a. Unauthorized Nutrient Content Claims

- Contains Omega-3 Fatty Acids
- High in Complex Carbohydrates

b. Unauthorized Health Claims

- Omega-3 Fatty Acids and Coronary Heart Disease

4. Products that bear authorized health claims or nutrient content claims that do not qualify for making the claims.

a. Examples of Products Not Qualifying for Content Claims

(Refer to the chart provided in the 7/29/99 training manual "Dietary Supplement Training Course" for additional examples.)

- "High Potency" used to describe individual vitamins or minerals containing (#) of the RDI per reference amount.
- "Rich in _____" used to describe a protein, vitamin, mineral, dietary fiber or potassium when present at (#) of the DV.

a. Examples of Products Not Qualifying for Health Claims

(Refer to the chart provided in the 7/29/99 training manual "Dietary Supplement Training Course" for additional examples.)

- Claim for Calcium and Osteoporosis--the product must contain (#) of the Daily Value for calcium.

5. Products that bear nutrition labeling "Supplement Facts" with significant format deviations.

- Products that bear nutrition labeling in the old pre-DSHEA format (e.g., "Nutrition Facts" panel).
- Failure to declare a required nutrient if present at a level above zero.
- Failure to bear the heading "Supplement Facts."
- Failure to enclose the "Supplement Facts" panel in a box.

6. Products in solid oral dosage form containing 30 mg or more of iron that fail to be packaged in unit-dose packaging.

a. Applies to products with any intentionally added iron source including:

- reduced iron
- iron salts
- iron (such as ferrous sulfate)
- sources of elemental iron such as carbonyl iron or PIC-iron

b. Does not apply to products:

- that might contain naturally occurring incidental iron (e.g., certain high-iron botanicals or liver powders)
- in liquid form or sold as loose powders

7. Products with added iron that fail to bear the following warning statement:

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor

or poison control center immediately.

- Applies to products containing iron or iron salts
- Does not apply to products with incidental iron contributed as a

of an ingredient (e.g., small amounts of declared iron contained in botanicals)

8. Products that fail to bear other mandatory label information.

- Statement of identity
- Statement of net quantity of contents
- Statement of name and place of business of manufacturer, packer, or distributor
- Ingredient statement

NOTE: Under section 403 (r) (6) of the act, a dietary supplement may bear certain claims, generally called structure/function claims, on its label or in its labeling provided that the firm has substantiation that the claim is truthful and not misleading, the firm has notified FDA within 30 days of marketing the product bearing the claim, and the claim includes a mandatory disclaimer.

Enforcement actions are not contemplated at this time against products bearing structure/function claims that do not also include the required disclaimer.

Enforcement actions also are not contemplated against products that bear structure/function claims for which manufacturers have not submitted the required 30-day notifications. The reasons for this enforcement policy are explained in detail in the preamble to the final rule (Part IV. Implementation Plan) published in the Federal Register on January 6, 2000 (65 FR Page 1044). If a structure/function claim is an unauthorized health claim under either FDA regulations or 403 (r) (3) (C), then it would fall under Area of Emphasis No 3 above.

The Agency will consider, on a case-by-case basis, enforcement actions against products that bear egregious disease claims or that may be unsubstantiated and false and misleading. Investigators should review claims made for dietary supplements in labels and labeling. Products that bear inappropriate disease claims or that appear to bear egregiously false or misleading claims should be referred to the Center for evaluation.

The preamble to the final rule provides important background and rationale for the agency's policies related to the structure/function and disease claims issue. In addition to the preamble discussion, the Agency intends to issue a guidance document to provide additional information regarding structure/function and disease claims. The guidance document would complement, rather than substitute for, the final rule.

(&)

DIETARY SUPPLEMENTS CONTAINING STIMULANT LAXATIVE INGREDIENTS

1. Background: The Center has concerns about dietary supplements containing stimulant laxative ingredients. These concerns stem from reports of serious adverse events associated with chronic, long-term use of such products. Following consideration of the safety of stimulant laxative ingredients by FDA's Food Advisory Committee, and meetings with members of the industry, the Agency deferred consideration of rulemaking to require warning statements on these products if industry would voluntarily use the warning notice required by the State of California on labels nationwide. The State of California warning statement became effective March 1, 1998.

2. Task: Review the firm's product inventory to determine whether products containing a stimulant laxative ingredient (See list below) bear a warning statement that is identical to or similar to the State of California warning statement:

Notice: This product contains (name of substance(s) and common name(s) if different). Read and follow directions carefully. **Do not use if you have or develop diarrhea, loose stools, or abdominal pain because (insert common name) may worsen these conditions and be harmful to your health.** ^Note: the California regulation provides that packages with less than 12 square inches available for labeling may use a package insert or tag to convey the warning statement|

The Center would like the following information reported: (i) identity of products containing a stimulant laxative ingredient; (ii) identity of the stimulant laxative ingredient(s) (including common name and Latin binomial name used on the label); (iii) identity of products that bear the disclaimer, including the exact wording of the disclaimer.

Labels or copies of labels may be provided in lieu of the information requested above. At this time, no regulatory/enforcement actions are planned or anticipated for products containing these ingredients.

<u>Common Name</u>	<u>Latin Binomial Name</u>
aloe (also known as cape aloe)	<i>Aloe ferox</i> Mill.
aloe (also known as aloe vera)	<i>Aloe vera</i> L., or <i>Aloe barbadensis</i> Mill. or <i>Aloe vulgaris</i> Lamk.
buckthorn	<i>Rhamnus catharticus</i> L.
casacara (also known as casacara sagrada, bearberry, bearwood, physic bit, healthwort, shittim-wood, casacara sagrada,	<i>Rhamnus purshiana</i> DC

chittem,
chittiana
bark,
chittem
bark,
Persian
bark,
Wahoo)

frangula *Rhamnus frangula* L. or *Frangula alnus* Mill.
 (also
 known as
 buckthorn)

rhubarb *Rheum officinale* Baill. or *Rheum palmatum* L. or *Rheum*
 root (also *rhaponticum* L. or *Rheum tanguticum* Maxim. ex Balf.
 known As
 Chinese
 rhubarb

senna *Cassia angustifolia* L., *Cassia acutifolia* Delile, *Cassia senna* L.,
Senna alexandrina Mill. (Alexandria senna, Tripoli senna, Ger.
 Alexandrinische senna, Palt senna, Indian senna, tennevelley senna,
 Mecca or Arabia senna)

senna (also *Senna obtusifolia* L.
 known as
 sicklepod
 senna)

senna *Senna tora* L.

NOTE: For purposes of collecting the labels, any product that represents: a different product form (tablet, capsule, extract); strength (500 mg, 400 mg); formulation (different ingredients or different levels of ingredients); or a different brand name for the product constitutes a different product. For firms that are packaging the same product under multiple brand names, you may select a representative label and provide a separate attached list of the different brand names under which the product is sold.

REPORTING FORM FOR PRODUCTS CONTAINING SELECTED INGREDIENTS NOTE: USE ADDITIONAL COPIES AS NECESSARY, COMPLETE CFN ON CONTINUATION SHEETS.			
DISTRICT:	CFN:	FIRM NAME:	
PRODUCT BRAND NAME:		FORM:	DOSAGE:
LIST ALL INGREDIENTS PRESENT IN THE ABOVE PRODUCT, INCLUDING THE ONES LISTED IN PART III SECTION A.3.			

INGREDIENT	LEVEL	INGREDIENT	LEVEL	INGREDIENT	LEVEL
a.		f.		k.	
b.		g.		l.	
c.		h.		k.	
d.		i.		m.	
e.		j.		n.	
PRODUCT NAME:		FORM:		DOSAGE:	
LIST ALL INGREDIENTS PRESENT IN THE ABOVE PRODUCT, INCLUDING THE ONES LISTED IN PART III SECTION A.3.					
a.		f.		k.	
b.		g.		l.	
c.		h.		k.	
d.		i.		m.	
e.		j.		n.	
Complete the above information for any product containing one or more of the ingredients of concern listed in Part III, Section A.3 of this compliance program when information on ingredients and levels is not listed on the product label.					

**TABLE OF ESSENTIAL NUTRIENTS AND THEIR
ESTABLISHED
REFERENCE DAILY INTAKE OR DAILY
REFERENCE VALUE LEVELS**

<u>Nutrient</u>	<u>RDI or DRV</u>
Protein	50 grams
Fiber	25 grams
Vitamin A	5,000 international units
Vitamin C	60 milligrams
Calcium	1 gram
Iron	18 milligrams
Vitamin D	400 international units
Vitamin E	30 international units
Vitamin K	80 micrograms
Thiamin	1.5 milligrams
Riboflavin	1.7 milligrams
Niacin	20 milligrams
Vitamin B6	2.0 milligrams
Folate	400 micrograms
Vitamin B12	6.0 micrograms
Biotin	300 micrograms

Pantothenic acid	10 milligrams
Phosphorus	1000 milligrams
Magnesium	400 milligrams
Zinc	15 milligrams
Iodine	150 micrograms
Copper	2.0 milligrams
Potassium	3,500 milligrams
Chromium	120 micrograms
Molybdenum	75 micrograms
Chloride	3,400 milligrams

RDI and DRV for Adults and Children over 4 Years of Age

Model Nutrition Labeling ("Supplement Facts") Review Format

Food _____ Sample # _____

Mark with:

- + = Information present and correct on label
- = Information present and incorrect on label
- O = Information missing from label

Label Format

1. Type size _____
2. Upper & lower case letters _____
3. Bars and hairlines present _____
4. Good color contrast _____
5. Bolding on primary nutrients and % DVs _____
6. Headings: Nutrition Facts, Amt/Serving, % DV _____
7. Footnotes _____
8. Simplified or shortened format (qualifies? correct?) _____
9. Serving size _____

10. Servings/container _____

Label Content

1. Calories _____

2. Calories from fat _____

3. Total fat (g & % DV) _____

4. Saturated fat (g & % DV) _____

5. Cholesterol (mg & % DV) _____

6. Sodium (mg & % DV) _____

7. Total carbohydrate (g & % DV) _____

8. Dietary fiber (g & % DV) _____

9. Sugars (g) _____

10. Protein (g) _____

11. Vitamin A (% DV) _____

12. Vitamin C (% DV) _____

13. Calcium (% DV) _____

14. Iron (% DV) _____

15. Voluntary additional nutrients _____

16. Order of listed nutrients _____

Use this form for recording observations only, do not submit to

STANDARD LANGUAGE FOR WARNING LETTERS

IN AREAS OF EMPHASIS 1, 2, 3, 6 AND 7

Follow the format in Chapter 4, page 89 of the August 1997 Regulatory Procedures Manual. Incorporate one or more of the following paragraphs as appropriate:

- The product is misbranded within the meaning of section 403(q)(5)(F) of the act in that the label

fails to bear nutrition labeling ("Supplement Facts" panel), which is required under 21 CFR 101.36, and is not exempt from this requirement.

- The product is misbranded within the meaning of section 403(r)(1)(A)/(B) of the act in that the label bears the nutrient content claim/health claim "___," which has not been authorized by FDA regulation or on the basis of an authoritative statement under section 403(r)(2)(G) or 403(r)(3)(C) of the Act.
- The product is misbranded within the meaning of sections 403(i)(1) and 403(s)(2)(B) of the act in that the label fails to identify the product using the term dietary supplement (21 CFR 101.3(g)).
- The product is adulterated within the meaning of sections 402(a)(4) and 402(g) of the act in that it is in solid oral dosage form containing 30 mg or more of iron, but fails to be packaged in unit-dose packaging (21 CFR 111.50).
- The product is misbranded within the meaning of sections 403(a)(1) and 201(n) of the act in that the label, labeling, or display of the product with added iron, fails to bear the required warning statement (21 CFR 101.17(e)).

Incorporate the following paragraph in each Warning Letter:

The above violations concern certain new labeling requirements, and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the dietary supplement to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes and regulations enforced by FDA.

NOTE: Under section 403(r)(6) of the act, a dietary supplement may bear certain claims, generally called "structure/function claims," on its label or in its labeling provided that the firm has substantiation that the claim is truthful and not misleading; the firm has notified FDA within 30 days of marketing the product bearing the claim; and the claim includes a mandatory disclaimer.

Enforcement actions are not contemplated at this time against products bearing structure/function claims that do not also include the required disclaimer.

Enforcement actions also are not contemplated against products that bear structure/function claims for which manufacturers have not submitted the required 30-day notifications. The reasons for this enforcement policy are explained in detail in the preamble to the final rule (Part IV. Implementation Plan) published in the Federal Register on January 6, 2000 (65 FR Page 1044). If a structure/function claim is an unauthorized health claim under either FDA regulations or 403 (r) (3) (C), then it would fall under Area of Emphasis No 3 above.

The Agency will consider, on a case-by-case basis, enforcement actions against products that bear egregious disease claims or that may be unsubstantiated and false and misleading. Investigators should review claims made for dietary supplements in labels and labeling. Products that bear inappropriate disease claims or that appear to bear egregiously false or misleading claims should be referred to the Center for evaluation.

The preamble to the final rule provides important background and rationale for the agency's policies related to the structure/function and disease claims issue. In addition to the preamble discussion, the Agency intends to issue a guidance document to provide additional information regarding

structure/function and disease claims. The guidance document would complement, rather than substitute for, the final rule.

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Hypertext updated by rog 2000-MAY-01



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Human Growth Hormone in aging
 Dr. Karl Folkers
Co-enzyme Q-10
 Dr. Denham Harman
Free radical theory of aging
 Richard Cutler, Ph.D.
Role of antioxidants in aging
 Dr. Peter Safar
Cardiopulmonary Resuscitation
 Senator John Glenn
Space and aging research
 Dr. Judah Folkman
Angiogenesis inhibitors for control of cancer
 Representative Dan L. Burton
(US House of Representatives)
 Advocacy of personal healthcare freedom

Dear Sirs:

As President of the American Academy of Anti-Aging Medicine, a non-profit medical society of over 10,000 physicians and scientists from 65 countries worldwide, I was disappointed with both the tone and structure of the September 10th hearing titled "Swindlers, Hucksters and Snake Oil Salesmen, the Hype and Hope of Marketing Anti-Aging Products to Seniors" held before the Senate Select Committee on Aging. Indeed, despite its title, the emphasis of the hearing was not on the topic of Anti-Aging Medicine, but rather a thinly disguised assault on the Dietary Supplement Health and Education Act.

I was dismayed by the fact that you chose to focus on Glen Braswell as an example of marketers of anti-aging products. Mr. Braswell's notoriety arising from his recent pardon and the widespread publicity concerning his legal problems clearly make him an exception among supplement marketers. More important, he is not a medical practitioner, and therefore his actions have nothing to do with the scientific discipline of Anti-Aging Medicine. Linking him to the serious practice of Anti-Aging Medicine is tantamount to linking a disreputable used car dealership to General Motors or Ford.

Equally disturbing was the fact that every individual that testified was hostile to the very notion of alternative and complementary medicine. For example, you presented Dr. Robert Baratz as an "expert" on alternative medicine. He is no such thing. Dr. Baratz works for an organization that has a long history of attacking complementary and alternative medicine. Therefore, he is a critic of the field, not an expert on it.

It was also interesting to note that there was not one single legitimate representative of either the supplement industry or of Anti-Aging Medicine on your panels. Rather, all that was presented was a succession of individuals who could be expected to be critical of anything that was even remotely outside conventional medical practice. It is also interesting to note that every individual who testified included in their remarks a criticism of DSHEA. This could hardly be an accident. It appears the deck was stacked to assure a predictable outcome. Indeed. Even the selection of a title for the proceeding smacks of bias.

What is perhaps most disappointing, however is the lost opportunity. You could have provided a forum that helped explained the basis of the emerging discipline of Anti-Aging Medicine: preventative health care. In short what Anti-Aging Medicine does is promote the use of a wide range of conventional and complementary medical modalities to help prevent the degenerative diseases of aging. Most of the techniques that we recommend would be endorsed by virtually all conventional physicians. These include such things as eating the proper diet, making sure to get exercise, use of the latest advances in technology for the very early diagnosis of disease and, yes, using some types of dietary supplements. Granted, our model for health care differs significantly from the conventional model that holds you should wait until someone gets sick and then treat the disease. However, it seems to the practitioners of Anti-Aging Medicine to try to keep the patient from getting sick in the first place. Is this such a radical or unreasonable assumption?

At a time in which our population is growing older, the cost of treating diseases traditionally associated with old age will pose an unbearable financial burden on society -- unless we find ways to prevent them. That is what Anti-Aging Medicine is about -- not as your hearing implied, duping senior citizens via the sale of questionable products.

It was particularly painful for my organization to see the tone and structure of your hearings, because our fundamental purpose is to help identify those medical modalities for preventing the diseases of old age which have a sound scientific basis and help educate America's doctors about them. Indeed, I should note that I spent over six hours in interviews with the Government Accounting Office helping them prepare the report that was released in conjunction with this hearing. In attempting to discredit the very concept of Anti-Aging Medicine, your hearing did a disservice to the medical profession and the nation.

I would point out the following facts:

- FACT: No lawsuits for wrongful death have been confirmed, determined, directly proven, or associated with a physician for practicing anti-aging medicine.**
- FACT: State licensing boards perceive innovative physicians -- such as those practicing anti-aging medicine, as ripe targets for administrative actions, to-date being unsuccessful in proving any actual medical practices violations.**
- FACT: Hormone replacement therapy, performed judiciously and administered in physiological doses by a qualified anti-aging physicians, is well researched and scientifically documented to improve health and has not been directly confirmed to cause any unhealthy adverse effects, such as cancer.**
- FACT: Anti-aging medicine is a multi-disciplinary model for wellness-based healthcare, uniting physicians and scientists across specialties in a spirit of cooperative research and application to promote a scientifically-validated whole-body approach to individual medical care.**
- FACT: Anti-aging medical therapeutics and interventions are taught as part of postgraduate medical education at many medical universities around the world.**
- FACT: Anti-aging medical education qualifies as Continuing Medical Education (CME) by the American Medical Association (AMA), the American Osteopathic Association (AOA), Chicago Medical Society, and overseas medical societies including the German Endocrinological Society.**

I call upon you to convene another hearing at which a more balanced point of view can be expressed. You and your colleagues were elected to represent all the people, not just representatives of government bureaucracies and self-appointed public guardians. If an Americans cannot get a fair hearing before a body of their own Congress, where can they be heard?

Sincerely,


Dr. Ronald Klutz
President

attachments: A4M History and Overview
Bio, Dr, Ronald Klutz



AMERICAN ACADEMY OF ANTI-AGING MEDICINE

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HISTORY AND OVERVIEW

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 Dr. Daniel Ruitman
Human Growth Hormone in aging
 Dr. Kari Folkers
Co-enzyme Q-10
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Anti-aging medicine is a medical specialty founded on the application of advanced scientific and medical technologies for the early detection, prevention, treatment, and reversal of age-related diseases. It is a healthcare model promoting innovative science and research to prolong the healthy lifespan in humans. As such, anti-aging medicine is based on principles of sound and responsible medical care that are consistent with those applied in other preventive health specialties.

Mission:

The American Academy of Anti-Aging Medicine ("A4M") is a not-for-profit medical society dedicated to the advancement of technology to detect, prevent, and treat aging related disease and to promote research into methods to retard and optimize the human aging process. A4M is also dedicated to educating physicians, scientists, and members of the public on anti-aging issues. A4M believes that the disabilities associated with normal aging are caused by physiological dysfunction which in many cases are amenable to medical treatment, such that the human life span can be increased, and the quality of one's life improved as one grows chronologically older. A4M seeks to disseminate information concerning innovative science and research as well as treatment modalities designed to prolong the human life span. Anti-aging medicine is based on the scientific principles of responsible medical care consistent with those of other healthcare specialties. Although A4M seeks to disseminate information on many types of medical treatments, it does not promote or endorse any specific treatment nor does it sell or endorse any commercial product.

Membership:

- Incorporated in 1993
- Membership of 10,000:
 - 80% physician members (M.D. or D.O.)
 - 12% scientist, researcher, health practitioner, and media members
 - 8% general public members
- 60 nations represented

Objectives:

- Make available life-extending information about the multiple benefits of anti-aging therapeutics to practicing physicians.
- Assist in developing therapeutic protocols and innovative diagnostic tools to aid physicians in the implementation of effective longevity treatment.
- Act as an information center for valid and effective anti-aging medical protocols.
- Assist in obtaining and disseminating funding for scientifically sound and innovative research in anti-aging medicine.
- Assist in the funding and promotion of critical anti-aging, clinically based research.
- Government outreach, education, and advocacy for anti-aging medicine.

Important and Notable Achievements by A4M -- Highlights:

- Since 1993, conducted seventeen world-class **international educational conferences** on Anti-Aging Medicine and biomedical technology (two in Spain, one in Singapore, two in Mexico, twelve in the United States).
- Provided **University-sponsored, AMA and AOA-recognized continuing education** for thousands of physicians and surgeons.
- Conducted **educational meetings on Capitol Hill** for the purpose of informing key legislators about the necessity of funding anti-aging research into clinical anti-aging therapies.
- Published the **first five medical textbooks** in the field of Anti-Aging Medicine.
- **Sponsors The World Health Network**, the Internet's leading anti-aging portal, at www.worldhealth.net, receiving more than 1.8 million hits monthly
- Sponsored production of an **educational cable television feature**, "Anti-Aging Update," aired weekly on The Family Channel, Primestar, DirectTV, Fox TV, and Health Cable seen in millions of homes throughout the US.
- **Generated hundreds of magazine, newspaper, television and radio appearances or stories to raise the profile of anti-aging medicine** as reputable, fact-based science. Such placements include *Lifetime*, *48 Hours*, *20/20*, *CBS Evening News*, *Oprah Winfrey Show*, *CQ Researcher*, *New York Times*, *Los Angeles Times*, *Chicago Tribune*, *CNN*, *USA Today*, *Forbes*, *The Futurist (World Future Society)*, *Harper's Bazaar*, *AM News (American Medical Association)*, *MacLean's [Canada]*, *Investor's Business Daily*, *Smart Money*, *Crajin's Chicago Business*, and *Art Bell Coast-to-Coast AM*.
- **Publications for clinicians, researchers, government agencies, and academic institutions:**
 - *Report of the Medical Committee on Aging Research and Education*
 - *Anti-Aging Medical News*
 - *Anti-Aging Physician Directory and Resource Guide*
 - *Anti-Aging Medical Therapeutics*
 - *The Science of Anti-Aging Medicine*
 - *White paper reports*
- **Publications for consumer audience:**
 - *New Anti-Aging Secrets for Maximum Lifespan (2000)*
 - *Ten Weeks to a Younger You (1999)*
 - *Brain Fitness (Doubleday, 1999)*
 - *Hormones of Youth (1998)*
 - *Grow Young with HGH (HarperCollins, 1998)*
 - *Stopping the Clock (1996)*
 - *Seven Anti-Aging Secrets (1996)*
- Over **one million pieces of educational material distributed annually** to physicians, scientists, educational institutions, the media and members of US and international government agencies.
- Scholarships for medical students and faculty to attend A4M educational conferences for physicians
- Furnishing medical schools and libraries with anti-aging textbooks

Dr. Ronald M. Klatz

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Dr. Ronald Klatz is recognized as a leading authority in the new clinical science of Anti-Aging Medicine. The founder and President of the American Academy of Anti-Aging Medicine, a not-for-profit public foundation, he has pioneered the exploration of new therapies for the treatment and prevention of age-related degenerative diseases. As President of the Academy, a scientific medical society which is exploring advances in biotechnology and preventive health-care, Dr. Klatz oversees educational programs for more than 10,000 physicians and scientists from 60 countries.

Further, his accomplishments include co-founding the National Academy of Sports Medicine, an internationally recognized educational institution, and serving as a Director of Life Science Holdings (LSH), a biomedical company which has been dedicated to the research and development of organ transplant and other advanced medical technologies.

Dr. Klatz is the inventor, developer, or administrator of 100-plus scientific patents. In 1993, he was awarded the Gold Medal in Science for Brain Resuscitation Technology, and in 1994 was honored with the Grand Prize in Medicine for Brain Cooling Technology.

A bestselling author and editor, Dr. Klatz served as Senior Medical Editor of Longevity magazine, a contributing editor to the Archives of Gerontology and Geriatrics, and was a syndicated columnist with Pioneer Press, a division of Time-Life Inc. He is the author of *Ten Weeks to a Younger You*, *Brain Fitness*, *Hormones of Youth*, *Grow Young with HGH*, *Seven Anti-Aging Secrets*, *Advances in Anti-Aging*, *Stopping the Clock*, *Death in the Locker Room/Drugs & Sports*, *The E Factor*, *The Life Extension Weight Loss Program*, and *Deprenyl - The Anti Aging Drug*.

Dr. Klatz has been a co-host of the national Fox Network television series *Anti-Aging Update*. A popular lecturer and television guest, he is a regular presenter at scientific conferences and has appeared on dozens of national and international television and radio broadcasts.

Dr. Klatz is a graduate of Florida Technological University, the College of Osteopathic Medicine and Surgery (Des Moines, Iowa), and The University of Central America Health Sciences School of Medicine. He is Board Certified in both Family Practice and Sports Medicine. Dr. Klatz maintains an academic research post at Oklahoma State University as clinical assistant professor in the Department of Medicine, and serves as Professor at Central America Health Sciences University. A consultant to the biotechnology industry, and a respected advisor to several members of the U.S. Congress and others on Capitol Hill, Dr. Klatz devotes much of his time to research and to the development of advanced biosciences for the benefit of humanity.

Accomplishments**2000**

New Anti-Aging Secrets for Maximum Lifespan
 Author

1999

Ten Weeks to a Younger You
 Author
Brain Fitness (Doubleday)
 Co-Author

1998

Hormones of Youth
 Author
Grow Young with HGH (Harper Collins)
 Author

1996

Stopping the Clock - Therapies for Anti-Aging
 Author
Seven Anti-Aging Secrets
 Author
Advances in Anti-Aging Medicine - Textbook and Clinical Treatments
 Author

1995

Issued U.S. Patent for Brain Resuscitation and Organ Preservation Device & Method
 Received INPEX Humanitarian Award
 Resuscitation Research Technologies

1994

Life Resuscitation Technologies, Inc.
 Director, New Product Development
 Awarded INPEX Grand Prize in Medicine for Brain Cooling technology

1993

Issued U.S. Patent for Brain Cooling Device and Method
 Issued U.S. Patent for Brain Resuscitation Device
 American Academy of Anti-Aging Medicine
 Elected President
 Awarded INPEX Gold Medal in Science for Brain Resuscitation Technology
 Deprenyl - The Anti-Aging Drug
 Co-Author

1992

Longevity Magazine
 Appointed Senior Medical Editor
Healthcare USA, News Magazine
 Senior Editor - Science and Technology
 Issued U.S. Patent for Brain Resuscitation Method
Death in the Locker Room II/ Drugs & Sports
 Co-Author
The "E" Factor
 Co-Author
 National Academy of Sports Medicine
 Founder