

Anti-Aging Medicine: The Legal Issues

Anti-Aging Quackery: Human Growth Hormone and Tricks of the Trade—More Dangerous Than Ever

Thomas T. Perls

Geriatrics Section, and The New England Centenarian Study, Department of Medicine,
Boston Medical Center, and Boston University School of Medicine, Massachusetts.

To assess the presence of quackery in the anti-aging industry, the Internet was surveyed for web sites marketing anti-aging products as well as those providing consumer advice regarding quackery and hucksterism. The United States Federal Food, Drug, and Cosmetic Act and its amendments were reviewed, particularly as they pertain to dietary supplements and human growth hormone. Anti-aging quackery and hucksterism are pervasive on the Internet and in clinics advertising anti-aging treatments. Review of the marketing techniques of the industry revealed 15 common ruses used by many in the industry to market their products. Federal law states that distributing or administering human growth hormone for anti-aging or age-related problems is illegal. Nonetheless, anti-aging clinics thrive, administering human growth hormone to thousands of gullible and oftentimes vulnerable patients. Anti-aging quackery has become a multimillion dollar industry exacting great monetary, health, and social costs. Consumers and health care providers alike are wise to educate themselves on how to recognize quackery. Congress must reassess the wisdom of the 1994 Dietary Supplements Health and Education Act, which facilitates and, in numerous cases, endangers Americans on a grand scale. In the case of some substances such as human growth hormone, adequate legal safeguards are impotent without adequate resources allocated to enforcement agencies.

RECENTLY, the *New England Journal of Medicine* decried the frequent citation by proprietors of the anti-aging industry of a 1990 article by Rudman and colleagues as proof that human growth hormone (hGH) is effective for curtailing aging and purported age-related problems (1–3). Citing a study out of context and misconstruing its results to sell a product is just 1 of 15 or so key strategies of quackery.

Dorland's Illustrated Medical Dictionary defines a quack as “one who fraudulently misrepresents his ability and experience in the diagnosis and treatment of disease, or the effects to be achieved by the treatment he offers” (4). In the report, “Quackery: A \$10 Billion Scandal,” produced by the United States House of Representatives Select Committee on Aging’s Subcommittee on Health and Long-Term Care, a quack is defined as “... anyone who promotes medical schemes or remedies known to be false, or that are unproven, for a profit” (5). Quackery is practically a millennium-old phenomenon. In the past 10 to 15 years though, new life has been breathed into this niche because of the convergence of the 1994 Dietary Supplements Health and Education Act (DSHEA), the aging of the 72-million-strong baby boom generation (born 1946–1964) and advertising of and accessibility to products and schemes via the Internet.

FEW FEDERAL SAFEGUARDS REGARDING NUTRITIONAL SUPPLEMENTS

With the 1994 U.S. congressional passage of the DSHEA, the quackery and hucksterism of the anti-aging industry and other pseudoscience industries has skyrocketed in growth (6,7). DSHEA provides a legal framework for a broad universe of substances to be marketed as dietary supplements that obviously lends itself to abuse. Dietary supplements as defined by the DSHEA are not only vitamins and minerals, but also include herbs or other botanicals, amino acids, “dietary substances for use by man to supplement the diet by increasing the total dietary intake,” or a concentrate, metabolite, extract, or combination of any of the preceding ingredients. The law is neither clear nor specific about the universe of substances that were intended to be included in each of these categories. This imprecision has led to numerous claims by entrepreneurs that certain substances are not drugs but rather food supplements; for example dihydroepiandrosterone (DHEA), once banned by the Food and Drug Administration (FDA), can now be marketed as a dietary supplement.

DSHEA also does not generally require premarket review or approval of dietary supplements. Therefore, products can be offered to the public without FDA approval, and the FDA can only take action after the fact against products that may

LOOK AT THESE AMAZING TEST RESULTS!	
Results from a study: [Effects of Growth Hormone administration on 202 patients ages 39-74]	
L. Casserry M.D., Ph.D. and Edmund Chein, M.D., Medical College of Wisconsin and Palm Springs Life Extension Institute.	
Body Fat Loss	82% improvement
Wrinkle Reduction	61% improvement
Energy Level	84% improvement
Muscle Strength	88% improvement
Sexual Potency	75% improvement
Emotional Stability	67% improvement
Memory	62% improvement

Figure 1. Example of citing results from a study without providing the journal citation (<http://www.77yy4.com/we/Research.php> for example).

be unsafe or that are promoted using bogus claims. Under DSHEA, manufacturers do not have to provide to the FDA any reports they receive of adverse events. For example, Metabolife International only reported to the FDA after congressional pressure and Justice Department investigations the 14,684 adverse events including 5 deaths, 18 heart attacks, 26 strokes, and 43 seizures related to its ephedra-containing product. Such pressure to disclose would never be necessary in the case of drugs. Labeling guidelines for products governed by DSHEA do not require warnings of known contraindications. In this manner, such supplements have entirely bypassed peer review and independent assessment of efficacy and safety procedures. All that the FDA is able to ask is that the manufacturer ensures that the dietary supplement is safe before it is marketed and that the product label information is truthful and not misleading. However, the label guidelines leave so much room for abuse that quackery and hucksterism thrive under these circumstances. The manufacturer can make numerous claims just as long as they do not claim that the product effectively diagnoses, prevents, treats, mitigates, or cures specific diseases. To make such claims would insinuate that the product is a drug. The FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> [codified at 21 C.F.R. 101.93(g)]. The FDA also has the opportunity to perform inspections to ensure products are manufactured in a responsible manner; however, the agency's limited resources only enable a fraction of the firms marketing supplements to be inspected each year.

While the FDA has been able to shut down a few web sites, many continue to operate unscathed and others have simply ignored FDA rulings. Judging from the rulings handed down thus far, the primary ability to impose some degree of oversight over industries that use the DSHEA as a loophole is through the Federal Trade Commission (FTC). The FTC regulates dietary supplement advertising. In

September 2002, the FTC reported that 55% of weight loss advertisements included claims that were false or misleading. In 1998, in reaction to FTC guidelines regarding false claims and advertising, an estimated 28% of companies selling dietary and specialty supplements withdrew deceiving language. By comparison, the percentage of companies that made no changes was more than 60% (6,7). In his testimony before the Senate's Special Committee on Aging, the previous Chief Financial Officer of the Brazwell Companies stated that the advertisements in the *Journal of Longevity* contained... "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" (6).

Figure 1 depicts a table appearing in multiple web sites advertising beneficial changes associated with hGH as an anti-aging treatment. The citation is both inaccurate and incomplete (8). The figure neglects to indicate that the "test results" were actually patient self-reports with a response rate to a questionnaire of 31%. The authors state "Herein, we report our clinical experiences with treating more than 2000 patients with adult growth hormone deficiency (AGHD) using our LD [low dose] hGH replacement regimen." Yet, questionnaires were sent to 1000 patients, the selection criteria of which were not stated. Of the 308 respondents, results from only 202 were reported with no reasons for the omissions reported in the paper. There is no mention of any Institutional Review Board oversight. The first author of the paper directs an anti-aging clinic in Palm Springs, California, that advertises the administration of hGH (www.totalhormonegenetherapy.com). The journal in which the paper appears is no longer in production.

In the case of drugs (as opposed to dietary supplements) such as hGH, the FDA does have jurisdiction over false or misleading advertising. Many web sites advertising hGH market the drug without indicating potential adverse effects,

while also providing expansive and detailed disclaimers. Such promotion of a drug without revealing potential adverse consequences is against the law (See 21 U.S.C. § 321(n); 21 C.F.R. § 1.21).

HUMAN GROWTH HORMONE FOR ANTI-AGING IS ILLEGAL

An alarming number of entrepreneurs interpret the DSHEA to allow hormones to be classified as dietary supplements. In the cases of DHEA and melatonin, the FDA has yet to clearly indicate whether or not these fall under the DSHEA umbrella. On the other hand, hGH (also called somatropin), contrary to the opinion of numerous hucksters, does not meet the criteria of a dietary supplement. The selling and administration of hGH is perhaps the most blatant and organized form of quackery today.

There are several reasons why hGH does not qualify as a dietary supplement. First, it was designated a drug by the FDA prior to the DSHEA and thus cannot be regarded as a dietary supplement. Second, substances covered by the DSHEA are meant to be ingested thus disqualifying the most widely distributed form of hGH, injectible hGH and sublingual so-called secretogues (e.g., somatostatin and growth hormone-releasing hormone). Third, hGH, along with anabolic steroids, must, according to the Federal Food, Drug, and Cosmetic Act (FDCA), be prescribed by a physician who also provides subsequent supervision of the patient (See 21 U.S.C. § 353(b)(1)(B) (9)). It is difficult to envision how physicians who provide hGH via the Internet are able to provide subsequent supervision of the patient. Nonphysicians distributing hGH can be prosecuted as narcotic dealers under the Controlled Substances Act. An example of direct sale of injectible hGH appears in Figure 2.

Today, authorized manufacturers of hGH such as Genentech, Eli Lilly, and Serono distribute the drug with strict oversight to only hospital (not community) pharmacies. Therefore, for a nonphysician to distribute hGH, they generally must have obtained the hGH from one of three sources: via theft or a drug-dealing physician, smuggled from another country, or counterfeit hGH.

Purveyors of hGH will often invoke what they call "the honorable tradition of off-label use" in prescribing and administering hGH as an anti-aging strategy. Such off-label use is not permissible in the case of hGH because of very narrowly defined circumstances under which its use is allowed. Section 303(f)(1) of the FDCA [otherwise known as section 333(f)(1) of Title 21 of the United States Code (21 U.S.C.)] allows physicians to distribute hGH in connection with either 1) "treatment of a disease" or 2) "other recognized medical condition," which has been authorized by the Secretary of Health and Human Services (HHS). The Secretary of HHS and thus the FDA have indicated that hGH for adults is allowed only for two conditions: wasting syndrome of AIDS and Growth Hormone Deficiency (GHD), which must meet two diagnostic criteria (10):

1. Biochemical diagnosis of adult GHD by means of a subnormal response to the standard growth hormone stimulation test (after growth hormone releasing hor-

none or argentine administration, a peak GH level of <0.5 ng/L),

2. Patients who have adult GHD either alone or with multiple hormone deficiencies (hypopituitarism) as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma or childhood-onset patients who were GH deficient during childhood.

Note that aging and age-related diseases are not listed among the diseases, treatments, or trauma where administration of GH is legal. Also note that GHD due to pituitary tumors and their treatment is very rare at a rate of 10 cases per million people per year (11,12).

Most entrepreneurs that prescribe or administer hGH claim that their clients have low growth hormone levels relative to young adults, but this is not a legal indication for hGH administration. Determining hGH or insulin-like growth factor-1 (IGF-1) levels is neither accurate nor sufficient for the diagnosis of GHD. The diagnosis of GHD requires the documentation that the anterior pituitary gland produces less than 5 ng/ml hGH after the intravenous administration of the amino acid arginine and/or GH-releasing hormone (>10 ng/ml is normal, 5–10 ng/ml is indeterminate; in some laboratories >7 ng/ml is normal) (13). The test is usually administered to diagnose hGH deficiency as a cause of growth retardation in children. In adults, the test is used to diagnose panhypopituitarism or isolated GHD, thus it would be highly unusual that people being treated for anti-aging would have a positive hGH stimulation test.

Some anti-aging marketers sell what they call secretogues, which they claim stimulates the production of hGH. The assertion that the production of hGH can be stimulated assumes that the anterior pituitary gland produces and stores normal amounts of hGH. Thus, secretogues by definition would not be indicated or effective for the treatment of GHD.

Human growth hormone has been approved for treatment of the wasting syndrome in AIDS. Specifically the Secretary of HHS has not approved recombinant hGH products for "anti-aging" treatment. Thus, prescribing, administering, marketing, or distributing of hGH for anti-aging or age-related problems is illegal, and for good reason. Human growth hormone has been demonstrated to have high rates of adverse side effects in the short term, and nothing is known about its potential long-term adverse effects (14). Mouse studies suggest that growth hormone levels beyond what is age appropriate leads to the opposite of what quacks claim, that is, premature aging and marked reduction in life span (15,16).

THE SOCIAL COSTS EXACTED BY THE ANTI-AGING INDUSTRY

In the 1992 black comedy *Death Becomes Her*, Goldie Hawn and Meryl Streep portray two women who are so distraught at the prospect of aging that they each pay a small fortune for a sip of a mysterious rejuvenation potion. The women, who never ask about the ingredients of the elixir, are thrilled with the results until they realize that as time goes by they are falling apart, literally. They get relief from their husband-in-common, a plastic surgeon, who artfully puts them back together again. However, as he ages, they

see their opportunity for immortal beatitude slipping away. The final scene of the film places them at his funeral after he escapes their efforts to conscript him into the ranks of the immortals and having enjoyed a fabulously productive and fulfilling old age.

Quacks first scare the unsuspecting, espousing dangerous and false myths about aging, and then convince the gullible and vulnerable that they have the cure. Anecdotes by hGH users of increased energy and libido and other improvements have fueled the hopes and fears of many consumers anxious to erase or even prevent a natural life process promoted as synonymous with ill health and growing dependency.

The economic harm imposed upon our older population by the anti-aging industry is particularly significant. Consumers unnecessarily spend an untold fortune each year on “anti-aging” formulations that promise to deliver just about everything on a fountain-of-youth wish list: increased muscle mass, the prevention of middle-aged spread, sharpened mental faculties, and a host of other claims. In 2002, the *Washington Post* cited one Las Vegas clinic that had one third of its 4000 patients spending \$400 to \$500 a month for growth hormone injections (17). The FTC estimated that the economic harm caused by 20 investigated companies that marketed such products to seniors was on average \$1.8 million per company (7). Some products are

HGH-How To Order

800.808.6975

WHAT IS HGH | WHY HUMAN GROWTH HORMONE | FAQs | ORDER HGH | MEDICAL STUDIES | ABOUT US | HGH LINKS | E-MAIL | HOME-HGH



HOW TO ORDER HGH

The **REAL INJECTABLE HUMAN GROWTH HORMONE** or HGH, not a releaser or homeopathic formula with limited results.

▣ **Ordering your Human Growth Hormone is as easy as 1-2-3.**

Call, fax or email us to place your order of hgh. Provide the information required in the simple online forms. Receive your order of Human Growth Hormone.

▣ **Human Growth Hormone (HGH) is a prescription medication.**

We will not ship the human growth hormone (HGH) unless we have had direct contact with the person intending to use it. We want to make sure you use the hgh safely and that you do not waste it needlessly. You must call us for a brief discussion.

▣ **Pricing of our Human Growth Hormone**

15 IU vial of HGH \$300.00 Minimum order is 2 vials
Medical review \$100.00 Includes prescription and follow up

It is our intention to be competitive in our pricing. Some competitors charge more than us. Some charge less per vial, but then add as much as \$1,500 or more for medical reviews, consultations and tests. All this makes their HGH cost more than ours even though at first glance it seems cheaper.

We can usually meet or beat the prices of anyone who is selling an FDA approved product obtained through legal means. Call us. We will do an “apples to apples” comparison for you and see if we can save you money.

Click here for the forms you will need to order.

To order your HGH please call 800.808.6975, send us an email or fax us at 800.808.6973 with your phone number, time zone and the best time to call you.

What is HGH | Why Human Growth Hormone | FAQs | Order Growth Hormone
Medical Studies | About us | HGH links | E-mail | SiteMap

<http://www.rejuvenationcentre.com/order.html>

Figure 2. The “HGH-How To Order” page of a web site advertising “Real HGH.” Note the statement “FDA approved product.” There are many web sites and anti-aging clinics advertising and selling human growth hormone (hGH) despite the fact that selling or administering hGH for anti-aging is not approved by the FDA, in fact it is illegal to do so.

“ People who have taken Human Growth Hormone (hgh) have found it to produce striking improvements in their health, energy level and sense of well being. The list of benefits, such as weight loss, seems to grow with each new study. ”

relatively inexpensive compounds that can be bought at the neighborhood health food store, while others, such as injectible hGH, require a financial commitment of a small fortune each year for what the huckster hopes to be the rest of the user's life.

Given its prevalence, quackery has become a true public danger. Some products contain undisclosed ingredients that are either addictive or are harmful to specific individuals. One recent case was Botanic Lab, Inc., which marketed a product called PC SPES, a popular product because of published claims that one of its herbal ingredients showed promise in treating prostate cancer (18). PC SPES was found by the California Department of Health Services to contain undisclosed warfarin and alprazolam. Other products produced by the company such as Arthrin, for joint stiffness, contained undeclared indomethacin, diethylstilbestrol, and alprazolam (19).

Numerous products have been noted to contain biologically meaningless amounts of the advertised substance, which in the case of hGH would ironically protect the buyer from their purchase. As reported in the *New York Times* recently, ConsumerLab, a company in White Plains, New York, tested for the content hGH or substances claimed to cause release of hGH in a number of products advertised on the Internet to "Increase Muscle Mass" and "Look and Feel 20 Years Younger." One product, for example, a nasal spray, which ConsumerLab indicates is an ineffective delivery mode for hGH anyway, was found to have 1000th of a pharmaceutically meaningful dose of hGH and which cost \$70 per bottle. The various companies and web sites mentioned in the article were, according to the reporter, unwilling to provide any comment (20). It should be noted that, along with the nasal form, hGH is too large a protein to effectively cross membranes, thus effectively making it biologically unavailable in a sublingual form. As a protein, if taken orally, it is destroyed in the stomach. Despite these inescapable biological facts, hGH is sold to the public through many web sites, clinics, and stores as pills and sublingual sprays.

Table 1 lists a number of products that have fortunately been caught by the so-far unacceptably permeable net of the DSHEA act-encumbered FDA and other watchdog organizations.

A less perceived danger, but no less innocuous, is that victims of quackery divert their money, time, and effort toward a strategy that does not help them and away from strategies proven to improve health and function (such as exercise, cessation of smoking and of excessive alcohol use, stress reduction, and diet). In the case of the anti-aging industry, the additional danger is the industry's pernicious and false portrayal of older people. The hucksters' sensationalized images of older people as withering and frail individuals staring at nursing home walls reinforce our youth-oriented society's inaccurate and bias-engendering perceptions of aging. Anti-aging has become synonymous with anti-old people.

The baby boomer generation in particular is increasingly looking for answers about what are appropriate and helpful strategies for improving how they age and for avoiding age-related illnesses—illnesses that some of them are witnessing

first-hand with their parents. In this day and age of terrific technological gains and medical breakthroughs, it is understandable how one can be tempted by and fall for purported discoveries of fountains of youth and elixirs. Based upon a recent survey of 1000 people, Eisenberg estimated that nationwide, 24.2 million people used specialty supplements (21).

THE 15 SIGNS OF QUACKERY

It is incumbent upon the medical community that we educate the public not only about sound strategies for maximizing healthy and active life expectancies but also about the usual signs of quackery. Park described seven typical warning signs that a "scientific claim" is nothing more than a huckster's ploy (22). Most of these signs are germane to quackery. The false claims along with other deceiving sales tactics that make up the typical armamentarium of quacks are listed in Table 2 and discussed in greater detail below.

1. *The Claim Is Pitched Directly To The Media Without Evidence of Unbiased Peer Review*

Peer review is a critical check that the scientific community and the public rely upon to differentiate good reliable science from hucksterism and quackery. When peer review is either bypassed or avoided and findings are taken directly to the media, one should be wary that peer review was bypassed for a reason. More than likely the findings would never stand up to usual scientific scrutiny. Notably, not all journals are created equal when it comes to standards of peer review. Some journals are nothing more than trade magazines primarily geared toward advertising. These journals can often be differentiated from more reliable journals by their absence on the National Library of Medicine's MEDLINE.

An excellent but most unfortunate recent example of going directly to the media was the announcement by a group called the Raelians claiming that its scientists at Cloneaid had successfully cloned a human being. Similar to other pseudoscientific claims, such announcements can have a profound and detrimental backlash on the scientific community.

When the media cannot be lured into promoting the huckster's claim, then many will resort to paid infomercials, perhaps claiming scientific proof while wearing white coats and stethoscopes but again doing so without any reasonable and reproducible scientific proof to back their claims. Internet and e-mail users are plagued on a daily basis with spam advertising, for example, penis enlargement pills and the fountain of youth in the form of hGH.

2. *The Purveyor's Work or Message Is Being Suppressed By the Scientific Establishment*

By virtue of their motivations and tactics, hucksters and quacks are constantly at odds with scientists, government regulatory and protection agencies, and consumer advocacy groups. One propaganda tool is to claim that critics professing to protect the public are just protecting their financial well-being. Another related tactic is to claim that

Table 1. Examples of Federal and State Actions or Sanctions

Company	Product	Claimed Effect	Reason for Legal Intervention	Legal Outcome
Mark Nutritionals Inc.	Body Solutions Evening Weight Loss Formula	Users lose weight without diet or exercise	False advertising	FTC imposed \$1 million settlement
Universal Nutrition Corp.	ThermoSlim	Weight loss	False Advertising	FTC imposed \$1 million settlement
MuscleTech	Hydroxycut (version containing ephedra or ma huang)	Weight loss pill	False advertising	In 2003, a California judge handed down a \$12.5 million false-advertising judgment
Cytodyne Technologies	Ephedra-free Xenadrine EFX (contains synephrine, a weaker relative of ephedra)	Synephrine is found in the herb citrus aurantium (commonly known as bitter orange); Products with synephrine can cause hypertension, heart attack, and stroke, especially when mixed with concentrates of other caffeine-rich herbs, such as guarana and mate	Cytodyne Technologies did not disclose that some of the ingredients in its ephedra-free Xenadrine EFX, including the banned horse stimulant Hordonine, have many of the same adverse health effects as ephedra	Company, which had changed its name to Nutraquest Inc., filed for bankruptcy, suspending litigation
Botanic Lab Inc.	PC SPES & SPES	PC SPES is an herbal compound for the treatment of prostate cancer	Found to contain warfarin (Coumadin) and alprazolam (Xanax)	Civil penalties, imprisonment currently under consideration, founders not allowed to conduct business in California
Christopher Enterprises, Inc.	Comfrey (contains toxic alkaloids and, when taken internally, can cause serious liver damage or death)	Its products could treat such ailments as asthma, arthritis, cancer, colds, coughs, cramps, herpes simplex, infection, multiple sclerosis, paralysis, polio, stroke, and tuberculosis, and that the products were safe.	FTC stated that did not have adequate scientific evidence to substantiate the safety or efficacy claims for their comfrey products	Defendants agreed to stop marketing the comfrey products and to include a warning on comfrey products, they also agreed to stop making the challenged safety and health benefit claims and to pay \$100,000 for consumer redress

Note: FTC = Federal Trade Commission.

they are a vanguard like Galileo and are being persecuted by the establishment, but in the end they will be vindicated.

3. Use Phrases Like “Scientific Breakthrough,” “Exclusive Product,” “Secret Ingredient,” or “Ancient Remedy”

Given the many technological feats and discoveries we are exposed to nearly every day, blanket statements such as a cure for cancer or doubling of the human life span seem less preposterous these days, particularly to the gullible and desperate. Perhaps this is why people seem more prone lately to fall for claims like these. Another related strategy is to claim that a new finding will yield results for humans within the year. Such statements though, often based upon findings at the microbiological level, are both irresponsibly premature and nearly certainly unlikely to come to fruition. History clearly speaks for itself in this case.

4. Testimonials and Anecdotes Are Pervasive

People respond positively to anecdotes in part because they can relate to the person who had the positive experience. As with the lottery, “why wouldn’t it work for me? I have as good a chance as the next guy.”

For example, on one web site selling an hGH product: “I ordered a 3-month supply of Ultimate HGH 1000 and just finished my first bottle. I don’t know if it is the product or just my head, but I have to say it is working! My muscle mass is increasing, I am sleeping better. I seem to be in a much better mood all the time, the bags under my eyes are gone and my skin is in much better condition. At 45 I feel like 30 at this point!”

Some entrepreneurs will claim that they themselves or the consumer cannot afford to wait for the conduct of responsible scientific trials of the product that might not even occur anyway because of the expense and time. Rather,

the testimonials have to be enough proof of efficacy and safety. The claim might be made that “science doesn’t have all the answers.” On the other hand, quackery is quick to claim that it has discovered the fountain of youth, the cures to incurable diseases, and miracle answers to obesity. Frequently accompanying the testimonials are statements such as “sold to thousands of satisfied customers.”

5. Centuries-Old Remedies Are Credible Because They Have Withstood the Test of Time

Examples abound of remedies where the efficacy is based upon their past use spanning centuries. This was a prevalent argument for defending the sale of ephedra, which is now banned by the FDA. People in remote Andean regions claim that the water from glacial runoffs, otherwise known as “glacial milk,” is the fountain of youth. Several web sites promote the sale of glacial milk as an anti-aging treatment.

6. Attempts to Convey Credibility: White Coats, “MDs,” “Academies,” and “Institutes”

Because the consumer is likely to at first be at least a little skeptical, it is critical for the huckster to appear credible. It is this feigning of credibility in the health field that makes the huckster a quack. The huckster will often appear in a doctor’s white coat with a stethoscope around his or her neck; so commonly seen in infomercials. Web sites will have pictures of people in lab coats looking in microscopes, or of other academic medical themes. When appearing in person, the effective quack will exude confidence, never letting up that what he or she is pushing is dishonest nonsense.

As the message becomes less believable, the attempts to convey credibility become more severe. Some organizations claim “board examinations” yet anti-aging medicine is not recognized by the American Board of Medical Specialties (ABMS). In December 2000, the founders of the American Academy of Anti-Aging Medicine, Ronald Klatz and Robert Goldman, were disciplined by the Illinois State Board of Medical Registration for adding the “MD” designation to their names (23).

7. The Absence of Adverse Reactions and the Making of Claims That Sound Too Good to Be True

The terms “all natural,” “herbal,” and “wholesome” may be used to intimate that the product has no associated adverse side effects. For example, many weight loss products claim to be “natural” or “herbal,” but this doesn’t necessarily make them safe. Such assurances, even if they are true, do not ensure their safety, as numerous adverse effects have been noted for many herbal products and for patients with specific conditions where the herb is contraindicated.

Unlike prescribed medications, under the 1996 labeling rules of the DSHEA, vendors of dietary supplements are not required to list either potential adverse reactions or potential interactions with medications. Thus, other than moral obligation, the vendor has no incentive to inform the public of these hazards. The result is that adverse reactions are rarely if ever mentioned by hucksters.

Table 2. Signs and Tricks of Quackery

1. The claim is pitched directly to the media without evidence of unbiased peer review
2. The purveyor’s work or message is being suppressed by the scientific establishment
3. Use phrases like “scientific breakthrough,” “exclusive product,” “secret ingredient,” or “ancient remedy”
4. Testimonials and anecdotes are pervasive
5. Centuries old remedies are credible because they have withstood the test of time
6. Attempts to convey credibility: white coats, “MDs,” “academies,” and “institutes”
7. The absence of adverse reactions and the making of claims that sound too good to be true
8. Simplistic rationales to dupe the lay public
9. Use celebrities and attempt associations with well-known legitimate scientists
10. “The esteemed medical tradition of off-label use”
11. Products are sold
12. Misleading interpretations of studies or outright false claims that something works
13. Disclaimers
14. Money back guarantee
15. “We are on your side”

The more hucksterism required to sell a product, the greater the efforts to dispel any concerns about it. If adverse reactions are mentioned at all, it is usually in the context of criticizing studies that warn against use of the product. In the case of many products covered by the DSHEA, or hGH, the quack will indicate a vast experience with treating hundreds if not thousands of his or her patients with the elixir with nothing but positive reports.

8. Simplistic Rationales To Dupe the Lay Public

Very few medical innovations and discoveries are simple. In the face of the multitude of behavioral, environmental, and genetic interactions that determine the tremendous heterogeneity in how we all age, the anti-aging quacks claim that the answer is as simple as modulating a single hormone. They observe with their costumes, white coats and stethoscopes, that hGH, melatonin, and DHEA decline with advancing age. Exclaiming that aging is a disease, they announce that administration of one or more of these hormones while carefully monitoring levels will not only restore youth but expand life span to 150 years. However, there is no more science to choosing specific levels as there is to using the hormones to stop aging. In actuality, the decline in growth hormone may be evolutionarily adaptive to reduce cancer risk and propensity for insulin resistance (24).

9. Use Celebrities and Attempt Associations With Well-Known Legitimate Scientists

Numerous sites and infomercials solicit celebrities who themselves may be conned by the quack, or are simply out to make money. Legitimate well-known scientists might suddenly find their names on stationery or web sites by virtue of accepting a recognition award, but in the process, and perhaps unknowingly, appear to endorse the institution or product.

Table 3. Helpful Anti-Quackery Resources

FDA's MedWatch program for reporting adverse effects and other concerns	Toll-free number: 800-332-1088, fax: 800-332-0178 or website: www.fda.gov/medwatch
FDA's Center for Food Safety & Applied Nutrition (CFSAN): Information about dietary supplements	http://www.cfsan.fda.gov/~dms/supplmnt.html
Consumers Reports	http://www.consumersunion.org/pub/core_product_safety/000961.html
FDA's <i>Tips for Older Dietary Supplement Users</i>	http://www.cfsan.fda.gov/~dms/ds-savvy.html
FDA's Office of Dietary Supplements	http://www.dietary-supplements.info.nih.gov
Federal Trade Commission's Consumer Site	http://www.ftc.gov/bcp/menu-health.htm
Federal Trade Commission's "Operation Cure All" for detecting Internet fraud regarding health-related claims	http://www.ftc.gov/bcp/conline/edcams/cureall/index.html
Federal Trade Commission Consumer Complaint Form	https://m.ftc.gov/pls/dod/wsolcq\$.startup?Z_ORG_CODE=PU01
National Council Against Health Fraud	With several helpful links to a number of quackery watch web sites: http://www.ncahf.org
Quackwatch	http://www.quackwatch.org

10. "The Esteemed Medical Tradition of Off-Label Use"

Quacks will often indicate their treatment as an "alternative" to traditional and FDA-approved uses of medications. However, alternatives in the world of quackery are unproven and often unsafe. To suggest efficacy, the quack often recommends using the product in conjunction with proven strategies such as exercise and weight loss. Of course, it is these latter behaviors that end up being responsible for any positive results sensed by the patient. In some cases, such as hGH and anabolic steroids, off-label use is illegal.

11. Products Are Sold

Anti-aging web sites and journals are rampant with conflicts of interest, with health care providers purporting to disseminate trustworthy information while using that very same information to sell their products. Simply, the marketing of products by people either pretending to be or who actually are licensed health care providers is likely the most important and reliable indicator of quackery.

12. Misleading Interpretations of Studies or Outright False Claims That Something Works

Out of necessity, by virtue of the products they are attempting to sell, quacks must deceive the public. Part of this deception entails misconstruing the results of published studies and outright fabrication of results. The publication of the Rudman article has led to hundreds of misleading quotes, misrepresentations, and summaries of the *New England Journal of Medicine* article (1,2).

In an unprecedented move, the journal now posts a warning on its web site (along with links to specific articles) in association with the Rudman article stating:

"Editor's Note, posted February 26, 2003: This article has been cited in potentially misleading e-mail advertisements. To give readers more complete information, the full text of the article, its accompanying editorial, and more recent articles about advertising dietary supplements and the question of growth hormone's role in the aging process have been made available online at no charge."

For example, a web site hawking hGH, states: "Dr. Daniel Rudman published in the *New England Journal of Medicine* his clinical findings of the effects of anti-aging. The results were startling to say the least. Working with volunteers over a period of 6 months the aging process was reduced from 10 to 20 years in the patients who received HGH. In the controlled group that didn't receive HGH, the normal aging process continued. Since Dr. Rudman's initial findings, thousands of additional studies have supported the fact that HGH can and does not only retard aging, but also reverses the process as well. **Look Younger **Lose Weight **Restore Hair Growth **Regain Hair Color**Reduce Wrinkles **Improve Skin Texture **Improve Skin Elasticity **Feel Younger**Restore Sex Drive**Increase Energy (http://www.healthinternal.net/new_page_2.htm). Nowhere in the Rudman article do the authors indicate that the aging process was reduced (1).

According to Senator John Breaux, Chairman of the United States Senate's Special Committee on Aging, in his review of a 2001 issue of the *Journal of Longevity*, "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" (6). Regarding the production of the *Journal of Longevity*, in his testimony, the Chief Financial Officer of the Braswell Companies stated that "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." Furthermore: "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."

13. Disclaimers

Disclaimers in and of themselves are not proof of quackery. Many reputable books and other sources of health information provide disclaimers to advise the reader that when making decisions that could impact upon their health, they are well advised to consult with their health care professional.

However, for many web sites, infomercials, and other quackery sites, the fine print absolutely contradicts the intention of the huckster. For example, one site states: "This information is not medical advice or diagnosis, nor is it to be construed as medical advice, medical information, medical diagnosis, or medical prescription for curing, removing, or preventing any disease, or related symptoms. You should not use the information on this site for diagnosis or treatment of any health problem or for prescription of any medication or other treatment. You should always speak with your physician or other health care professional before taking any medication or nutritional, herbal, or homeo-

pathic supplement, before starting any diet or exercise program or before adopting any treatment for a health problem.”

Such clear contradictions and what appear to be excessive attempts to shrug responsibility should be regarded as a warning to the consumer. Some web sites have disclaimers that are multiple pages long attempting to protect the quack from any potential legal action. Rather than claim to cure, the quack might claim that the product balances the person's pH, detoxifies the body, or establishes youthfulness. Such language protects the quack, since it is impossible to prove what, if any, changes took place.

14. Money-Back Guarantee

Numerous mail order and web site hucksters offer money-back guarantees for their products. Given the disclaimers most of these sites have, it is hard to imagine the circumstances under which they would return money. The origin of a number of sites makes it clear that the entrepreneur has no intention of honoring a guarantee. Use of NetworkSolutions' WHOIS feature allows the consumer to look up the owner of a specific web site (http://www.networksolutions.com/en_US/whois). Many sites have off-shore origins, particularly Belize and China. Finding addresses such as these should give a person reason to suspect the veracity of the web site.

15. “We Are On Your Side”

In attempts to appear to be the consumer's true advocate, the huckster or quack might claim that they have information that doctors, the FDA, or the American Medical Association, for example, do not want them to know. They often claim that the consumer must have the freedom to choose, and they are there to help them make the decision. One hGH sales site attempted to convey they were the visitor's advocate by providing them the opportunity to report unwanted e-mails. However, further investigation revealed that such reports went to an Internet marketing firm that was the source of the e-mail advertising the site in the first place.

CONCLUSION

How ironic it is that some patients will refuse, perhaps as a matter of principle, medications and even antibiotics, which have well-characterized efficacy, contraindications, and potential adverse effects while at the same time they turn to supplements that, in the words of Melvin Benarde are, **“unregulated, untested, unstandardised and of unknown effects”** (25). It is by virtue of the **quackery** that pervades the anti-aging industry that enough people are hoodwinked into using these products, thus allowing the industry to sustain itself and in some cases facilitate the fortunes of a few. Also, **inexcusably weak oversight by both federal and state agencies** that should instead be empowered to protect people from the physical, social, and financial harm exacted by the industry must share the blame.

While freedom of access and the freedom to choose are important rights, people also have the right to safe and reliable choices. Clearly a balance between these two rights must be achieved. However, the scales are severely tipped in favor of the quacks and hucksters, where people are steering blind, having no idea of the safety, content, contra-

indications, side effects, or efficacy of their purchases. Even worse, patients may believe they are being offered sincere and accurate information when in fact they are being duped.

Congress might have been attempting to achieve that balance with passage of the DSHEA in 1994. Clearly, however, the amendment did not afford citizens with even the bare minimum of protection from quackery and hucksterism that they deserved. Since the DSHEA, Congress has entertained the passage of legislation that would make such matters even worse with the provision of insurance coverage for these products and to allow entrepreneurs to make disease- and cure-related claims for their products (26,27). Alternatively, Congress is also considering House of Representatives bill 3377 and Senate bills 722 and 1538 to enhance consumer protection (<http://olpa.od.nih.gov/legislation/108/pendinglegislation/dietary.asp>).

Despite legislation that should keep substances such as hGH and anabolic steroids out of the hands of quacks, the FDA and other agencies are not afforded the resources they need to adequately protect citizens. Even with subpoenaed appearances before Congress, quacks and hucksters simply plead the Fifth Amendment in the face of admonishments for their unethical behavior, and continue to make millions of dollars taking advantage of the vulnerable and desperate, many of whom are older people (6). With such blatant disregard for the public good and with the tardy ban of ephedra fresh in the minds of Congress, the DSHEA and hormone pushers must be dealt with by Congress with effective legislative changes that will give the FDA, FTC, and state agencies the laws and resources they need to ensure that citizens receive the accurate information and assurances they need to make sound choices about their health.

The billions of dollars Americans are currently spending on alternative supplements mandates that resources be dedicated to conducting well-designed studies to determine the efficacy and safety of supplements that show promise or to debunk supplements that show no promise but are used by a substantial number of people. Short of such legislation and until responsibly performed studies provide the answers, **health care providers and consumers would be wise to familiarize themselves with the quack's and huckster's arsenal of tricks.**

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Address correspondence to Thomas T. Perls, MD, MPH, Geriatrics Section, Boston Medical Center, Robinson 2400, Albany Street, Boston, MA 02118. E-mail: tperls@bu.edu

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