

AMERICAN ACADEMY OF ANTI-AGING MEDICINE

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1341 W. Fullerton, Suite 111 Chicago, Illinois 60614 Phone: 773-528-4333 Fax: 773-528-5390 http://www.worldhealth.net A4M@worldhealth.net

12 August, 1999

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Mr. Bob Moore Office of Dietary Supplements I-IFS-456 Food and Drug Administration 200 C Street, NW Washington, D.C. 20204

Re: The Consumer Education and Research Council of The American Academy of Anti-Aging Medicine

Dear Mr. Moore:

I am writing to you on behalf of the 7,500 physicians and scientists of the American Academy of Anti-Aging Medicine (A4M) who are dedicated to battling the degenerative diseases of aging.

Since our founding in 1993, we have seen an explosion of anti-aging products in the health care marketplace. Anti-aging -- being the new frontier of medical science -- has attracted both ethical and unethical marketers. Frankly, we are concerned about defending the hard-won reputation of anti-aging medicine as a legitimate clinical medical science.

This is what we are doing to protect the integrity of our field.

We have established the Consumer Education and Research Council (CERC) of the A4M. Its mission:

- 1) to protect the consumer from unethical marketing practices;
2) to raise and distribute resources to advance clinical anti-aging research;
3) to promote anti-aging health policy in the U.S. and overseas, as well as curriculum development at schools of medicine, public health, nursing, nutrition, chiropractic medicine, and other health fields.

I enclose an overview of CERC, as well as the Ethics Guidelines which participants must adhere to.

While we cannot prevent unethical products from entering the marketplace, we feel that this program will empower the consumer to make better-informed decisions about products and services that are available. Moreover, we intend to provide you and related agencies with reports which come to us from consumers.

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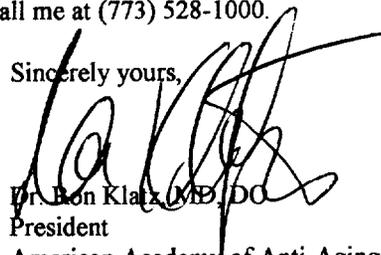
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We believe this effort supports the consumer protection activities of your agency. We would like your feedback. Kindly respond to the following three questions.

- 1) Do you support the goals and objectives of this Council?
- 2) How can we forge a professional relationship with you at the Food and Drug Administration to help maintain the high standards of our new medical specialty?
- 3) What steps can we take to help our membership alert you to bad players in the marketplace who are deserving of scrutiny?

We appreciate your consideration and response. If you have any questions, please call me at (773) 528-1000.

Sincerely yours,



Dr. Ron Klitz, MD, DO  
President  
American Academy of Anti-Aging Medicine

Cc: HFD-6  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857



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Linus Pauling Ph.D.  
*Nobel Laureate*

Vitamin C and megadose vitamin  
*role in health*  
Dr. Raymond Damadian  
*MRI Scanner*  
Dr. Daniel Rudman  
*HGH role in aging*  
Dr. Karl Folkers  
*CoQ10*  
Dr. Denham Harman  
*Free radical theory of aging*  
Richard Cutler Ph.D.  
*Antioxidants role in aging*  
Dr. Peter Safar  
*Cardiopulmonary Resuscitation*  
Senator John Glenn  
*Space and aging research*



## The Consumer Education and Research Council of the American Academy of Anti-Aging Medicine *Established 1999*

### What is the Future of Anti-A&g Medicine?

Following seven years of scientific discoveries and advances in clinical practice, anti-aging medicine stands at an important crossroads.

### Clinical anti-aging research remains critically under-funded

According to Richard Sprott, former Deputy Administrator of the National Institute of Aging (NIA), less than \$1 million is spent annually on clinical anti-aging research. What could be more important than continuing the search for the mechanisms of aging, developing novel optimum treatment protocols, and reporting on trends of patient outcomes?

### The challenge of the unregulated marketplace

Scientifically proven, life-enhancing products currently compete with less credible merchandise. The latter is often sold by those employing pseudo-science, fraud, trickery, and unsubstantiated claims to represent products which are, at best, ineffective, and at worst, unsafe. Anti-aging, being the new frontier of medical science, attracts the very best, and perhaps also the less than the best, in health care marketers.

**To what standards and guidelines does your competition adhere? How is the anti-aging marketplace perceived by consumers, by regulators?**

**A4M** is committed to an open and competitive marketplace, where products are universally accessible. At the same time, this society also bears the duty and obligation to defend the hard-won gains of anti-aging medicine among the medical, scientific, and consumer audiences, *A4M stands committed to the philosophy of scientific integrity and ethical truth-based marketing.*

### Continuing its service to this extraordinary science, A4M has established the Consumer Education & Research Council (CERC)

#### CERC's mission:

1. To protect the consumer from unethical marketing practices
2. To raise and distribute resources to advance clinical anti-aging research
3. To promote anti-aging health policy in the U.S. and overseas, as well as curriculum development at schools of medicine, public health, nursing, nutrition, chiropractic medicine and other health fields

**CERC's message to industry:** IS FDA and/or FTC regulation inevitable? Can we take steps to distinguish sound science from exploitation? Can the anti-aging marketplace regulate itself?

**CERC's message to the consumer:** Become your own advocate for optimum health and vitality. Work with your anti-aging physician to integrate longevity into your daily life. And, most importantly, use products and services that are committed to integrity, both in research and marketing practices. Look for the CERC logo. When you see it, you'll know that the manufacturer adheres to a strict set of guidelines for the ethical marketing of anti-aging products which protect you.

**Participation in CERC:**

As a member in good standing (see requirements and Ethical Guidelines attached), you may place the CERC logo and participation statement on all your products:



Member in good standing of the Consumer Education and Research Council (CERC) of the American Academy of Anti-Aging Medicine (A4M). We subscribe to the By-Laws of A4M and Ethics Guidelines of CERC	1
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Soon, **consumers** will look for the emblem as readily as they examine a food label. It will represent protection from unsubstantiated claims and unethical marketing practices.

Proceeds **from** CERC memberships are designated as restricted funds, and as such, are dedicated solely to CERC activities. Through a ballot system, CERC participants will have an opportunity to voice their opinion on the development, prioritization, and allocation of funds for A4M research projects. This consensus will be valuable input for the Board of A4M in its process of issuing its directives on research efforts.

Five tiers of participation are commensurate with your company's total annual U.S. domestic dollar sales volumes.

<b>Level</b>	<b>Participants</b> <i>(Annual A4M membership is a prerequisite)</i>	<b>Annual Contribution</b>
<b>Member I</b>	Individuals only	\$ 250
<b>Member II</b>	Government agencies and non-profit organizations	\$1,000
<b>Associate</b>	Anti-aging clinics and private practices	\$2,500
<b>Supporting</b>	Companies with total annual U.S. domestic dollar sales volumes of \$0 - \$199,999	\$5,000
<b>Sponsor</b>	Companies with total annual U.S. domestic dollar sales volumes of \$200,000 - \$499,999 Minimum recommended level for companies seeking use of CERC emblem.	\$10,000*
<b>Benefactor</b>	Companies with total annual U.S. domestic dollar sales volumes of \$500,000 - \$1 MM.	\$25,000*
<b>Patron</b>	Companies with total annual U.S. domestic dollar sales volumes of over \$1 MM	\$100,000*

\* May participate in the CERC logo distinction program.

## Safety & Efficacy Internet Index

CERC operates the Safety & Efficacy Internet Index, a searchable consumer-friendly database of anti-aging product information.

Companies who participate in the CERC Logo Distinction Program and **wish to** remain **in** good standing are required to provide the general public, through this site, with the following information:

- Product literature, packaging and labeling
- Related scientific studies and **clinical** trials
- Testimonials and anecdotal information
- Complaints/resolution of complaints

Consumers can search by product **or** product category, as well as provide feedback to the site, which will be updated and reviewed by the CERC scientific advisory board.

**A4M/CERC** has established cooperative relationships with the Food and Drug Administration, the Federal Trade Commission, and States Attorneys General

CERC is committed to empowering consumers to make well-informed decisions, and to supporting those manufacturers that adhere to CERC standards of scientific integrity and-ethical marketing. Neither the **A4M**, nor CERC, endorses any product or service.

### CERC raises the standards of ethical practice and scientific medicine

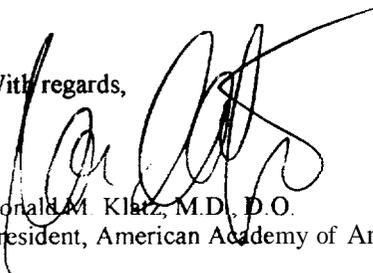
This is your opportunity to be recognized for your dedication to the integrity of this science. Who stands to gain more than those companies that advocate sound scientific methodology, and responsible/ethical marketing practices?

**Take a stand for the future of this exciting science.** Make a commitment to clinical anti-aging research by supporting the Consumer Education & Research Council.

Please **complete and return the enclosed-form to secure your affiliation** with the Consumer Education & Research Council. Upon approval by the Board of **A4M**, you will be provided with an electronic version of the CERC emblem to place on your product packaging and sales literature. You will also receive a certificate, suitable for **framing**, which you may proudly display to show your commitment to the Council.

As President of this organization now serving members from fifty countries worldwide, I thank you for your continued and generous support of our young medical society. Please accept our best wishes for continued happiness, prosperity, youthfulness, and productivity in your endeavors. ***Stay young with me, the best in medicine is yet to be.***

With regards,



Ronald M. Klatz, M.D., D.O.  
President, American Academy of Anti-Aging Medicine

enclosures



**CERC**  
*Consumer Education & Research Council*  
**PROPOSED ETHICS GUIDELINES**

- Businesses affiliated with **A4M** shall not knowingly or deliberately misrepresent the scientific truth relating to the efficacy of products and services.
- Businesses affiliated with **A4M** shall not use statements of, or assign statements to, individual physicians, authors, or scientists without obtaining prior written approval. This applies to all mediums of advertising, including but not limited to, print, Internet, e-mail, etc.
- Businesses affiliated with **A4M** shall refer to published bodies of research Work such that no statements are quoted out of context.
- Businesses affiliated with CERC:
  - Shall not knowingly or deliberately misrepresent or mislabel products.
  - Shall provide full disclosure of the source and content of all ingredients (active and inert).
  - Shall take measures to ensure that the quantity of ingredient(s) claimed on the product packaging is consistent with its manufacture.
  - Shall, upon request, provide assays and certifications attesting to the composition of their products.
- Businesses affiliated with **A4M** shall clearly distinguish the use of testimonials as separate from, and not the same as, independently conducted third party research.
- Businesses affiliated with **A4M** shall clearly distinguish the use of in-house or contracted self-generated evaluations as separate from, and not the same as, independently conducted third party research.
- Businesses affiliated with **A4M** shall resolve all consumer complaints, returns, and other issues pertaining to unsatisfactory products no later than ninety (90) days after receipt.

**ENFORCEMENT:**

- Enforcement of the Guidelines shall be conducted by the Ethics Review Panel (ERP), composed of **A4M** Board members and representatives selected from the anti-aging products and services industry.
- In the case of an infraction of these Guidelines, ERP shall issue a written warning notification, describing the violation and offering a period of sixty (60) days for correction. If the infraction is either ignored or not corrected to the satisfaction of the ERP within this time period, the ERP may discharge the business from CERC and revoke the use of **the emblem**. Such discharges are effective immediately and **A4M** or CERC fees shall not be **refunded**.
- In the event that a dispute arises that cannot be resolved through the **administrative review** of the ERP, the business involved shall reimburse all expenses incurred by **A4M** and the ERP, including, but not limited to, legal fees, court costs, and counsel and staff services.
- All ERP actions and rulings are to be considered as final and binding.

*PLEASE SIGN AND RETURN AS PART OF YOUR CERC APPLICATION*

\_\_\_\_\_ (COMPANY) wishes to be accepted as a participant of the Consumer Education & Research Council of the Academy of Anti-Aging Medicine and agree to abide by CERC Ethics Guidelines.

SIGNED: \_\_\_\_\_ DATE: \_\_\_\_\_