

## CORRESPONDENCE



## Inappropriate Advertising of Dietary Supplements

**TO THE EDITOR:** With regard to Dr. Drazen's Perspective article on the inappropriate advertising of dietary supplements (Feb. 27 issue),<sup>1</sup> a recent survey, conducted by Harris Interactive for Robert Butler and the International Longevity Center, showed widespread and potentially dangerous public ignorance of the regulation and labeling of vitamins, minerals, and food supplements. Most people believe wrongly that dietary supplements must be approved by a government agency such as the Food and Drug Administration (FDA) (59 percent of the respondents), that manufacturers are not allowed to make claims about their safety and their effectiveness unless there is solid, scientific evidence to support such claims (55 percent), and that the government requires that labels include warnings about potential side effects or dangers (68 percent). It is alarming that so many people believe that dietary supplements are regulated as if they were pharmaceuticals, when of course they are not.

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1. Drazen JM. Inappropriate advertising of dietary supplements. *N Engl J Med* 2003;348:777-8.

**TO THE EDITOR:** According to the Dietary Supplement Health and Education Act of 1994, the manufacturer of a dietary supplement is responsible for determining that the product is safe and that any claims made are substantiated by adequate evidence. This requirement has several practical implications.

First, the manufacturer does not have to disclose to the FDA or to consumers what evidence it has to back up its claims about the product or its safety. Second, the manufacturer is not required to record, investigate, or forward to the FDA any reports of adverse events. Finally, the manufacturer establishes its own manufacturing practice guidelines to ensure

that the dietary supplements are safe and contain the ingredients listed on the label. The FDA does not routinely analyze the content of dietary supplements. The only notification that the FDA may receive is that a dietary supplement contains a "new dietary ingredient." However, it is up to the manufacturer to determine whether an ingredient is "new," since there is no authoritative list of "old" dietary ingredients.

I hope most consumers are aware of these caveats.

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**TO THE EDITOR:** In his Perspective article, Drazen states, "New legislation has made it legal for companies to market dietary supplements without ap-

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proval of the Food and Drug Administration.” This statement is incorrect; throughout American history, vitamins and herbs have been sold without prior federal permission. The Dietary Supplement Health and Education Act of 1994, to which Drazen apparently refers, formalized the status of supplements in response to fears that those products could be banned.

Under this act, manufacturers must submit safety documentation for new ingredients, which the FDA may disallow at will. Existing products that prove to be hazardous can also be prohibited. These requirements strike a fair balance between laboratory science and human experience. The safety of common herbs is as well established by traditional knowledge as is the safety of many vegetables, spices, and beverages with presumed fitness for consumption that is unsupported by rigorous American studies in animal models or clinical studies. Indeed,

arguments against the act carry the bizarre implication that dual-use botanicals, such as ginger, may be safe when eaten as vegetables but hazardous when taken as supplements.

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**DR. DRAZEN REPLIES:** The letters from Drs. Applequist and de Lemos and Mr. Taylor all indicate that consumers in the United States are confused about the exact status of dietary supplements. Since, for all practical purposes, these materials are advertised as if they were medicines, they should, in my opinion, be regulated as such.

Jeffrey M. Drazen, M.D.

## Human Growth Hormone and Aging

**TO THE EDITOR:** Vance’s discussion of growth hormone (Feb. 27 issue)<sup>1</sup> omits important reports in the literature. The combination of growth hormone and exercise (unlike exercise alone) has been shown to increase type II muscle fibers in the elderly<sup>2</sup> — an important finding, since frailty and sarcopenia are predominantly related to the loss of type II fibers. There is no mention of the fact that decreased levels of insulin-like growth factor I have been reported to be associated with angina pectoris,<sup>3</sup> myocardial infarction,<sup>4</sup> and atherosclerosis,<sup>5</sup> which are the leading causes of death in this country. The discussion also excludes a recent report that aging men with low levels of insulin-like growth factor I die earlier than those with high levels.<sup>6</sup>

Long-term prospective studies on the potential of growth hormone will take decades. In the meantime, the use of growth hormone should be based on a patient’s clinical status and on a candid patient–physician discussion of current information on the pros and cons of such therapy.

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1. Vance ML. Can growth hormone prevent aging? *N Engl J Med* 2003;348:779-80.
2. Hennessey JV, Chromiak JA, DellaVentura S, et al. Growth hormone administration and exercise effects on muscle fiber type and

diameter in moderately frail older people. *J Am Geriatr Soc* 2001;49:852-8.

3. Conti E, Andreotti F, Sestito A, et al. Reduced levels of insulin-like growth factor-1 in patients with angina pectoris, positive exercise stress test, and angiographically normal epicardial coronary arteries. *Am J Cardiol* 2002;89:973-5.

4. Conti E, Andreotti F, Sciahbasi A, et al. Markedly reduced insulin-like growth factor-1 in the acute phase of myocardial infarction. *J Am Coll Cardiol* 2001;38:26-32.

5. van den Beld AW, Bots ML, Janssen JA, Pols HA, Lamberts SW, Grobbee DE. Endogenous hormones and carotid atherosclerosis in elderly men. *Am J Epidemiol* 2003;157:25-31.

6. Ruiz-Torres A, Soares de Melo Kirzner M. Ageing and longevity are related to growth hormone/insulin like growth factor-1 secretion. *Gerontology* 2002;48:401-7.

**DR. VANCE REPLIES:** Dr. Mahmud correctly notes that the combination of growth hormone and exercise increases type II muscle fibers in the elderly. As stated in my Retrospective article, changes in body composition with growth hormone administration do not improve function in the elderly. Reduced levels of insulin-like growth factor I may be associated with other diseases, although such an association is not proof of cause and effect and may echo the effect of disease; for example, insulin-like growth factor I may be low in young women with anorexia nervosa.<sup>1</sup> That older men with low levels of insulin-like growth factor I may die earlier than those with high levels may reflect underlying diseases. Rudman et al. reported that elderly men living independently had