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## When 'Health' Supplements May Do Harm

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Recently, I entered a store specializing in dietary supplements, curious about the information I would receive when I explained to the teenage clerk that I was particularly interested in preventing a heart attack.

I did not mention that I was a physician specializing in the prevention of heart disease, or that there were relatively few measures proven to reduce heart disease risk. But so many patients had brought in bags of supplements and "vitamins," convinced of their cardiovascular benefits, that I wanted to see how these products were being marketed.



In the self-described "health" store, the sales clerk asked a few questions about my cholesterol, blood pressure, exercise habits, etc. Then she showed me over half a dozen products, from \$8 to \$36 apiece, and assured me that they would address a variety of health risks.

These products included a pill that was supposed to improve my circulation and another that would supposedly boost my "metabolism." Another was listed as an herbal "vascular health" pill, with a long list of plant species names, none of them familiar.

Most products had labels containing descriptions of vague medical benefits, like "for cardiovascular health," with a notation that the Food and Drug Administration had not evaluated these claims.

I asked the clerk about proof that these pills worked and about risks when taking these various agents together. She assured me that they were "all completely natural and very extensively tested." After all, she went on, "they are mostly vitamins."

In truth, only half of the bottles she recommended contained any vitamins at all. One of these was a combination of vitamins B6 and B12 and folic acid to lower blood levels of homocysteine, an amino acid byproduct associated with increased cardiovascular risk when it is elevated.

The remaining products were neither vitamins nor minerals — some were pulverized plant leaves or seeds. Others were from crushed bacteria. I thanked the clerk for spending the time to educate me.

Conventional medical education and treatment guidelines discourage the use of vitamins and supplements as therapeutics for heart disease, largely because they have not been shown to have any benefit. Interestingly, while diets emphasizing foods rich in certain vitamins correlate with improved cardiovascular and cancer risks, the pill forms of these same nutrients have proved to be no more effective than placebos.

In some studies, the vitamins have proved to be worse than placebos, while in other trials, combinations of vitamins have actually reduced the benefits of proven treatments.

Nonetheless, the appeal of supplement medications is understandable, especially when the costs, complexity and publicized risks of prescription medications are all on the rise.

In promoting a product as a "supplement," manufacturers often rely on a combination of factors: vague claims made by sellers, word of mouth, and the distrust by many of organized medicine and the pharmaceutical industry. Supplement manufacturers are permitted to use advertisements and testimonials claiming that their products are "all natural" and "completely safe, without side effects."

The manufacturers of prescription drugs are allowed to make claims only about efficacy and safety that are based on results from controlled clinical trials approved by the F.D.A.

When Congress passed the Dietary Supplement and Health Education Act of 1994, it created this inequity between the marketing of medicines and supplements. This legislation places the burden on the F.D.A. to prove that a "supplement" is harmful before it can be removed from the market. In stark contrast, medicine approved by the agency must satisfy many safety and efficacy requirements before it can be sold.

The absence of a prospective review process may very well have contributed to the late discovery of harm associated with supplements like ephedra, the contamination of another supplement with a prescription blood thinner warfarin and an anxiety medication, and the fatal effects of an amino acid product.

Even when the offending supplement manufacturer is forced to withdraw a product, little can be done to prevent the fresh marketing of the product under a new brand name.

In August, the Justice Department began a criminal investigation of Metabolife International Inc., which makes a popular brand of ephedra that has been linked to dozens

of deaths, strokes and seizures in recent years and refused to report patient complaints to the F.D.A.

A spokeswoman for Metabolife said the safety of the company's ephedra-based dietary supplements had been supported by studies carried out over 20 years.

Still, the presumption of safety until harm is proved represents a flawed approach.

Many of my patients who readily take supplements or high doses of vitamins assuming that "they can't hurt" are reluctant to accept prescribed therapies whose risks are clearly defined on the label.

From my health store experience, I can understand why vague claims are implied without any reference to safety or efficacy.

Clearly, the time has come to demand that the burdens of proof and disclosure regarding the marketing of supplements be made similar to those required for prescription medications.

In the meantime, a healthy dose of skepticism seems to be the best supplement of all.