Current law and regulations classify natural health products or dietary supplements in a special category under the general umbrella of “foods,” not medications. These do not need approval from the FDA before they are marketed. They cannot be promoted as a treatment, prevention, or cure for a specific disease or condition because they would be considered unapproved – and thus illegal – medications.

The restrictions against promoting natural health products as treatments for disease, however, are easily bypassed. For example, although these products cannot be promoted as treatments for obesity (a disease), they can be advertised to promote a “healthy weight.” Not surprisingly, this approach resonates with obese people, who are eager to lose weight. Similarly, natural health products cannot be promoted for treatment of hypercholesterolemia (high cholesterol), which is a risk factor for heart disease. Claims that these products can help maintain healthy cholesterol levels are, however, permissible. These loopholes around regulatory wording, known as “structure-function claims,” are legal, but misleading.

It should be noted that medications for the treatment of obesity and hypercholesterolemia require extensive scientific documentation and FDA approval, while natural health products with similar intended uses need no documentation or approval.

Is the manufacturing process regulated?
At this time, manufacturers of natural health products or dietary supplements are not required to register their facilities or their products with the FDA, or with any other regulatory agency, before initiating marketing. Also, there are no manufacturing quality regulations for natural health products or dietary supplements that would establish minimum standards similar to the regulations enforced for prescription and over-the-counter medications.

There is no guarantee that what is listed on the label of a natural health product or dietary supplement is actually in the bottle. Even more troubling are the large number of reports that prescription medications such as ephedrine (a stimulating agent), corticosteroids (anti-inflammatory), anabolic
steroids (performance enhancing) and sildenafil (Viagra) have been added to natural health products without declaration on the label. In early 2008, the FDA warned consumers not to purchase two dietary supplements that contained hazardous levels of the trace element selenium. The agency had received reports from consumers in nine states who had experienced serious adverse reactions using these products. Analyses of samples of these dietary supplements found up to 40,800 micrograms of selenium per recommended dose or serving, more than 200 times the amount of selenium stated on the
labels of these products! The usual recommendation is only 200 micrograms of selenium. The safety of natural health products is discussed in more detail in Chapter 10.

The FDA issued regulations in June 2007 addressing Good Manufacturing Practices (GMPs) for natural health products or dietary supplements. The new regulations established standards for consistent manufacturing of these products with regard to their identity, purity, strength, and composition. They also include requirements for manufacturing facilities, establishing quality control procedures, and product testing. The regulations became effective in September 2007, but there is a staggered phase-in for companies to comply. Large manufacturers had until June 2008 before the FDA began audits. Small producers have until June 2010 to comply with the regulations. It is not known if Congress will appropriate sufficient funds to achieve adequate oversight of this industry.

**How are sales and promotion regulated?**

There is no law or regulation that requires a manufacturer of a natural health product or dietary supplement to provide the FDA or consumers with any proprietary information about the safety or purported effectiveness of their products.

The sale of natural health products or dietary supplements is ubiquitous. There are no rules. These products are sold in grocery stores, gas stations, convenience stores, pharmacies, and on the Internet. The estimated sales in 2007 in the U.S. amounted to $4.8 billion. Recommendations for their use to treat serious medical conditions most often come from inadequately trained sales people who have no formal medical or pharmacological education.

**What is being done to address the lack of documentation?**

A large number of studies published in peer-reviewed medical journals report conflicting results regarding the harms and benefits of natural health products and dietary supplements. In 1999, Congress established the National Center for Complementary and Alternative Medicine (NCCAM) within the National Institutes of Health (NIH) to address complementary and alternative medical practices (including natural health products and dietary supplements) through rigorous scientific testing and clinical trial methodology. NCCAM was also given the responsibility to disseminate authoritative information about complementary and alternative medical practices to health-care professionals and the public.

NCCAM-funded clinical trials have rigorously tested glucosamine-chondroitin in the treatment of arthritis; the herb Echinacea for the prevention and treatment of colds in adults; and Hypericum perforatum, an herb commonly known as St. John’s Wort, for depression. Generally, the results
of these trials have been disappointing and do not support recommendations that these natural health products and dietary supplements be used for the conditions for which they are promoted.

A recently completed NCCAM-supported clinical trial tested Gingko Biloba for the prevention of Alzheimer’s disease and memory loss in 3,069 older adults. Over an average of 6.1 years, 523 participants were diagnosed with dementia: 246 in the placebo group and 279 in the Ginkgo group. The study concluded that Gingko in older adults with normal cognitive function or mild deficits did not reduce the risk of developing dementia.

More information about these trials, including links to the original articles, can be found on the NCCAM Web site at www.nccam.nih.gov/research/results/

The NCCAM was established to scientifically determine if natural health products and dietary supplements actually work. NCCAM, however, does have its critics. Since 1999, the government has spent almost $1.5 billion in grants for research into alternative treatments. NCCAM has spent almost half of this amount and has found little evidence of benefit for complementary and alternative medical therapies. Some critics question why taxpayer money continues to be spent testing implausible natural health products and dietary supplements which science has shown to be ineffective. In our opinion, the manufacturers ought to cover the cost of documenting the benefit-harm balance.

What is a “functional” food?

In recent years, the food industry has marketed certain foods as “functional foods.” Although there is no formal or legal definition for “functional foods,” the term is used to imply that there are foods or dietary components that may provide a health benefit beyond basic nutrition.

Key messages

- There is no regulatory requirement to test the safety of natural products before they are made available to the public.
- The manufacturing of natural products is not regulated by the government in a manner similar to prescription or non-prescription medications.
- Consumers cannot be sure a product’s label actually lists the correct contents in a bottle of a dietary supplement or natural product.
- Undeclared substances added to a natural product by the manufacturer may be harmful.
- In spite of limited documentation, these products are widely used.