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Dietary Supplements and Their Future in Health Care: Commentary on Draft Guidelines Proposed by the Food and Drug Administration

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Abstract

The Dietary Supplement and Health and Education Act of 1994 gives the U.S. Food and Drug Administration (FDA) responsibility for oversight of the dietary supplement industry. Recent draft guidelines proposed by the FDA to insure the safety of new dietary ingredients would significantly alter the ability of manufacturers to bring new dietary ingredients to market, and may cause many products introduced since 1994 to be discontinued. These changes will have an impact on health care, but with limited research on dietary supplements and how their use affects the health care system, there is no way to predict what their overall effect on health will be. Since the natural raw materials for dietary supplements are often inexpensive and generally cannot be patented, manufactures have little incentive to conduct the research which might otherwise be warranted. Appropriate clinical trials that evaluate the use and efficacy of various supplements may be critical for our health care system. If inexpensive dietary supplements are found to be safe and effective, such research could yield significant cost savings as well as health benefits. *Antioxid. Redox Signal*. 16, 461–462.

Introduction

> "… The desire to take medicine is perhaps the greatest feature which distinguishes man from animals."
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> —Sir William Osler, M.D. (1849–1919)

In 1994, Congress passed the Dietary Supplement and Health and Education Act to authorize the regulation of dietary supplements by the Food and Drug Administration (FDA). Under this law, manufacturers are required to notify the FDA before new dietary ingredients are marketed. However, this process was poorly defined, creating confusion over the ensuing years. In July 2011, the FDA released proposed guidelines concerning this notification process that, if implemented, will significantly affect the supplement industry. The guidelines specify that new ingredients in supplements must be proven to be safe. Many commonly used supplements may be impacted. These draft guidelines have caused considerable contention between the FDA and manufacturers. The FDA is mandated to ensure that the public is protected from unsafe products. However, manufacturers contend that the cost of proving safety will be so burdensome that the regulations may cause some supplements to be dropped from production and/or some firms to drop out of the market. Most would agree that unscrupulous manufacturers—who for example, spike allegedly "natural" diet pills with amphetamine analogues—should be penalized, but reputable manufactures may also face repercussions. Overall, it is hard to predict the true impact of the proposed FDA guidelines on health, and yet it is critical for us to be able to do so. Supplement use has become a significant part of health behavior—half of all Americans take supplements, and the number has been increasing (1). In an era of increased concern about health care costs, it is vitally important to understand the impact of both supplements and their regulation on the health and economy of America. This will require research that evaluates the effect of the proposed guidelines, and the effect of the supplements that are being regulated.

Supplements can offer significant health benefits, but also may cause negative ramifications such as increased health care cost and adverse effects (3, 8). In some cases, supplements have established themselves as important tools in the fight against disease. Folic acid supplements reduce the incidence of neural tube defects during fetal development (6), and long-chain omega-3 fatty acids prevent mental illness (5). Probiotics have an important role in preventing gastrointestinal illness in a variety of clinical situations (7). Many important drugs we use today (*e.g.*, aspirin and digitalis) would have been classified as supplements in centuries past (2, 4),

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and it would not be surprising if some of the supplements in use today will one day have an established role in disease prevention and treatment. A quick review of the variety of supplements involved in ongoing clinical research trials listed on the clinicaltrials.gov Web site makes it clear that many researchers are in fact investigating supplements in a rigorous way. To the extent that the new guidelines influence the availability of safe new supplements for research, the guidelines could affect future breakthrough discoveries. Also, to the extent that the guidelines promote greater use of beneficial supplements, the guidelines may produce cost savings through prevention of costly debilitating disease.

Supplements are paid for out of pocket, and therefore do not add directly to the cost of health care in the same way as do prescription drugs. Even if supplements are only acting as placebos, they may still have an effect on the health care system. No one knows how often a placebo will keep a potential patient out of a doctor's office and eliminate the expensive care that can result. Conversely, no one knows how often such placebos will cause harm if seriously ill patients use them to postpone critically needed medical care, resulting in greater suffering and health care expense.

One of the reasons there is so much uncertainty regarding supplements is that they are not required to undergo the same rigorous testing that is required for patent pharmaceuticals. It is this issue that goes to the heart of the problem we face. Since it is difficult to claim exclusive patent rights to a supplement, there is little financial incentive for a manufacturer to pay for the multicenter trials that are the gold standard for clinical efficacy and safety. Thus it naturally falls to the government to fund these trials. Unfortunately, the millions of dollars the government has spent on such research cannot begin to match the billions spent by the pharmaceutical industry. Clinical trials evaluating various supplements may be critical for our health care system; such research has the potential to provide true cost-cutting breakthroughs for improving the health of the country.

There are many other unknowns concerning the effect of the proposed guidelines. Will beneficial supplements become more expensive and less utilized? Will reduced supplement use increase the burden of disease and the cost of traditional medical care? Or conversely, will the stricter guidelines result in safer supplements and fewer adverse reactions requiring medical attention? Is it reasonable to assume that the supplement industry can shoulder the initial required testing costs, even if the costs are ultimately passed on to the consumer? If the new guideless result in certain supplements being taken off the market, will continued demand create a completely unregulated, underground economy that will create unforeseen problems?

For such critical questions, it is imperative that the appropriate studies be undertaken to determine the effect of the proposed guidelines. It is not enough to focus on the lack of observable effects, adverse or otherwise, that result. Also, promising supplements must be studied to determine whether they have a beneficial effect on health. It seems only prudent that if certain dietary supplements have the potential to cut the costs of providing health care for those with chronic disease, then appropriate research should be applied to give us the answers we need to make wise decisions. Is the $28 billion spent in 2010 on supplements having an impact on pharmaceutical costs, which are valued at more than 12 times that amount? The proposed FDA guidelines may affect these costs, our economy, and our health; we need to thoroughly understand the issues. The health of the nation and the health of the economy may depend on it.

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Disclaimer

The opinions expressed here are those of the authors and do not necessarily reflect the positions of the National Institute on Alcohol Abuse and Alcoholism, the National Institutes of Health, or the Substance Abuse and Mental Health Services Administration.

Author Disclosure Statement

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Abbreviation Used

FDA = Food and Drug Administration