Yet another evidence-based study continues the drumbeat of alarms regarding potential risks of "dietary-nutritional supplements." Our nation has a craving for these products despite the dangers of them. The problem is further accentuated by America's lax-to-nonexistent regulation.

Published in the current *New England Journal of Medicine*, entitled "ER Visits for Adverse Events Related to Dietary Supplements," researchers from the CDC and the FDA (led by Drs. Andrew Geller and Beverly Wolpert) analyzed representative surveillance data from 63 hospital ERs over a 10-year period (2004-13). Statistical analysis projected about 23,000 visits resulting from ingestion of supplements annually, about one-tenth of which led to hospitalization.

Young adults (age 20-34) comprised 28 percent of the ER visits, who often had cardiac complaints (palpitations, chest pain) resulting from herbs or botanicals taken for energy or weight loss. Thirty-eight percent of visits involved older patients (over 65), who reported having swallowing difficulties due to "micronutrients" (ie, large vitamin-mineral pills); 21 percent involved un- or poorly-supervised children ingesting supplement products.

According to DSHEA (the Dietary Supplements Health and Education Act of 1994), supplements cannot be marketed for the treatment or prevention of disease. The estimated number of supplement products increased from 4,000 in 1994 to more than 55,000 in 2012 (the most recent year for which data are publicly available). Approximately half of all adults in the United States report having used at least one dietary supplement in the past month. In 2007, out-of-pocket expenditures for herbal or complementary nutritional products reached $14.8 billion, one third of the out-of-pocket expenditures for prescription drugs a figure that is certainly much higher today.

The Food and Drug Administration (FDA) is tasked with the oversight of dietary supplements: if a dietary supplement is found to be unsafe, the FDA can have the manufacturer remove the product
from the market. However, the regulatory framework differs from that for prescription or over-the-counter pharmaceuticals. Manufacturers of dietary supplements containing ingredients that were introduced after October 15, 1994, are required to notify the FDA before marketing and to provide a rationale for the safety of the ingredients, such as historical use. However, neither safety testing nor FDA approval is required before the marketing of dietary supplements.

According to a 2012 NEJM perspective piece [2] by America's leading expert on supplement dangers, Dr. Pieter Cohen of Harvard Medical School, the ugly facts are these: "DSHEA stipulates that for new ingredients (those introduced since 1994) manufacturers must provide the FDA with evidence supporting a 'reasonable expectation of safety.' Regrettably, this aspect of DSHEA has thus far not been enforced. Since DSHEA became law, the number of available dietary supplements has skyrocketed from an estimated 4000 to more than 55,000. It is not known how many of the estimated 51,000 new supplements now on the market include novel (post-1994) ingredients, but the FDA has received adequate notification for only 170 new supplement ingredients since 1994 undoubtedly a small fraction of the ingredients for which safety data should have been submitted. Indeed, both the industry and the FDA acknowledge that many new products have been introduced without any assessment of safety."

With few exceptions (iron pills), supplements are not even required to be sold in childproof packaging. We've been through this before and will again, until the horrendous DSHEA is modified or repealed (Sens. Harkin, now retired, and Hatch should be embarrassed, but their supplement-maker support will likely keep them from being too distressed). As we said in 2012 [3]:

_These supplement makers can market anything they want in any dose and it is acceptable. With 100 million Americans spending $28 billion annually on some type of vitamins, minerals, herbal remedies, or other dietary supplements, it is clear that many people are under the impression that supplements are both safe and effective. The current situation with supplements would be laughable if it weren't tragic. We don't know how many people are harmed by these products. And billions of dollars are being wasted on supplements for which there is no evidence of efficacy or safety._

Recent news reports about the tragic case of Lamar Odom, former NBA player, highlights the concerns we have about DSHEA and the industry in general. Mr. Odom was found unresponsive at a Nevada brothel, and his acute illness was initially attributed to an overdose of an herbal supplement.

Now at least we have a clearer idea of how many people are harmed, maybe someone will do something to regulate these products.