

Pushing back on the supplement alarmists



The release of a new study has prompted yet another frontal assault on supplements. Last week, the U.S. public was regaled with headlines like:

“Dietary Supplements Send 23K to ERs in U.S., Study Says”

“Unregulated Supplements Send Thousands to Hospital Each Year”



“Dietary Supplements Are Doing Much More Measurable Harm Than Good”

“Are Your Dietary Supplements Putting You at Risk?”

And, the inevitable exhortations to action by opportunistic politicians and fans of government regulation:

“Blumenthal: Dietary Supplements Can Be Dangerous”

“Editorial: FDA Should Regulate Dietary Supplements”

Judging by your emails and Facebook comments, many of you are looking to me to clarify the situation, as I frequently have been called upon to do in the past.

I was in damage control mode as soon as the press release thundered through the media, and I was asked to help draft this excellent response by the Alliance for Natural Health (ANH): “New Study Totally Misrepresents Adverse Events Related to Dietary Supplements”

Some points of fact about the study:

- The study DID NOT actually demonstrate, as alleged, that over 23,000 individuals were hospitalized in the U.S. in one year due to dietary supplements. In fact, it was based on a small sample of just over 2,000 reports of adverse reactions, and statistically extrapolated to yield an estimate of 23,000 across the entire country. Moreover, of the thousands of individuals who showed up at emergency rooms, only a small fraction required hospitalization—less than 10%. Of those, NONE died.
- By contrast, the frequency of emergency room visits and hospitalizations resulting from routine use of over-the-counter and prescription medications is 30-50 times higher! And, needless to say, there were many deaths.
- 21% of the ER visits involved unsupervised children under 4; kids aren't supposed to eat shoe polish or scented candles either, but they do anyway, resulting in thousands of emergency room visits annually.
- Among adults over 65, more than 1/3 of the hospital visits were due to choking on supplements (not adverse reactions to the supplement ingredients)
- Especially among younger people, use of weight loss or energy supplements accounted for 72% of supplement-related adverse events, including palpitations, tachycardia, or chest pain.
- Notwithstanding all the hubbub about Lamar Odom's misadventure in which “herbal Viagra” was implicated, sexual

supplements accounting for only 3.4% of hospital visits. Odom's case is not typical: He is said to have taken as many as 10 doses of an illicit sexual enhancer already identified by the FDA as containing significant amounts of a known erectile dysfunction prescription drug, and he may have simultaneously ingested unknown amounts of cocaine and alcohol during a marathon binge in a brothel.

It's not clear how many of the adverse reactions recorded in the study occurred in consumers taking regular supplements—not edgy weight loss, energy, or sexual enhancement supplements—AS DIRECTED. But the percentage of individuals suffering adverse consequences from taking recommended doses of supplements manufactured by responsible, mainstream companies is likely to have been negligible.

The number 23,000 sounds enormous, but we're a big country of 335 million people, over half of whom are regular supplement takers. For perspective, every year there are more than 75,000 skateboard injuries—and I haven't heard any calls to regulate skateboards!

In 30 years of experience recommending myriad supplements to patients, I can recall only three episodes of possible harm:

One occurred in a patient who was simultaneously taking Chinese herbs and several medications known to place stress on the liver. When a blood test revealed him to have elevated liver enzymes, his primary care doctor was quick to blame the supplements. After discontinuing both the drugs and the supplements, he was fine.

Another time, one of my patients who was in the habit of taking his vitamins in the dark right upon arising accidentally took 16 niacin pills, mistaking them for other supplements. He showed up at the emergency room with a hell of a niacin flush, was hospitalized for observation, but was released within 24 hours with no lingering effects.

In another strange incident, one of my patients, a supplement zealot who took handfuls of pills, accidentally choked; she was rescued by her landscaper, who noticed her distress through the kitchen window and rushed inside in time to administer the Heimlich maneuver.

True to Rahm Emmanuel's famous dictum of "Never let a good crisis go to waste," would-be regulators and politicians trotted out the tired meme that "supplements are unregulated." They urged prompt action to empower the FDA to police natural supplements the way they vet prescription drugs:

"The FDA needs to assume a greater role in making sure that dietary supplements are safe and effective before they reach store shelves. Congress should strengthen the law to give the agency more power to provide greater oversight. It shouldn't take a spate of deaths or severe illnesses for federal regulators to put consumer safety above placating an industry with far too few controls." – *Tampa Bay Times* editorial, Oct. 18, 2015

But Alliance for Natural Health Executive Director Gretchen DuBeau disputes that contention:

"Most of the stories about supplements in the media claim that nutritional supplements are not regulated by the FDA, but this is simply untrue. The FDA is fully empowered to remove any product from the market that is unsafe, misbranded, or adulterated. Supplements must contain what is on the label or the FDA has the right and obligation to remove that product from store shelves. The agency is charged with enforcing the Dietary Supplement Health and Education Act, which holds supplement manufacturers to "good manufacturing practices" (industry standards for product quality); and it may take any necessary action based on adverse event reports. Both the FDA and the FTC also have the power to stop any fraudulent advertising."

The problem is, the FDA and FTC have been remiss in removing dangerous, adulterated supplements from the marketplace. A small minority of unscrupulous manufacturers have introduced products containing harmful stimulants—or even actual prescription medications like erectile dysfunction drugs—which “fly under the radar” of regulators.

Government regulators have not done a good job of keeping these products off the market, even though they’re empowered to do so. An innocent explanation is that they’re simply understaffed and unequal to the task of playing “whack-a-mole” with all the miscreants.

A more insidious motive might be that the regulators have been deliberately hanging back, knowing that more tragedies will fuel indignation that will empower them to regulate supplements like drugs—definitely on the wish list for regulators and their allies in Congress, in the media, and in academic medicine.

This would be a tragedy for the millions of Americans who currently rely on supplements for their health. Requiring pre-approvals for new supplements, as is the goal of supplement critics, would entail untold millions of dollars for research and development, and for overcoming cumbersome bureaucratic hurdles; the expense would drive all but the largest supplement manufacturers out of business; Deep-pocketed Big Pharma companies, accustomed to schmoozing the FDA and FTC with fleets of lawyers and lobbyists, would then swoop in and dominate the supplement marketplace. Innovation would be quashed, and only the blandest supplement formulations would ever reach consumers.

Nonetheless, there are some useful take home messages from this survey:

- Supplements should only be taken as directed. Never exceed the recommended dosage unless specifically advised to do so by

a nutritionally-savvy health professional.

- In general, energy supplements, sexual enhancers, and those ubiquitous sports panaceas are a bad bet. They may contain hidden stimulants, illicit ingredients, or even unapproved prescription drugs.
- Avoid supplements whose labels are written in foreign languages or do not properly disclose their ingredients according to FDA regulations.
- Always seek out natural products manufactured by large, reputable companies that adhere to GMP (Good Manufacturing Practices) regulations
- If you're older, or have swallowing problems, stick to smaller capsules and avoid large tablets, or invest in a pill-crusher. Alternatively, seek out powder or liquid versions of the supplements you use. Always take supplements WITH food, not on an empty stomach, unless specifically directed.
- Keep supplements AWAY from inquisitive young children. Since calcium and iron supplements account for an unusually high percentage of childhood poisoning incidents, it might be a good idea for manufacturers to consider packaging them in child-proof containers.
- While it might sound self-serving, I recommend that anyone undertaking a serious supplement program, particularly those with serious health problems or those taking prescription drugs, do so under the supervision of a knowledgeable health practitioner.

I hope this article has helped to clarify the true results of this study for you, and that it has eased any hesitation you may have had about the safety of the supplements in your medicine cabinet. As always, *Intelligent Medicine* promises to keep you as up-to-date and well-informed as possible when it comes to the formulations that help to keep you in ideal

health.

Please share this article, so that others who may have been fooled by the reaction to this study can know the reality of the findings as well.