



## The Government Wants to Seize Your Vitamins

Consider the efforts by the Food and Drug Administration to make it impossible for you to buy the vitamins you want. The FDA first tried to make many supplements illegal in the early 1990s. But its overzealous persecution of vitamin makers (I was one of them) caused millions of consumers to demand that Congress block the FDA.

As a result, in 1994 Congress passed the Dietary Supplement Health and Education Act (DSHEA). While the law was far from perfect (what federal legislation ever is?), it did protect the right to take the supplements of our choice. The only way the FDA could intrude was if it could prove a supplement was unsafe. I don't know of a single case in which that happened. So for 17 years, those of us who take vitamins to protect our health were safe from government meddlers.



Unfortunately, there was a dangerous loophole in that 1994 law. While supplements that existed at the time were protected by law, the FDA was given the authority to regulate any new ingredients that were introduced after Oct. 15, 1994.

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What happened? At first, nothing did. For 17 years, the FDA took no action.

That's been a good thing, because for 17 years the dietary supplement industry continued to innovate. It discovered new ingredients and formulations and found better ways to extract and concentrate the most effective natural ingredients. As a result, millions of consumers benefited. They protected their hearts and arteries, found relief from joint pain, improved their memory, protected their prostate, and much more.

Meanwhile, some deadly dangers did exist. Pathogens like E. coli in food kill at least 2,000 people every year. Acetaminophen, the painkiller in Tylenol and other drugs, is known to kill hundreds more. An FDA researcher estimated that there may have been more than 27,000 deaths linked to the use of Vioxx before the FDA finally took the drug off the market.

Now, the FDA wants to act like the past 17 years never happened. The agency has drafted a proposal to regulate what it calls "new dietary ingredients." If this proposal is implemented, some of the most effective nutrients you take will be pulled from the market. Nutrients like resveratrol, ubiquinol CoQ10, bacopa, strontium and more.

That's not all. Under these guidelines, the FDA can define almost *anything* as a new dietary ingredient. For example:

- If a supplement includes more of an ingredient than was used 17 years ago (even something like



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vitamin C), it's new.

- If an ingredient uses a different extraction process (like baking or fermentation), it's new.
- If a supplement uses an ingredient at a different "life stage" (such as using ripe rather than non-ripe apples), it's new.
- If a supplement duplicates an ingredient in a laboratory rather than extracting it from the food (even though it's chemically identical), it's new.
- And if a probiotic formula includes a strain of bacteria that wasn't found in yogurt 17 years ago, it's new.

What would happen to these "new" ingredients? The manufacturers would have to take them off the market until they could prove the ingredients are safe — even if those ingredients have been safely used for 17 years.

What kind of proof is the FDA demanding? According to the guidelines, many companies would have to conduct animal studies using a dosage that's 1,000 times the typical dose.

I'm not kidding. The FDA wants vitamin makers to do studies for a full year, at 1,000 times the typical dose.

So a fish oil manufacturer would have to conduct a one-year study in which animals are force-fed the human equivalent of 240,000 milligrams of fish oil each and every day. Do you think this outrageous overdose might injure or kill its victim? Of course it could. And that would give the FDA all the excuse it needed to outlaw any product that contained it.

But wait, it gets even worse. If one fish oil manufacturer performed such a study and it passed, it doesn't mean that other fish oil makers can use the same data. No, sir. They are still required to go out and do their own studies before they're allowed to sell their product.

These studies are very expensive. A study like the one above typically costs \$100,000 to \$200,000 to perform. Multiply that by several ingredients in several products and you get an idea of the cost.

Say a company carries six products containing six ingredients each. It would cost between \$3.6 million and \$7.2 million in studies before that company could even offer the products for sale. For a larger company offering 50 products or more, the costs would be astronomical.

Even if the company did all of that, every penny of those new and higher costs would be passed on to you, the consumer.

Anyone on a tight budget (and that's almost all of us these days) would find the supplements they rely on becoming prohibitively expensive — if they were even on the market anymore.

Few supplement makers will be able to afford these studies. Many of them will be forced out of business. The ones that remain would still be at the mercy of the FDA. That's because there are no requirements for the FDA to approve anything. It can approve or reject anything it wants. In the past, it has rejected the majority of ingredients submitted to it.

That means most of the nutrients you buy today will be pulled from the market and never return. Those that do return will be a lot more expensive — or may be available only as prescription drugs.

This is a blatant abuse of power. What the FDA is doing is performing an end-run around the existing law. According to the law, the FDA has to prove a dietary supplement is unsafe for it to be taken off the



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market. These new guidelines turn that on its head. They are clearly not what Congress intended.

Fortunately, these FDA guidelines have not yet been finalized. All Federal agencies are required to give the public an opportunity to comment on a draft before it is made final. In this case, the FDA has given interested parties until December 1 to comment on the draft. That means there's a small window of opportunity for you to voice your disapproval.

Frankly, I wouldn't bother commenting to the FDA. The process is deliberately cumbersome. Those unelected bureaucrats don't care what you think, anyway.

Instead, please contact the people you do elect: your Congressman and your two U.S. Senators. They have the power to rein in the FDA, and they have done so before — when enough voters complained.

We may not be able to kill the monster, but we can drive it back into its cave. Whether we do is up to you.

Until next time, keep some powder dry.

**Chip Wood** was the first news editor of *The Review of the News* and also wrote for *American Opinion*, our two predecessor publications. He is now the geopolitical editor of *Personal Liberty Digest*, where his *Straight Talk* column appears weekly. This article first appeared in [PersonalLiberty.com](#) and has been reprinted with permission.

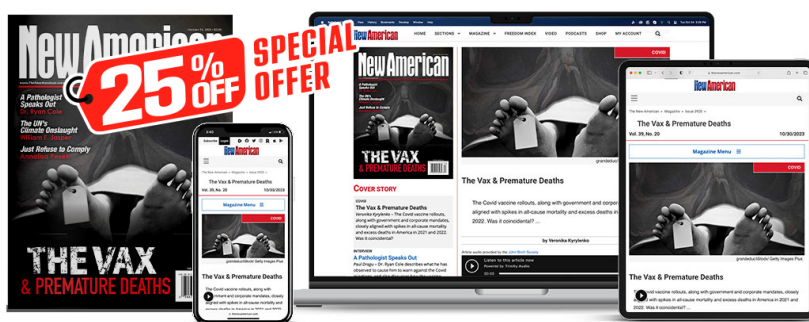


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