

## NEWS RELEASE

# Why H.R.3380 is our only means now to stop the FDA's Vitamin Grab

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## The Only Game In Town

If the Food and Drug Administration has its way, **thousands** of supplements will be removed from store shelves. We've heard this cry before, but this time it is very true. Supplements that you and I might take for granted – like resveratrol, L-GABA, curcumin, bioperine, and many more – which have not hurt a soul but only helped the health of millions, are slated for oblivion because the outlaw FDA thinks that it alone can decide whether they are safe or not. It might seem like a joke, but the FDA is dead serious.

Ignoring the law passed by Congress back in 1994, the FDA wants all new dietary ingredients (i.e., those on the market from October 15, 1994 on) to jump through regulatory hoops that Congress never intended for them. More specifically, the FDA's draft Guidance for Industry on New Dietary Ingredients (issued last July) would subject these "new" supplements to expensive, drug-like testing requirements for safety that will effectively eliminate thousands of supplements because it simply will not be cost-effective for companies to spend the millions of dollars on each dietary-supplement ingredient. Sales will not justify the expense and the products will be dropped like hot potatoes.

### The NHF's Answer

Immediately upon hearing the news last July about the FDA's latest power grab, the National Health Federation (NHF) decided that the FDA should get a taste of its own medicine. Through the astute work of NHF's lobbyist Lee Bechtel in Washington, D.C., that reflexive thought has taken substance in the form of a new bill introduced last October in the House of Representatives by freedom-oriented Rep. Dan Burton (R-IN). Called the "Dietary Supplement Protection Act" (H.R.3380), the DSPA moves the defining date of October 15, 1994, to a more realistic and recent date of January 1, 2007. In this one simple act, the bill encompasses within that previous grandfathering clause all of the "new" dietary-supplement ingredients that have appeared in that 13-year interval and that would otherwise be subject to the onerous requirements of the FDA Guidance.

Of course, NHF wanted a later date as the new grandfathering date. But the legislators pointed out that January 1, 2007, could be logically tied to the starting dates for the Adverse-Event Reporting (AER) and Good Manufacturing Practices (GMP) start dates. Their arguments in support of H.R.3380 are that the old 1994 grandfather date should no longer apply since supplements are both safer and more accountable under the AER and GMP rules and regulations.

To be honest, H.R.3380 is not a panacea for all of the problems found in the FDA's draft Guidance. But then it was never meant to be. Instead, it is a politically expedient "salami slice for freedom" that will take care of our FDA problem for now. Later, the problem will need to be addressed again; but, it does buy us valuable time right now and it will set a precedent for future legislative action.

This is the most realistic and pragmatic approach to tackling a large part of this FDA usurpation of our health rights that would otherwise occur were its draft Guidance to be put into effect. The anti-supplement and anti-health forces have been salami-slicing their way into our rights for years now. It is about time that we turned that strategy right back on them in order to keep our health rights.

### **Others' Answers**

Unfortunately, except for the National Health Freedom Coalition, National Health Freedom Action, and the Texas Health Freedom Coalition, which have thrown their support behind H.R.3380, the dietary-supplement industry and trade organizations and other health-freedom organizations have done nothing but sit on the fence. Where are the heroes of the early 1990s who led the mass charge to pass DSHEA?

Most of them are busy negotiating with the FDA! Can you believe it? The FDA could trot out the most rotten and odious piece of garbage and most players in the industry want to sit down with the FDA and figure out how to sprinkle perfume on it so that the rest of us will accept it! We have said this many times before and we will say it again: If it is garbage, then it is garbage and no amount of perfume will change it. Put it in the garbage can where it belongs!

Besides, negotiating with the FDA will at best only result in cosmetic changes. The essence of the FDA's outlaw actions will remain and a precedent set for the FDA to take even more drastic action against supplements in the future.

A few others have called for the FDA to withdraw its draft Guidance. Even the NHF, in its comments submitted to the FDA last December, urged the FDA to withdraw the Guidance. But we could never really hope that the FDA would ever be enlightened enough to voluntarily withdraw its prized Guidance. After all, this is its chance to help its pharmaceutical-industry friends by squelching supplements and the competitive threat they pose to drugs.

Similarly, the [Hatch-Harkin letter](#) written to the FDA and asking it to withdraw the draft Guidance has failed. While we salute Senators Hatch and Harkin for their noble efforts to promote freedom and help all of us, the FDA has done its predicted stalling routine and politely declined to withdraw its draft Guidance.

Those organizations such as the Natural Products Association and the Council for Responsible Nutrition, who are hanging their hats on this Hatch-Harkin letter, will be disappointed. What then?

### **The Only Answer**

So, negotiations with the FDA will not result in anything except, perhaps, cosmetic changes – fresh lipstick on a very ugly pig. The Hatch-Harkin demand letter, too, will fail. All of these industry and health-freedom players will slowly wake up to the fact that we pointed out long ago: H.R.3380 is the only answer, the only game in town, that has a hope of succeeding. But, for it to succeed, we all need to pull together to get it passed.

H.R.3380 now has three sponsors/cosponsors. It needs more. If the trade and other organizations supposedly representing your interests are too slow to take action, then those of you reading this need to give them all an appropriate kick in the butt to get behind this important bill. Now. We need more co-sponsors, we need more groundswell of support. And if we do not pass it, then the FDA will succeed. You and I will lose thousands of vitamin-and-mineral supplements that we have come to rely upon. It's time for action, not cowardice.

During a telephone call I initiated with the past Director of the Natural Products Association, I pled for NPA's support of H.R.3380. Amazingly, he told me that "some members" were concerned that H.R.3380 might "open up" DSHEA and result in unfavorable changes to that law. I told him that was cowardice and that DSHEA was being "opened up" anyway by our opponents each and every year regardless. Were we to cower in a corner, wringing our hands in fear, while our opponents continued to salami-slice our freedoms away? Or rather should we not stand up and take decisive action of our own? He had no answer.

NHF does have an answer and a decisive plan for action that we are enacting every day. We hope and trust that you agree with us, that you will take action now to write Congress, to persuade your friends, family members and organizations, to get off their knees and out of that corner. It is time now to speak with a united voice to our servants in Congress, to remind them that the FDA is our servant and not our master, and that the FDA cannot take away our health simply to serve the money interests of its puppet masters.

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