Revisionist History

A new guidance document from the FDA could threaten your health freedom.

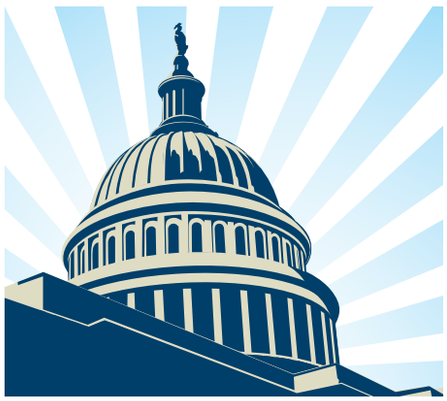
With another month comes another potential attack on health freedom. The Food and Drug Administration will soon release its revised "Guidance Document" on new ingredients in nutritional supplements. One possible outcome is that health food stores may empty their shelves of supplements that consumers have taken for decades to promote their health and well-being.

What's Old Is New Again

A New Dietary Ingredient (NDI) is a supplement ingredient that came onto the market after the Dietary Supplement Health and Education Act of 1994. Since DSHEA, dietary supplement manufacturers or raw material suppliers must notify the FDA about NDIs and demonstrate that they are safe before they can be sold to the public as supplements. The NDI process was ostensibly established to protect the public from dangerous ingredients.

When these NDI rules were established, supplement ingredients that had been in use before 1994 were "grandfathered" into place. These are the ingredients that the FDA's new guidance document could potentially target and pull from health food stores' shelves. The possible reasoning behind this move: The grandfathered ingredients never underwent the scrutiny that today's ingredients undergo in order to establish safety.

In a worst-case outcome for health freedom, new NDI guidance rules might recall thousands of nutritional supplements, removing them from health food stores, so that those supplements could be subjected to safety tests. But could such a drastic measure—carried out in the name of protecting Americans' health—ever really be necessary?



Protect Us From What?

What may be most puzzling about this NDI guidance scenario is that the ingredients in the hypothetical crosshairs would be those with the longest history of safety. In fact, the majority of nutritional supplement ingredients in use before DSHEA was enacted in 1994 have a safety track record that spans *decades*.

Consider: About 183 million people take supplements. Among these supplements are hundreds of ingredients that have been used in formulations since well before DSHEA. If these "grandfathered" ingredients had potentially dangerous effects that needed re-examining as the FDA may propose, then there would be a history of health issues associated with these supplements ... right?

Wrong. According to the early rounds of supplement Adverse Event Reporting, roughly one out of every 303,000 people may experience an adverse event from taking supplements. This should come as no surprise—dietary supplements have an overwhelming history of safety. With that in mind, the possibility of an FDA recall for "safety reasons" just doesn't make sense. Supplements are already safe, and the American public has expressed in no uncertain terms that they want to continue taking them.

The nightmare scenario of a tyrannical new FDA Guidance Document on NDIs is even more troubling when we look at the larger health picture. In contrast to the miniscule number of supplement adverse events, such events associated with drugs are dead serious: A 1998 study published in the *Journal of American Medicine* revealed that over 100,000 people perish from pharmaceutical drug side effects every year. Are the FDA's resources best used to protect us from supplements, or from pharmaceutical drugs?

Take control of your own health destiny, and remember that Congress works for you. The FDA's new guidance document is expected to be released by the end of June. Join the Nutritional Health Alliance at www.nha2011.com and find out exactly what the document contains and how it may impact your right to take supplements. If the document turns out to threaten the supplements you depend upon, then make your voice heard in Washington. For the sake of health freedom, join the NHA today! ❖

*This editorial is a public service announcement sponsored by the Nutritional Health Alliance (NHA).