



Here Come the FDA Storm Troopers!

By Jonathan W. Emord

When government denies you the freedom to choose foods that are safe and when it denies you the freedom to exchange information on the health benefits of those foods in the market, you may rightly view yourself the subject of tyranny. If you thought the “change” the Obama administration would bring to FDA would set you free, would include greater tolerance for dietary supplements (by protecting

their availability and the health information concerning them), you are in for a rude awakening.

FDA Chairman Margaret Hamburg and her aides, including the highly controversial, anti-supplement lawyer Michael R. Taylor, are implementing a strategy that will shut down approximately 1/3 of all supplement companies in the United States, reduce the availability and variety of dietary supplements, and

increase their cost. They are also expanding FDA censorship, ignoring First Amendment mandates in five federal court decisions my clients won against the agency.

In other words, FDA storm troopers are not fictive figures in some B-rated movie or comic; they’re here. The day when supplements are removed from the market is not what may happen, it is happening. The assault on freedom of informed choice, on your right to

receive truthful nutrient information, is not threatened, it is taking place. Those who love their freedom of choice cannot ignore the problem but must rise against it. Delay or denial means precious liberties will be lost along with essential products that half of all Americans use daily to protect their health.

A short time ago, FDA reversed the selenium/cancer risk reduction and antioxidant/cancer risk reduction claims that it was required to allow by federal court order. It did so unilaterally, along with a series of additional selenium and antioxidant/site specific cancer claims. It is now preparing to declare a new policy on nutrient claims that will make them all but extinguished from the American market. A new age of censorship is upon us.

Within the last few months, FDA has engaged in more prosecutorial activity and has exacted heavier penalties against sellers of supplements and homeopathic drugs than ever before in that short span of time. On the very thin evidentiary basis of less than two dozen adverse event reports (none of which was corroborated) out of hundreds of millions of units sold, FDA coerced and cajoled Lovate, makers of the dietary supplement hydroxycut, out of the market. FDA did the same to Matrixx Initiatives, Inc., makers of Zicam Cold Remedy, a homeopathic over-the-counter drug. The days of warning letters followed by corrective action plans has been replaced increasingly with direct threats of prosecution followed by

forced product withdrawals and consent decrees that put costly restrictions on supplement companies that last for years. The new approach is to attack without proof of harm and threaten greater adverse action unless the companies cave and withdraw products from the market. This is the method of jackbooted thugs, not of a people who follow the Constitution or believe in due process of law.

The new GMP regulations pose a mortal threat to the supplement industry. If you were sincere about wanting to protect the public from the very rare incidence of unsafe dietary supplements, you would require testing of finished products. But if you really wanted to achieve another objective, a reduction in the number of companies in the business and a humbling of those that remain (intimidating them into doing precisely what you wish), you would impose process controls, governing every aspect of the manufacture, holding, distribution, and sale of those products. The latter is what FDA achieved in the GMPs.

The GMPs make supplement companies maintain extensive records of every aspect of production, holding, and distribution. They are very onerous and costly. The GMPs were not invented by FDA; they were proposed by the industry itself. Industry leaders, who undoubtedly understood the anticompetitive potential of costly new process controls, recommended them to FDA through their trade association, the National Nutritional Foods Association

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(NNFA), now called the Natural Products Association. FDA adopted the rules but with a kicker: They made the rules even more onerous than the NNFA proposed, thus revealing that the lobby for the rules miscalculated its clout. The only party likely to benefit greatly from the new GMPs is not the dietary supplement industry; it's the drug industry.

Ironically, the two members of the U.S. Senate often touted as friends of the supplement industry were primary cheerleaders for FDA adoption of the GMPs, Orrin Hatch and Tom Harkin. Many in the industry believed the rules would help them curry favor with FDA. They also believed that the rules would reduce competition by driving out of existence small companies. I am sure they were right on both accounts. FDA no doubt was surprised and delighted to see that the industry gave FDA the noose needed to hang all supplement companies. FDA has stated directly in the GMP final rule that it anticipates enforcement will eliminate as much as a third of the industry.

The FDA gladly adopted the GMPs but made them so onerous that they threaten all dietary supplement companies and they invite pharmaceutical companies to enter the market void, becoming the new suppliers of dietary supplements. As I have said many times, the elephant in the room is not the dietary supplement industry, it's the drug industry. The supplement industry is like a flea on the elephant. The blind jockey riding atop the elephant

is the FDA. If the flea irritates the elephant, the jockey uses his crop to whack it. The direction for FDA is, of course, set by the elephant, not the flea. When the supplement industry brought FDA the GMP rule, it overestimated its bargaining position in the FDA universe. It is now paying the price for that miscalculation. Already FDA has enjoined over three dietary supplement companies from operating on the basis that the GMP rules have been violated. FDA threatens to conduct at least 200 GMP inspections of companies containing 20 or more employees by the end of the 2009 Fiscal Year.

In a very few years we will see many supplement companies driven out of business by the iron boot of FDA GMP enforcement. We will also see far more FDA censorship, not only of nutrient-disease claims but increasingly of so-called structure/function claims. The failure to act against these measures means that they will occur rapidly and will be followed by more of the same kind. There is no excuse for inaction if you truly believe in liberty.

Many fear taking action. Many companies in the industry fear that if they defend themselves by taking FDA to court or advocating publicly that consumers take action against FDA measures by urging passage of legislation, FDA will retaliate. It may. Nevertheless, this, like many other occasions in our history, requires bravery and defense of freedom or it will be lost. I repeat, there is no excuse for inaction.

What can be done? Litigation and legislation. The solution lies in responding to these assaults on freedom of informed choice with litigation and legislation. On the litigation front, my firm is pursuing three suits against FDA (one opposing the selenium/cancer censorship; one opposing the antioxidant/cancer censorship; and one opposing the GMPs). Certain of my clients along with public interest groups have united to sue FDA.

In addition, Congressman Ron Paul will introduce before the August recess three bills that I wrote for him that, if passed, would end the crisis. The Health Freedom Protection Act strips FDA of the power of prior restraint and of every power over nutrient-disease claims. The federal government is restricted to suit only against false claims. The Health Information Protection Act strips FTC of the power to condemn supplement companies as deceptive advertisers without the government first proving the claims made false. The Congressional Responsibility and Accountability Act prohibits any regulation adopted by an independent regulatory agency from becoming law unless Congress adopts it in the way in which the Constitution provides for laws to be adopted. Many people are shocked to learn that over three-quarters of all federal laws are not the product of their elected representatives but are produced by unelected heads of federal agencies. We are ruled by a bureaucratic oligarchy, not the republic the founding fathers

created for us. This bill would restore constitutional government.

You may share my concerns. You may love liberty as I do but wonder what you can do. There is much you can do. Indeed, without your help, we cannot succeed. The litigation is funded by voluntary contributions. It is costly. Any contribution will help us keep fighting. Here's where you can send contributions. Checks should be made payable to Emord Trust Account and mailed to Emord & Associates, 11808 Wolf Run Lane, Clifton, VA 20124. In the memo section, put Claims Appeal or GMP Appeal or both (in which case funds will be split evenly between the two funds). The names of all contributors will be kept secret.

This is not the first time, nor will it be the last, when our liberties are threatened with destruction by those who abuse power. The critical moment now upon us will, however, determine whether future generations enjoy freedom or increasingly suffer from abject slavery. May I remind you in closing of Thomas Paine's brilliant call to arms of December 23, 1776, which is poignant in our present circumstances:

*The summer soldier and the sunshine patriot will, in this crisis, shrink from the service of their country; but he who stands by it now, deserves the love and thanks of men and women. Tyranny, like hell, is not easily conquered; yet we have this consolation with us, that the harder the conflict, the more glorious the triumph. **HK***

Jonathan W. Emord is a constitutional and administrative lawyer in Washington, D.C. He has defeated the FDA in federal court a remarkable six times. Congressman Ron Paul calls Jonathan a "hero of the health freedom revolution." He is the author of three critically acclaimed books, "Freedom, Technology, and the First Amendment" (1991); "The Ultimate Price" (2008); and "The Rise of Tyranny" (2009). His books are available for purchase through Amazon.com. He is the host of Health Law and Politics on the Talk Star Radio Network. He is the 2008 recipient of the Cancer Control Society's Humanitarian of the Year award.

