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The Food and Drug Administration Has Blood on Its Hands

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Congressman Ron Paul (Texas), running for President these days, is more than an anti-war candidate; he has launched his campaign with the introduction of legislation in the House of Representatives that is likely to gain him plenty of recognition and unarguable public support. Congressman Paul, not a government expansionist by any measure, has introduced legislation that would rein in the Food and Drug Administration's absurd restrictions regarding health claims for dietary supplements.

Lest we forget, passage of the Dietary Supplement Health & Education Act in 1994, which staved off efforts by the FDA to designate dietary supplements as drugs, was buoyed by more letters to Congress than for any other prior issue facing the nation. Americans don't like government snooping into bedrooms, messing with their guns, and certainly not restricting their access to vitamin pills.

For years, the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have continued to censor and engage in heavy-handed attempts to restrict access to supplements and educational information for Americans, even when courts have ruled the public has a right to information about dietary supplements and should judge the merits of health claims for supplements for themselves rather than having the FDA make such decisions.

The Health Freedom Protection Act

The bill, H.R. 2117, the Health Freedom Protection Act, would stop the FDA from censoring truthful claims about the curative, mitigative, or preventative effects of dietary supplements, says Scott Tips of the National Health Federation, a Monrovia, California-based organization that is leading the charge behind this legislation.

In regards to this issue, it's easy to see why Congressman Paul has said enough is enough, and puzzling why other Congressman haven't lifted a word in protest to the FDA. A primary example of FDAs absurd policies can be seen in the recent debacle between cherry growers and the agency.

FDA picks on cherry growers

It began in 1999 when a peer-reviewed report in the Journal of Natural Products, published by the American Chemical Society, the world's largest scientific society, concluded that tart cherries may relieve pain better than aspirin and many other anti-inflammatory drugs. It turns out that consumption of about 20 cherries reduces inflammation in a similar manner as aspirin or Cox-2 inhibiting drugs without the lethal side effects of gastric bleeding or

vitamin depletion associated with these drugs. The molecules in cherries, called anthocyanins, work to reduce inflammation at ten times less dosage than aspirin. [Journal Natural Products 1999 Feb; 62(2): 294–6] Pills that provide concentrated anthocyanins would make it even easier to consumers to achieve these health benefits.

When cherry growers began to cite this scientific study, the FDA followed by sending a warning letter to 29 companies that market cherries, threatening regulatory action if they did not remove the scientific information regarding the anti-inflammatory properties of cherries from their websites. The FDA declared cherries to be *"drugs"* once health claims for a disease were associated with the product.

Bob Underwood, who sells capsules containing concentrated cherry paste, was quoted in an Associated Press story in 2006 as saying: *"We have the government telling people to eat more fruits and vegetables, and we have the U.S. Department of Agriculture funding some of these fruit studies, and now we have another arm of the federal government that says you can't use the research."* But the problem is much worse than government censorship. A more foreboding problem lay ahead.

Lives could have been saved

While the FDA was threatening cherry growers, it was giving approval to a drug maker for a new type of COX-2 inhibiting anti-inflammatory drug that claimed it was safer than ibuprofen or aspirin. The FDA also permitted this new prescription-only anti-inflammatory drug to be advertised on television, even though long-term safety data was not available. As it turns out, this drug wasn't any safer than aspirin and the FDA took no subsequent action against the drug maker that submitted misleading preliminary safety data in its application for FDA approval. This anti-inflammatory drug went on to cause thousands of side effects and was associated with the deaths of an estimated 20,000 Americans, mostly due to mortal heart attacks. An FDA *"whistleblower,"* Dr. David Graham, had to alert the public to this problem.

If only the public knew about the anti-inflammatory properties of cherries, thousands of Americans would have not met their early and avoidable demise. The FDA has blood on its hands regarding this issue. It should have elected for cherry stains instead.

The FDA doesn't disagree with the scientific information about cherries, but it does say that cherries have not been recognized as safe and effective when used as labeled. Do we need a double-blind placebo-controlled study to prove cherries promote health?

Jeffrey May, editor of CCH Trade Regulation Reporter (the *"publication of record"* in the antitrust and trade regulation fields), quotes Rep. Ron Paul as saying there is a need to stop *"federal bureaucrats from preventing Americans from learning about simple ways to improve their health."*

Burden of proof on government

The proposed Health Freedom Protection Act would place the burden of proof on the FTC to establish that an advertisement for a dietary supplement or a dietary ingredient is *"false and misleading and that the advertisement actually causes consumers to be misled into believing to be true that which is demonstrably false."*

The FTC has required *"supplement manufacturers to satisfy an unobtainable standard of proof that their statement is true,"* according to Rep. Paul. The bill also requires that the FTC warn parties that their advertising is false and give them a chance to correct their mistakes.

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