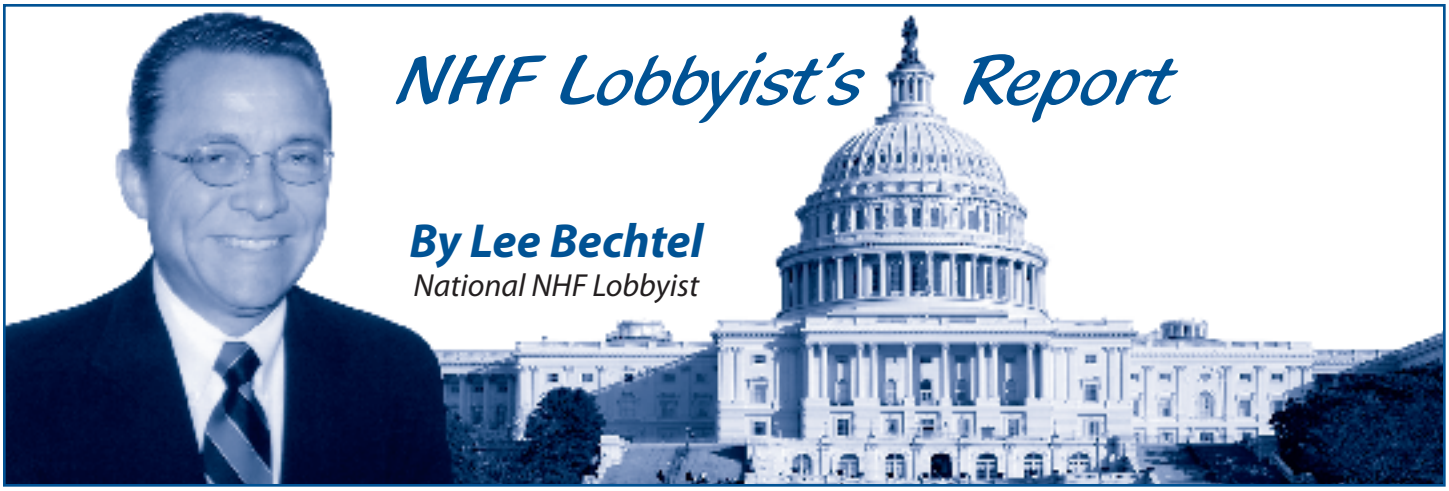

NHF Lobbyist's Report

By Lee Bechtel
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PUTTING THE FTC IN PERSPECTIVE

As the Congressional lobbyist for the National Health Federation, I keep close tabs on, among other things, all issues related to supplements, nutritional foods, and the Dietary Supplement Health and Education Act (DSHEA). My experience with the DSHEA law goes back to 1994, when Congressman Waxman and Senators Harkin and Hatch had the epic DSHEA showdown, which Waxman lost. More so than perhaps others, I am deeply aware of Waxman's legislative tactics and attempts to repeal DSHEA over the years.

For example, Waxman made an attempt in 2005 to amend the "Cheeseburger bill" so as to change the DSHEA law and require dietary supplement companies to file Adverse Event Reports (AER) with the FDA. This bill, which did not pass the House, would have also required fast-food restaurants to disclose the fat content of the cheese put on hamburgers. The Waxman amendment was overwhelming rejected.

Then, equally noteworthy are Waxman's slithery, behind-the-scenes efforts on the Durbin and Son-of-Durbin legislation. Senator Durbin's anti-DSHEA legislation was introduced in the Senate, both in a free-standing bill and within the so-called "Son-of Durbin" bill (which was an anti-DSHEA amendment to the Department of Defense spending bill), and would have mandated AER reporting for supplement companies. These attempts were two years before the AER legislation for supplements and over-the-counter drugs were finally passed by Congress and enacted into law. The NHF opposed and lobbied against all of this legislation, while the supplement industry inanely supported it.

Public Statements by the FTC and FDA

It is a matter of administrative-law fact that the FTC and the FDA have, and are, actively pursuing dietary-supplement manufacturers that are advertising and marketing supplements with claims to cure, prevent, or treat medical conditions. This is nothing new. In an October 22, 2009, speech before the Council for Responsible Nutrition (CRN), David C. Vladeck, the Director of the FTC's Bureau of Consumer Protection, presented the FTC's priorities for advertising enforcement for the dietary-supplement industry, both presently and for the near-term future. The FDA's Principal Deputy Commissioner, Joshua Sharfsten, did the same from the FDA's perspective. These speeches are public statements, and not hearsay, about these two Agencies' current activities and future plans. (*See Health Freedom News*, Vol. 27, No. 4, "Lobbyist's Report," p. 27).

Vladeck and Sharfsten said that investigations of unsubstantiated efficacy claims for health products and dietary supplements will continue to be an active area for FTC and FDA enforcement. Vladeck stated that "Some marketers of dietary supplements make disease treatment and prevention claims that far exceed the bounds of the structure and function claims that are permitted under the 1994 Dietary Supplement Health and Education Act (DSHEA)." In 2009, the FTC took 11 actions against supplement manufacturers that had national public-advertising campaigns that included claims that their products would cure or treat certain cancers. They also took action against manufacturers allegedly making false-and-deceptive claims that various nutritional supplements could treat, reduce the risk of, or prevent HIV/AIDS, diabetes,

Alzheimer's disease, Parkinson's disease, strokes and heart attacks, multiple sclerosis, herpes, asthma, and glaucoma.

The FTC's objections were that these health claims were made without having *any* peer-reviewed scientific support or publication of studies to support the claims that were being made. The defendants in one case claimed that one of their products was scientifically proven to be an effective treatment for AIDS. The products were sold primarily in a marketing vehicle that was a nationally broadcast, live, hour-long radio call-in program.

This writer is no fan of the FTC and is fully aware of the target that has been placed by the FTC on the dietary-supplement industry. However, it is important for health-freedom organizations within the community to present facts truthfully and within their correct regulatory authority context. In this regard, the FTC only regulates national advertising campaigns by dietary-supplement companies when promoting their products so as to persuade people to buy their products. Because of last Fall's FTC case against Lane Labs (which the FTC lost), future FTC injunctive orders involving supplement advertising now require settling defendants to provide more precise language to describe what type of evidence from one or two studies provided by those defendants can be used to contradict the FTC evidence used as the basis for an injunctive order against a company to cease an advertising campaign.

Changes Ahead

This means that the FTC will be changing the way in which it handles product advertising claims in the dietary-supplement and the functional-food markets. The FTC will be proposing a new definition of competent and reliable scientific substantiation, to be used in its new consent decrees, with the likely goal of extending it throughout the entire dietary-supplement industry by changing its Dietary-Supplement Advertising Guide.

In short, the FTC will require at least two "adequate" (to the FTC) and well-controlled human studies of ***the*** product or of a substantially-similar product, conducted by different experts, independently of each other. These studies will have to conform to acceptable designs and protocols with results that, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate the advertising representations being made are in fact true.

Most unfairly, however, while a company cannot rely on third-party studies to back its claims, *the FTC* can use third-party studies to refute a company's study. This is a huge change in the current interpretation of existing administrative law for advertising claims. This change will do to advertising regulation what the FDA did with its use of studies to support its ban on ephedrine alkaloid-containing supplements.

However, this development stems from the *Lane Labs* case, and is not related to the so-called "Waxman" amendment in H.R.4173. Importantly, this new development will fundamentally change the industry and not in a good way. Ultimately, this will be far more important than any FTC language in H.R.4173.

FTC/FDA Memorandum of Understanding

It is important to realize that there is an existing FTC and FDA Memorandum of Understanding (MOU) that governs the regulatory interaction between the two Agencies. This MOU covers advertising and enforcement actions against supplement and other companies. The genesis of this relationship goes back to 1971, and was updated with the enactment of DSHEA. In fact, David Vladeck's October 22nd speech included references to the FDA and FTC currently having three Working Groups to share information regarding conventional-food and dietary-supplement advertising claims. The FDA/FTC MOU is at *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm*.

The FDA and FTC MOU states that "to facilitate the purposes of this agreement, it is specifically agreed that: (*A*) With exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics; and, (*B*). The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising. In the absence of express agreements between the two agencies to the contrary, the Food and Drug Administration has primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics." So, there is a long-standing FTC and FDA partnership regarding which Agency has more controlling authority over dietary supplements. The FTC oversees national advertising campaigns, and the FDA everything else that is DSHEA related. This is the opposite of the interpretative claims made by some observers that the FTC "was under no restraints" concerning the FDA and FTC relationship.

FTC & FDA Regulatory Authority

Two claims made regarding FTC and FDA regulation of supplements were that "If the Waxman provision becomes law, the FTC will gain the power to override the limited protections for supplements that already exist under DSHEA. The FDA would still have to respect DSHEA, but the FTC would be under no such constraint." This is nonsense because the so-called "Waxman" amendment, and the interpretation given to it by these commentators, would contradict the current and actual working relationship between the two Agencies.

To those who know the Truth in Advertising law, the FTC works with the FDA against those advertising campaigns that present false or misleading health claims made in TV commercials, infomercials, and other TV and radio broadcasts for supplement and nutritional food products where the health claims go far beyond the DSHEA-allowed, structure-and-function claims. The fact that the FDA has not issued industry Guidance on allowed supplement health claims does complicate industry compliance. It also permits shady advertising promoting product health claims to consumers. At the same time, the FTC also has a shoddy record of allowing all sorts of bad operators to plague the internet with false-and-misleading claims.

The FTC also has an industry Guidance document for supplement manufacturers and health claims. In *Dietary Supplements – An Advertising Guide for Industry*, the FTC itself states that the FTC and the FDA work together under a long-standing liaison agreement governing the division of responsibilities between the two Agencies. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has responsibility for claims made in advertising, including print and broadcast ads, infomercials, and catalogs. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media.

In fact, there are numerous legal documents and public statements on the respective roles of the FTC and FDA when it comes to the regulation of dietary supplements. Even the *Advertising Guide* makes clear that, with respect to the FTC and FDA interagency working relationship, "the FTC and the FDA will generally have to arrive at the same conclusion when evaluating unqualified health claims. As the Food Policy Statement notes, there may be certain instances when a carefully qualified health claim in advertising may be permissible under FTC law, in circumstances where it has not been authorized for labeling by the FDA. However, supplement marketers are cautioned that the FTC will require both scientific support and careful presentation for such health claims." All of this information points to the fact that the so-called "Waxman" amendment to give the FTC the ability to end-run the FDA on DSHEA is, to say the least, way off base.

The FTC Industry Guidance document and the FTC Bureau Director Vladedck's speech to CRN can be downloaded from the NHF website at and *http://www.thenhf.com/government_affairs/federal/suppguidanceCRNspeech.pdf*.

In Summary

While the FTC has sought increased regulatory power through H.R.4173, that power has been thwarted as against supplement companies. The real threat has come through the FTC's Guidance Document, with its "heads I win, tails you lose" philosophy of scientific substantiation of health claims.

Too, the wild claim of a few that, through H.R.4173, the FTC would circumvent and subvert DSHEA is unfounded as a matter of law and as a matter of existing regulatory understanding and interaction between the FTC and the FDA. Such a claim makes great copy; but when held up to the daylight, it evaporates into nothingness.

As most know, DSHEA covers a range of dietary-supplement issues, including new supplement products, products with new dietary supplement ingredients, pre-market approvals, Good Manufacturing Practices for supplement manufacturers, and reporting of adverse medical outcomes associated with supplements. The NHF has a long history of opposing FDA positions and actions, in both the legislative, regulatory, and Codex arenas. NHF was even a named plaintiff in the original *Pearson v. Shalala* case involving the FDA's denial of structure-and-function health claims. However, to imply that the FTC would, with the adoption of the so-called "Waxman" amendment, circumvent and subvert DSHEA is disingenuous to the health-freedom community. More Nanny State control is never good, and should be opposed; but we need to address real threats, not imaginary ones. HFN