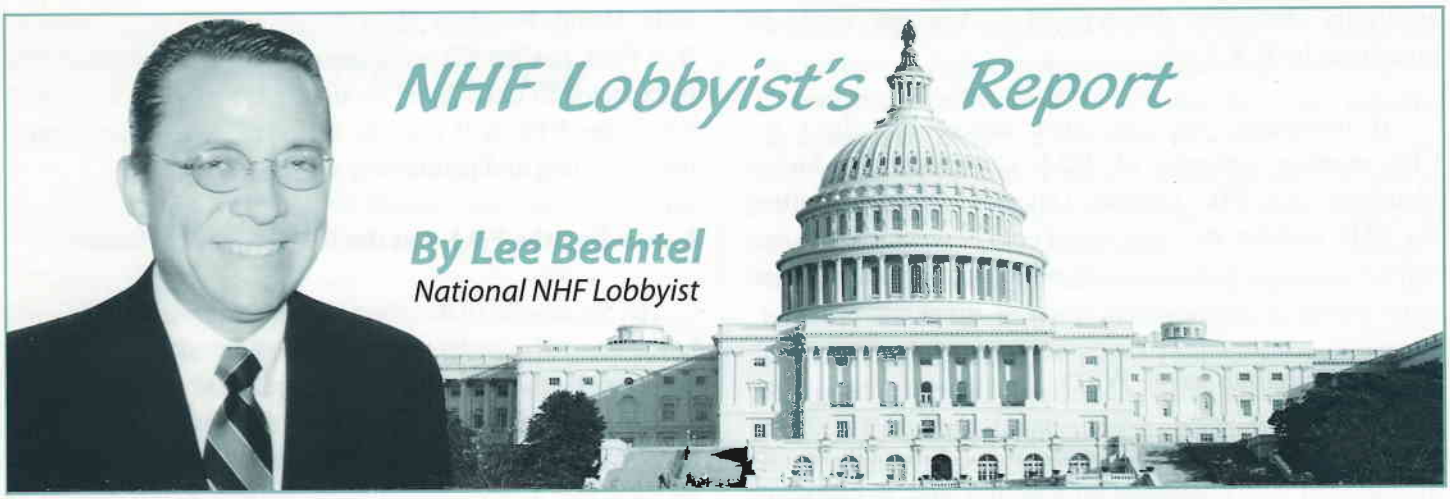

NEW HEALTH FREEDOM ISSUES IN 2010

Since the beginning of the 2009 session of this Congress, we were expecting the Pelosi, Waxman, Dingell, Reid, and Durbin Democratic leadership in Congress to pursue anti-health-freedom, pro-big-government, and pro-bigger FDA and FTC command-and-control legislation and regulations. Unfortunately, our expectations have been met and exceeded, and they will continue into 2010 when Congress reconvenes on January 19, 2010.

FTC and FDA 2010 Dietary Supplement Regulatory Priorities

The regulatory heads for dietary-supplement claims and advertising for the Federal Trade Commission (FTC), David Vladeck, Director of the Bureau of Consumer Protection, and the Food and Drug Administration's (FDA) Principal Deputy Commissioner Joshua Sharfstein, recently spoke at the annual meeting of the Council for Responsible Nutrition (CRN). Curiously, while the CRN has been a supporter of the Dietary Supplement Health and Education Act of 1994; it has also supported the enactment of legislation and FDA regulations that undermine that Act by regulating supplements more like drugs and increasing their costs. But then, remember, the CRN of today has several pharmaceutical-industry members and other members who do not mind at all closing the opportunity door behind them so as to exclude small- and medium-sized competitors.

The two speakers outlined both Agencies' regulatory-enforcement priorities for 2010. There is to be, they said, increased cooperation between both Agencies for enforcing bureaucratic standards of substantiation for supplement advertising. For the FTC's part, after new guidelines are issued in the coming months, it will not just be the ultimate advertiser that will be held liable for the substantiation of a health claim for a product. All of those companies which are the sources for the advertising claim (including the ingredient suppliers and any contract manufacturers) will also be held responsible by the FTC for advertising claims. Any and all advertisers will be held to the same tough standard of substantiation of competent and reliable scientific evidence, including advertisers who use personal endorsements or testimonials.

As a result of the recent Federal-court decision against the FTC in the *Lane Labs* case, future FTC injunctive orders on supplement advertising must provide more precise language to describe what type of evidence is required to meet the conditions of an injunctive order. Apparently, from FTC's perspective, evidence from one or two studies contradicting or inconsistent with the FTC evidence will not be sufficient in the future to substantiate an advertising health claim – even if those studies are performed according to standard, reliable, scientific protocols. This is precisely the type of arbitrary FTC action that would be prohibited by H.R.3394 and this is precisely why the FDA's and FTC's new proposed line of action of claims substantiation might sound reasonable but in fact will not be because of those Agencies' capricious enforcement methods.

In 2010, FDA enforcement activities will concentrate on those supplements the FDA bureaucrats feel pose serious health risks because they carry label and/or labeling claims for serious diseases. Sharfstein also indicated that the FDA will focus on supplement products that have been spiked with pharmaceutical substances being masked as a supplement ingredient. The FDA is already pursuing criminal investigations in this area.

Most importantly, Sharfstein indicated that in 2010, the FDA will use the existing dietary-supplement Good Manufacturing Practices (GMP) regulations and the supplement Adverse Event Reporting system requirements as its tools to bring FDA enforcement actions against end-source supplement manufacturers or suppliers. When

arbitrarily employed, this type of FDA action would be prohibited by H.R.3395.

If interested, you can view and/or download the CRN-meeting remarks of FDA Commissioner Joshua Sharfstein and FTC Director David Vladeck by visiting the NHF website at: *www.thenhf.com/government_affairs/federal/SharfsteinCRNRemarks.pdf* and *www.thenhf.com/government_affairs/federal/VladedckCRNRemarks.pdf.*

U.S. Participation in the WTO

The World Trade Organization (WTO) is a multi-country international treaty/organization that has and is exercising undue influence over trade and domestic commerce in the United States since it joined as a member in 1994. The stipulated WTO requirements and authorities extend to the FDA and color its participation in the Codex Alimentarius (Codex) process as well as in the implementation of international food-harmonization and dietary-supplement standards. The NHF strongly objects to continued U.S. membership in the WTO.

The process for non-renewal of U.S. membership in the WTO occurs once every five years. The United States may withdraw from the WTO by exercising the procedures set forth in the WTO Agreement. Withdrawal requires a six months' notice to the WTO by the U.S. President, the submission of a report by the President to Congress recommending his position on participation, which is required, and then passage of a Congressional Withdrawal Resolution, with final approval/disapproval by the President.

Withdrawing from the WTO will once again be on the agenda in 2010 and is a Congressional action that the NHF strongly supports. The House Committee on Ways and Means must consider any joint withdrawal resolution that is introduced within 45-days or face automatic discharge from the Committee, pursuant to House rules. After the 45-day period, if not discharged, any Member of the House may bring it to a vote on the floor of the House. A joint resolution of withdrawal must be passed by both Houses of Congress, and signed by the President within ninety days of introduction to be effective. What is not well known is that even if enacted (i.e., signed by the President or a Presidential veto is overridden), a resolution does not actually require the President to begin withdrawal actions.

In 2000, the House voted down a withdrawal resolution. In 2005, the House-approved resolution died in the Senate. The legislative/political environments in both Houses of Congress, as they were in 2009, present us with up-hill battles for pushing through any withdrawal resolutions. In previous efforts, a strong health-freedom supporter and an NHF Health-Freedom Hero Award winner, Congressman Ron Paul, has led the withdrawal effort in the House. This is expected to once again be the case; and is an issue with which the NHF will need its members' active, grass-roots letter- writing and petitioning assistance.

Expanding the FDA and the Reimportation Dance

By the time NHF members read this, President Obama will have released his budget for 2011. The final numbers are being reviewed by the Office of Management and Budget (OMB), but Congressional Appropriations Committee staff indicate that the spending request for the FDA will again be substantially increased by at least $750 million dollars, to a total of $3.8 billion per year. Most of the increase is proposed to be spent on FDA "infrastructure," i.e., more bureaucrats and internal systems for food safety and drugs. Surprisingly, there is also an administration-backed initiative to create an FDA-regulated system to allow for the "safe" re-importation of less-expensive prescription drugs from Canada and European countries.

Remember that Obama supported re-importation as a Senator and during his Presidential campaign, but then made a deal with the big pharmaceutical companies to not support or include re-importation rights in any Congressional health-care reform legislation. And, in fact, neither the House nor the Senate reforms bills being reconciled in a Conference committee allow reimportation. The Senate even recently voted down Senator Dorgan (D-ND)'s bill that would have allowed the reimportation of less-expensive drugs into the United States. This bill, too, was opposed by the Obama Administration and most Senate Democrats. However, people involved with the big pharmaceutical companies are upset that the Administration is apparently now breaking its deal not to change current FDA policy that prohibits re-importation of cheaper drugs. These companies are already planning how to lobby Congress against this Federal policy change. Again, the Administration's policy change is not yet official and still must pass muster with the OMB; but this new proposed initiative reverses the long-standing FDA/pro-drug cartel position against re-importation.

Because this initiative has yet to be finalized at the time of this writing, the jury is still out. While this may be good for health-freedom advocates (the NHF has supported re-importation) and many Americans, it also shows that the Obama administration is willing to break its promises purely for political gains. In this case, it is to help reverse the downward trend in the President's approval ratings stemming from the overall public's rejection of the Congressional health-care, government take-over, reform bills, continued massive spending and increased taxes, and the "bigger government is better" government leadership philosophy.

Other 2010 Congressional Bills and Regulations

There are many other Congressional carry-over bills that the NHF supports and opposes under consideration that can be viewed on the NHF website at *www.thenhf.com/government_affairs_federal.html*. These have been discussed in detail in previous Lobbyist's Reports.

A brief comparison of the ***key*** differences between the House and Senate health-care reform bills, which still remain to be resolved, appears immediately below. Final passage and enactment into law is expected. There are, however, several strong constitutional issues not listed in the Table that are also expected to impact the final bill's full implementation in 2013 or 2014, except for Federal tax increases which are effective starting in 2010.

Comparison of Key Differences to Be Reconciled Between the House and Senate Passed Health-Care Reform Bills

	House H.R.3962	Senate H.R.3590
Name	Affordable Health Care for America Act	Patient Protection and Affordable Care Act
Individual Requirements	Everyone but a small group of exempt persons will be required to obtain health insurance. People who do not get coverage will pay a penalty fee of 2.5% of adjusted gross income.	Everyone except a small group of exempt persons will be required to obtain health insurance. People who do not get coverage will pay a fine of $95 in 2014, which will rise to $750 or 2% of income by 2016.
Illegal Immigrants	Illegal immigrants could participate in the exchange, but could not receive Federal subsidies.	Illegal immigrants could not participate in the exchange.
Public Plan	A new government-run public plan will be offered on the exchanges to compete with private insurers. The government would negotiate payment rates with medical providers.	The bill does not include any public insurance option. Instead, the Federal Office of Personnel Management would contract with private insurers to offer at least two national health plans on the exchange, at least one of which would have to be a non-profit plan.
New Taxes	A 5.4% surtax would be levied on individuals who earn more than $500,000 per year and families that earn more than $1 million. A new 2.5% excise tax would be levied on medical devices.	The Medicare payroll tax would increase from 1.45 to 2.35% for individuals and families. A new tax would be levied on high-value insurance plans worth more than $8,500 for individuals and $23,000 for families. New annual fees would be levied on health-care companies, including drug makers, medical device manufacturers, and insurance companies, allocated by market share.
Abortion	Private plans offered on the exchange would not be allowed to cover abortion services if they take any customers who receive Federal subsidies. The public plan would not cover abortion services.	Health-care plans could choose whether or not to cover abortion. But States would be allowed to bar plans offered on the State-based insurance exchanges from offering abortion coverage.

Although we have taken flak from some in the health-freedom community for our opposition to this supposed health-care reform, we do not apologize for our consistent stand in support of health freedom. As time passes and this monstrous violation of our civil and health-freedom rights continues to unfold, more and more individuals will awaken to the true threat that it is.

The NHF is committed to following and lobbying on the full range of Congressional and Federal agency regulatory issues impacting health freedom, both domestically and internationally, as well as to work directly and through NHF's many country organizations to protect health freedoms in Europe and elsewhere.