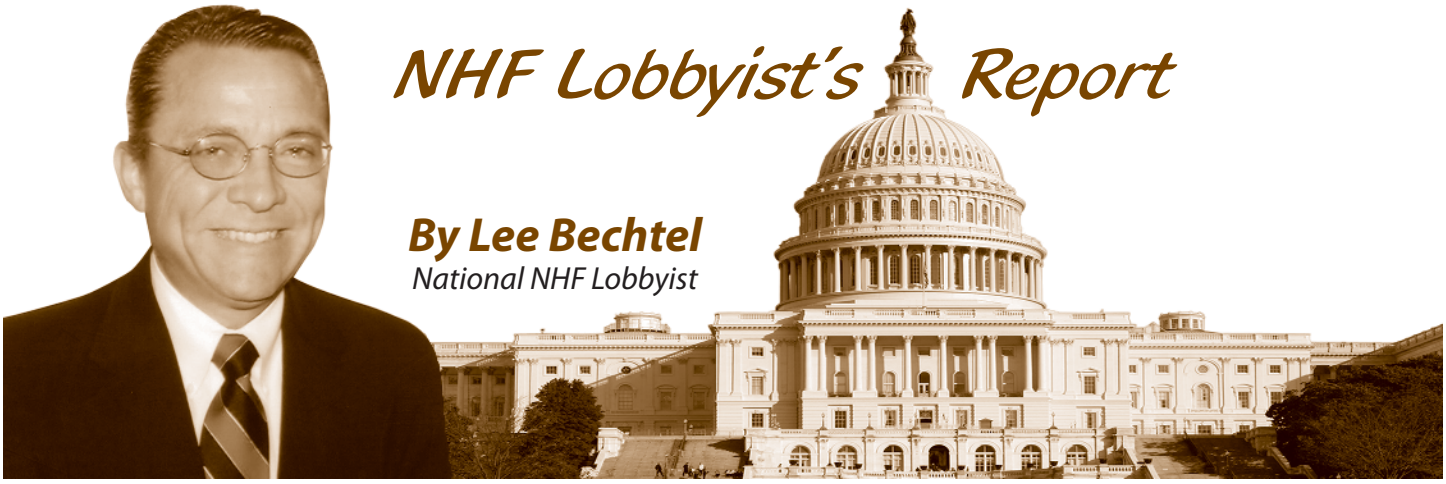

NHF Lobbyist's Report

By Lee Bechtel
National NHF Lobbyist

IT'S ALL ABOUT FDA USER FEES

The Democratic-controlled Congress and their leadership have put government-run, universal healthcare on hold for the rest of this year. The Kennedy/Durbin/Dingell/Waxman axis is apparently waiting until next year to implement Obama-Care or Hillary-Care. This is unless John McCain wins the Presidential election, or Republicans regain control of either house of Congress. The first could happen, but the second would be a big political stretch. The health-issue focus has shifted instead to the Food and Drug Administration (FDA).

Watch for the Code Words

In the political lexicon, "transforming" or "modernizing" the FDA are code words for spending more taxpayer dollars and giving the FDA more power to control people's lives and the products it regulates. On the money front, a Task Force headed by former FDA Commissioner Mark McCullen released a report recommending ***a billion more*** in spending in order to hire more FDA bureaucrats, mostly for the FDA's drug functions. I recently received an email from the FDA informing me that the FDA is in the process of hiring 300 new bureaucrats over the next two years. Of course, every Federal agency always wants more of our money. Historically, though, Congress has granted no or only modest increases in the FDA's annual budget. So, the FDA has increasingly relied upon industry "user fees" paid to the FDA to make up its budgetary shortfalls. Until now, the imposition of FDA user fees on dietary supplements and nutritional foods has been off the table.

FDA Globalization Act

As of this writing, there are an incredible 305 bills pending in Congress dealing with the FDA – everything from domestic pet turtles to tanning machines, prescription drugs, and other issues. The latest health-freedom legislative threat of any importance, however, is the "FDA Globalization Act," sponsored by Rep. John Dingell (D-MI), Chairman of the House Energy and Commerce Committee, and supported by his colleague Rep. Henry Waxman, in the House, and an identical and yet to be numbered draft bill sponsored by Senator Kennedy in the Senate.

These bills would require domestic and foreign food companies to register each year with the FDA, establish an army of inspectors to monitor companies that manufacture nutritional foods, supplements, drugs, and medical devices abroad, and would institute ***new*** yearly FDA "user fees" assessed against these companies to pay for this expansion of FDA command and control. For example, foreign-based companies that import supplements for distribution in the US would be required to register products and production facilities every year, and to pay a user fee. As a bonus, this legislation also gives the FDA one-sided legal authority to recall contaminated "foods" as "unsafe medications."

As pointed out on the NHF's Government Affairs webpage (*www.thenhf.com*), the bill as introduced does not specifically exempt dietary-supplement and nutritional-food producers and manufacturers from registration and user-fee requirements. This is not surprising given the two anti-supplement Congressmen who are primarily behind the bill.

Conflicting FDA Authority over Supplements

Not surprisingly, the FDA Globalization legislation would create conflicting FDA regulatory authority, which is never good. As introduced, the legislation is at odds not only with the consumer-safety requirements already mandated by DSHEA but the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) as well, the latter of which Congress passed into law (PL 109-462) in 2006. The DSNDCPA was known more commonly at the time as the AER bill and was strongly opposed by the NHF (although supported by some industry members intent on "proving" that supplements are safe, a fact already well-documented). Regardless, the FDA has a sleazy history of subverting, or trying to subvert, the Dietary Supplement Health and Education Act (DSHEA); this new proposed law would just make it even easier.

When Congress passed the FDA Amendments Act of 2007, the NHF was the only health-freedom group that actively lobbied in Congress to prevent Senator Dick Durbin

from adding his Food Safety Agency to the legislation, and lobbied to get clarification that the Durbin Food Registry amendment that was added instead to the bill did not apply to dietary supplements and nutritional foods. This was the Hatch-Harkin colloquy on the Senate floor when the Senate passed its version of the bill. The truly bad situation, from the policy and legislative perspective, is that the FDA already has the registration requirement for supplements in place as a result of the AER law, but existing laws do not grant the FDA the authority to charge user fees. In short, the game is still on with the anti-supplement and anti-health-freedom Democratic leadership members of Congress.

There is more. On April 24th, Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition (CFSAN) at the FDA testified before the Dingell Committee on the bill. At no time during his testimony was any reference made to excluding supplements and nutritional foods from the scope of the Globalization bill. Of course, neither Dingell nor Waxman bothered to ask him about this issue. This was not surprising. If anything, it is proof positive that the "Globalization" bill, insofar as supplements and nutritional foods are concerned, is just another attempt by the anti-health-freedom Democratic leadership axis to subvert DSHEA, with the complicit help and approval of the FDA.

This complicit help and approval of the FDA has plenty of historical and factual merit. Being charitable, all of this borders on professional incompetence by FDA personnel and shows the usual political subterfuge and usurpations being employed by the FDA and Congressional Democrats to establish supplement and nutritional food user fees as a result of the imported conventional food and pet-food safety snafus of the FDA. What we do have is the long anti-supplement history of the FDA on a number of dietary-supplement issues and its efforts to regulate supplements as if they were drugs. Then, there is the passage of the AER law with its drug-like treatment of supplements. There is the Congressional intent in the Senate from last year on this ***very same issue***. Then, we have the Director of CFSAN at the FDA not even knowing (or pretending not to know) that he also has the authority granted under the DSHEA and AER laws, and certainly not explaining the conflicting legal requirements presented by the Globalization bill with these laws. It is either intentional or the Forrest Gumpism of – "Stupid is as stupid does"?

Honestly, I believe that it is intentional and that the players believe that the health-freedom community will not learn about it, nor care enough about it to make a concerted effort to oppose user fees. I hope this is not the case. I do know that as of this writing, the Natural Products Association has not issued a position on the legislation. Neither have any of the actual health-freedom groups for consumers, except for the NHF.

What could this mean for health-freedom advocates? If enacted as introduced, it means more FDA command and control with US taxpayers and foreign- and domestic-based supplement manufacturers and/or distributors, and consumers ultimately footing the bill through company pass-down of user fees. Not having exemption language in the Dingell bill will also lead to less access to nutritional foods and dietary supplements.

In my view, in its current form, this legislation will have a meaningful impact on health freedom of choice. The NHF needs your help and the health-freedom community needs to get behind our lobbying efforts to obtain clarification/exemption language included in the Globalization legislation.

Dietary Supplement Medical Expense Tax Parity

On the positive side, at this point, there are a number of Congressional cosponsors for the "Dietary Supplement and Healthy Meal Replacement Tax Parity Act of 2007" (H.R.1107), a bill that would create a tax deduction for dietary supplements taken for medical conditions and which bill the NHF supports, has increased to twenty-four Representatives. Sponsored by Congressmen Edolphus Towns (D-NY) and Ron Paul (R-TX), the bill is still pending in the House Ways and Means Committee.

Visit the Government Affairs page on the NHF webpage at *www.thenhf.com* to view the Staff/Member Memo from Dingell on the FDA Globalization legislation, and send a letter to your Congressional representatives on this and other health-freedom bills currently pending with Congress. Without NHF members' lobbying support, our Federal and State health freedoms will be controlled by others.

As the oldest and best-respected health-freedom group on Capitol Hill, the NHF continues to be the credible source of objective assessment, and proactive actions on Congressional legislation and FDA matters that have meaningful impacts upon our freedom-of-health choices and access to dietary supplements and nutritional foods. HFN

"The problem isn't too much money in politics; it's too much power in government. As long as government has the favors to dispense, people will find ways to get the money to it."

— *Chip Mellor*