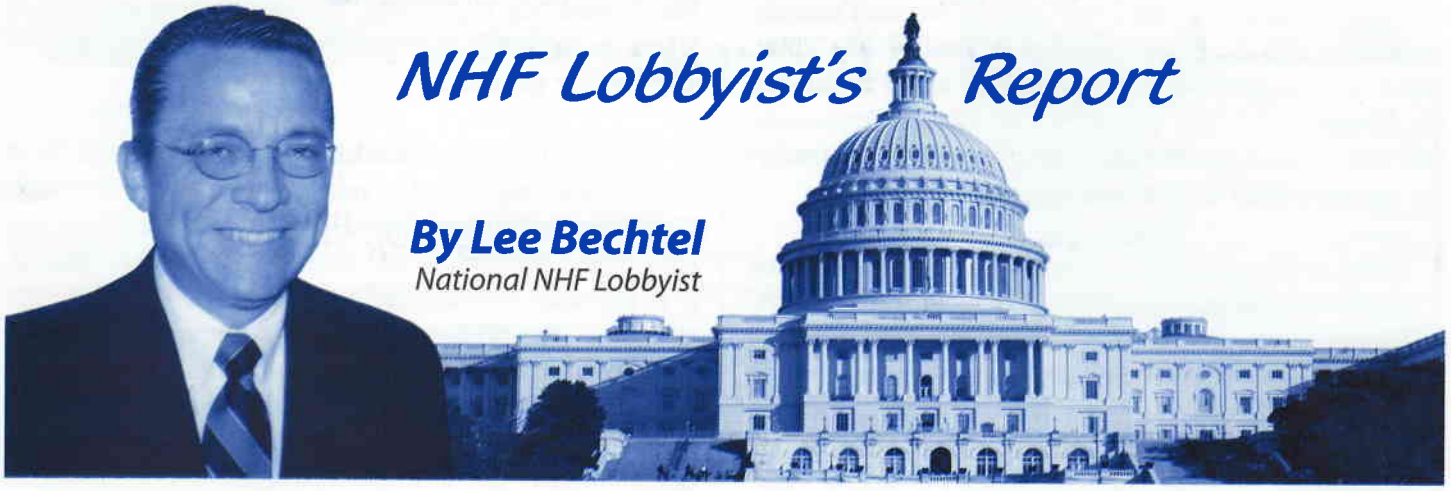

NHF Lobbyist's Report

By Lee Bechtel
National NHF Lobbyist

OBAMA HEALTH CARE, CODEX, AND SUPPLEMENT SAFETY

When it comes to congressional politics, I am not particularly a fan of reading tea leaves and making statements on what is going to happen based upon past experience and present indications – even though I successfully predicted that Henry Waxman would take the Chairmanship of the House Energy and Commerce Committee away from John Dingell. In my Winter 2008 *Health Freedom News* article (Vol. 26, No. 4, pp. 26–28), I looked ahead at the health-freedom agenda for this Waxman/Dingell/Durbin/Kennedy-led Congress. Thus far, these prognostications have mostly been correct. But what was incorrect was the speed with which the Democratic leadership in Congress, backed by President Obama, would be moving toward socialized medicine.

Federal Health Insurance Moving Fast

In the recently-passed and signed-into-law American Recovery and Reinvestment Act, the so-called "Economic Stimulus" package included the creation of a Federal Coordinating Council for Comparative Effectiveness Research (CER). This was considered in the last Congress but not acted upon. The creation of the CER was the first step toward fuller government control over health-care treatment options for all Americans. The Stimulus law included $1.1 billion – yes, billion – dollars for its activities. The Council is directed to "assess the comparative effectiveness of health care treatments and strategies and develop medical outcomes data analyzing the effectiveness and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions." In other words, this means basically any and all forms of health care, preventative or diagnosed, available to Americans and practiced in our country.

The CER is headed by the Secretary of the US Department of Health and Human Services (HHS) and is composed of 15 Senior Federal Officers from seven Federal agencies, including the FDA and Medicare. By law, no fewer than fifty percent of the senior Federal-agency representatives must be physicians. There will be no broad-based input from the private sector or from different physician (either conventional or CAM specialist) professions, consumers, disease-based or patient-advocate groups, medical-treatment companies, drug companies, or the like. In place of real-world representatives for health care, Federal-agency physician bureaucrats will be directing cost-effectiveness research, collecting medical outcomes data, while other bureaucrats will be analyzing and making recommendations to President Obama and Congress on what forms of medical care should or should not be covered when government-run health care is imposed upon U.S. citizens.

This was just the start of the assaults on individual medical-care decision-making that will occur in the future. In his first budget, President Obama requested over 600 billion dollars for a "federal health care reform fund," to be used for transitional payment to a national health-insurance program. With the expected passage of the Federal health-care reform funding in the budget, regardless of the billions of US taxpayer dollars authorized by Congress to be spent, the only remaining decisions the Congressional Democratic leadership will have to make will be how to structure a State-sponsored, national health-insurance program for all Americans, and the names of the new Federal agencies that will be created to managed it. This is also expected to pass Congress later this year. National, or government-run, health insurance and Federal control over health-care freedom of choice is rolling out faster than many, even those in Washington in the know, had anticipated.

Senator Kennedy and Congressman Waxman recently announced that they have both set the end of July 2009, before the August Congressional recess, as the target date for House and Senate passage of an Obama/Democratic national health-insurance plan bill. So, look to September for this to heat up in Congress, if not before.

Also in March, the 15 members of the Coordinating Council for Comparative Effectiveness Research (CER) were appointed. This body, despite assurances to the contrary, establishes Federal government intrusions into medical decision-making. Of the 15 newly appointed members, 9 are federal-agency bureaucrat MDs, 3 are federal-agency bureaucrat PhDs, 1 is a bureaucrat EdD, and 2 are federal-agency bureaucrat JDs. Importantly, none have any background with alternative or naturopathic medical practice. It is interesting to note that one member, an attorney, served on the Obama health-care task force. This person is a political appointee at HHS. A list of the members and their professional biographies is available by going to the following web address: *www.hhs.gov/recovery/programs/os/cerbios.html*.

Making FDA Toe the Line on Codex

By the time NHF members read this, Congressional Representatives Dan Burton and Diane Watson are expected to introduce the "Dietary Supplement International Protection Act" (Bill number as yet to be assigned). This legislation would require the Food and Drug Administration (FDA), which represents the United States and its citizens at Codex Commission and Committee meetings, to follow existing United States law against harmonizing our laws with Codex guidelines and standards. For many years now, FDA attendees at Codex meetings have been pushing for harmonization and further restrictions upon dietary supplements, all in violation of existing U.S. law.

The Food and Drug Administration Modernization Act (FDAMA) of 1997 exempted dietary supplements from international harmonization standards. For over ten years the FDA has refused to publish regulations reflecting this clarification of the law and Congressional intent on exempting supplements and other vitamins and minerals from harmonization. The Codex bill would keep Congress involved in the FDA review process on any future Codex evaluations or approvals of international guidelines or standards impacting U.S. supplement laws. It would also reject the 2005 Codex Guidelines on Vitamins and Mineral Food Supplements. Without this bill, there will continue to be a lack of FDA transparency and accountability to both Congress and the public when FDA Codex representatives participate or agree with what other international FDA-like bureaucrats might believe is in the best interests of US citizens for the sake of international harmonization of standards or guidelines.

The NHF and its President and Legal Counsel, Scott Tips, have a long record of protecting supplements against Codex, and with presenting NHF views and concerns before the Codex Commission and various Committees. Indeed, it is the only health-freedom organization with the right to do so. The NHF took a hand in helping to draft and refine the language of this Bill; it also of course supports and is actively lobbying on its behalf. In particular, I am actively working with members of Congress and other health-freedom groups to get it passed.

If signed into law, the bill would put an end to yet another long-standing FDA abusive practice of wrongfully restricting U.S. consumer access to vitamin-and-mineral products and other supplements. It would also ensure that those laws Congress has already passed will not be unilaterally and flippantly superseded by FDA bureaucrats with the adoption of guidelines or standards developed within the Codex Alimentarius process, or in FDA concert with other international harmonization organizations.

Federal Food Safety Agency Reintroduced

Representative Rosa DeLauro (D-CT) has reintroduced the "Food Safety Modernization Act of 2009" as H.R.875, a bill to remove all of the dietary-supplement functions and authorities of the Center for Food Safety and Applied Nutrition (CFSAN) from the current FDA and create a new Food Safety Administration (FSA) within the Federal Department of Health and Human Services. The new bill has 36 cosponsors and would also rename the FDA the Federal Drug and Device Administration. To the extent that it would remove dietary supplements from the jurisdiction of the FDA, this new bill, as introduced, is better than the previous Durbin/DeLauro food-safety agency bills introduced in the last Congress since the old bills envisioned FDA continuing to control dietary supplements under a drug-focused system of control and management. An identical Senate bill has yet to be introduced at the time of this writing.

Having reviewed the DeLauro bill line by line, as introduced, in this lobbyist's view, the transfer of the regulation and enforcement of supplements, vitamins and minerals, and herbal products out of the current FDA would be an improvement compared to the current regulatory structure. The alleged and real continued inside influence of pharmaceutical interests on supplements would at least be lessened and an institutional barrier to regulating supplements like drugs would be established, where one

does not currently exist. It would also take several years to reintegrate programs into a new agency structure, potentially taking resources away from and diminishing the activities against supplements as the newly named and created agency focuses more on traditional/conventional food safety issues.

The DeLauro bill will be considered by the House Energy and Commerce Committee and its Chairman, Henry Waxman (D-CA). The Durbin/Waxman control over the legislative processes on both sides of Congress, however, cannot be ignored and the latest information is that H.R.875 will be blended into H.R.759, the Dingell "FDA Globalization Act," which the NHF opposes as well. The Dingell bill does not even have the slight benefit of segregating out supplements from drugs; it would leave supplements with drugs in the renamed and restructured FDA, to be treated as drugs. At present, there is no action on either of these two bills, but this could change.

Regardless, the NHF ***opposes*** these two Bills because both propose total Federal government control over and tracking of food production, distribution, and sales supposedly to ensure "food safety" but which powers in fact would be unconstitutional and unnecessary. This new agency would empower the government to regulate food production at all levels, up and down the chain of production. For violations, the bill provides for criminal prosecution for producers, manufacturers, and distributors who fail to comply with these regulations, and punitive property seizures and large fines of as much as $1 million for each offense upon conviction.

The supposed reason for the launch of this bill is that all of these burdensome regulations – heaped on top of already-existing, unevenly-enforced burdensome regulations – will somehow make the nation's food supply safer. Standards would be set and legions of bureaucratic enforcers would descend upon food establishments of all sorts, including "food production facilities" comprising even the smallest farms, ranches, orchards, and poultry-raising operations. Recordkeeping would be mandated and costs of compliance would soar resulting in a boom for professional accountants and lawyers, who would of course be in increased demand.

The H.R.875 bill text can be viewed online at *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h875ih.txt.pdf*. NHF members should continue to lobby Congress on these legislative matters.

Senate and House Democrats Attempt BPA Ban

Two bills (S.593 and H.R.1523) have been introduced, which propose to ban the use of Bisphenol A (BPA) in the liners of beverage and food containers. S.593 is currently being sponsored by Senators Diane Feinstein (D-CA) and Chuck Schumer (D-NY), while H.R.1523 is being supported by Representatives Edward Markey (D-MA), Tammy Baldwin (WI), Maurice Hinchey (NY), Mazie Hirono (HI), and Janice Schakowsky (IL).

Bisphenol A has long been considered by many to be a poisonous or deleterious substance, the use of which in hardening plastics could render the contents of food and beverage containers injurious to human health. As a result, six major US baby-bottle manufacturers have already announced plans to stop using the chemical even though an FDA-conducted safety assessment completed last year concluded that "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults." Yet, the NHF has little confidence in the FDA to do anything right, now or ever, when it comes to passing on safety, particularly in this case where BPA is so ubiquitously present as a contaminant in human and animal fat tissues throughout the World.

While passage of this legislation might potentially impact vitamin and dietary supplement manufacturers and distributors, its prospects are not close at this stage of the Congressional process. None of the conventional food or beverage manufacturers in Washington have a position on the bill. Second, none of the chief backers – Feinstein, Schumer, and Rep Markey – to date, sit on the appropriate committees. The fact that the FDA has concluded that its use at current levels does not pose a threat may be viewed as good or bad in terms of public health safety risk. As of late, the FDA does not have much credibility with members of Congress. For once, though, this is a belief shared by both members of Congress and the NHF alike.

As a free-standing bill, chances are slim to none on Congressional passage the rest of this year. However, the bill will carry over into next year – most likely, though, as an amendment to any one of a number of FDA bills that would present a vehicle for congressional enactment. Bill sponsors will have to go to the authorizing committee for approval even if adding it as an amendment on the floor of the House or Senate. This prospect for legislative action is also contingent upon a major public-health calamity arising, like the peanut butter or pistachio nuts matters, or a major scientific study rebutting the aforementioned FDA position on the use of BPA. The NHF will be closely following developments with this legislation because its members are quite concerned about the contaminating presence of BPA in food and beverage containers.