



NHF Lobbyist's Report

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FROM "SMOKE AND MIRRORS" TO NEAR REALITY – GOVERNMENT-RUN HEALTH INSURANCE AND THE FDA

As we in the health-freedom community watch the political "change" that is rapidly descending upon Washington and Congress, we ponder what this means for the future direction of the Food and Drug Administration (FDA). How will the FDA tackle dietary supplements and nutritional foods? And what Congressional actions are being plotted even now to more strictly regulate dietary supplements and nutritional foods? Yet, equally if not more importantly, what is happening with the strengthening undercurrent mandating government-run, national health insurance and how will that affect our health?

Struggles Ahead with FDA

The FDA has been the subject of widespread Congressional criticism in recent years, particularly from senior Members of the Congressional committees having jurisdiction over agency affairs. The allegations are that the Agency has not been enforcing existing laws and not adequately protecting public health. Drugs have been at the top of the list, but supplements and conventional food safety are also in the Congressional mix. My previous Lobbyist's Report (*HFN*, Vol.26, No.3, p.27) discussed the Dingell FDA Globalization Bill that would impose expansive new requirements for conventional and nutritional food producers. Unfortunately, this Bill will be revived in the next Congress; but NHF will be targeting it for defeat as it did once before. If passed, this legislation, or its spawn, will impose even tighter restrictions on dietary-supplement manufacturers; hugely encouraged by the previous passage of the so-called Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 (DSNDCPA, aka the Dietary Supplement Adverse Event Reporting law) as well as the FDA's issuance of a Manufacturers Guidance on that law for dietary-

supplement manufacturers. The full guidance document can be accessed at <http://www.cfsan.fda.gov/~dms/dsaergui.html>. (See also *HFN*, Vol.26, No.1, p. 26, for my Lobbyist's Report on this subject.)

With anti-health-freedom and anti-DSHEA legislators in full control in the House and Senate, it is and should be expected that renewed efforts will materialize to "fix the problems" with the DSNDCPA, using the issues raised by the FDA in its Manufacturers Guidance. In addition, on the FDA regulatory front, the Agency has asked for public comments on a possible proposed regulation designating as drugs those food substances that have undergone substantial public clinical trials. (*Federal Register*, Vol.73, No.146 at 43937 (7/29/08)).

While a long ways from a regulation, should the FDA fall on the wrong side of the divide on this issue, then this would create a major shift in the divide between how the FDA regulates foods and drugs. The FDA's questions to the public on this issue highlight a conflict between two federal statutes (DSHEA and the recently-passed FDA Amendments Act of 2007 or FDAAMA). An FDAAMA provision on the issue of substantial public clinical trials issue is broader and more all-encompassing than the existing law for dietary supplements established by DSHEA (which classifies as drugs those ingredients that are the subject of *authorized* substantial public trials). Knowledgeable food-and-drug lawyers feel strongly that the DSHEA standard is the legally prevailing one for dietary supplements.

Leaving aside the policy and regulatory conflicts, from a Congressional political perspective, this is yet another

issue upon which the anti-DSHEA legislative decision-makers – that is, Waxman, Dingell, Kennedy, and Durbin – will pounce in order to justify their need to “fix problems” by handing FDA increased regulatory powers over dietary supplements and nutritional foods. With today’s political climate and congressional makeup, these regulation-happy politicians will not have to look far for “justification.”

To be clear, the NHF does not support yet-more restrictive FDA regulations on manufacturers or coercive FDA interference in consumer health freedom of choice in the marketplace. FDA is the problem, not the solution.

Universal Health Insurance

At the time of this writing, the Senate Chairmen of the Health, Education, Labor and Pensions (HELP) as well as the Finance Committees – Senators Baucus and Kennedy, respectively – both have blueprints for creating a national health-insurance program, or universal health insurance. On the House side of Capitol Hill, Congressman John Dingell introduced national health-insurance legislation in 2007, with reintroduction in 2009 to be expected. Representative Dingell has already sent a letter to President-elect Obama (as did Senator Baucus with his Senate bill), seeking support for new federal controls over the health-insurance industry and individual healthcare decisions. (The Baucus blueprint and the Dingell letter are available on the NHF website at www.thenhf.com/government_affairs/federal/BaucusNatHealthInsu25C771.pdf & www.thenhf.com/government_affairs/federal/DingellObamaNation25C745.pdf.) NHF will release more Congressional action updates on these issues when the new Congress gets organized and starts up again in January. For example, there is still the yet-to-be released national health-insurance plan by Senator Kennedy to be reviewed.

The Obama Transition team for the federal healthcare departments and agencies was also recently announced. It is headed by William Corr. Mr. Corr previously served as the Staff Director of the Health Subcommittee of the House Energy and Commerce Committee, reporting directly to both Congressmen John Dingell (D-MI) and Henry Waxman (D-CA). He was their senior health advisor for many years, before leaving two years ago to head up a public interest group. And, in a recent press conference of House Democratic leaders on health care in the next Congress, President-elect Obama and Congressional Democrats have apparently begun to frame their position for “universal” health care as a job-creation measure in response to the current economic downturn. The political spin is that universal coverage will lower healthcare costs and make companies more willing to hire new people,

as well as create new healthcare jobs. These are just the start of the efforts to bring about “change” that people can believe in, to paraphrase an Obama campaign theme. To be sure, our healthcare system needs to be reformed. The real question, however, is whether more federal government control over individual healthcare decisions is the best way to go. Will it simply result in more of the coercive orthodox healthcare that NHF members eschew? And in answering these questions, remember that healthcare in the United States has trended markedly downwards ever since the federal government first got involved in 1965.

As released in November 2008, the Baucus “universal” healthcare plan, entitled “Call to Action, Health Reform 2009,” is broadly compatible with the proposal put forth by President-elect Obama in his campaign. Under the Baucus plan, a personal income tax penalty would be assessed against anyone who chooses not to obtain government health-insurance coverage. The “freedom to choose” not to have health insurance coverage on an individual or small-employer basis would come with a new federal tax, or a federal penalty, for small businesses. Employers would be forced to offer health insurance for workers or else have to pay into a federal insurance fund. The plan requires all U.S. residents to obtain health coverage over a period of ten years; and for those who cannot afford it, taxpayers will be forced to subsidize them as well. Of course, there is no mention of whether illegal immigrants residing in the U.S. would or would not be eligible for taxpayer-funded national health-insurance coverage. Right now, in the Southwestern States, the State Medicaid programs pick up this cost at taxpayer expense.

A new Medicare-like, government-run program would be established, and people could shop for insurance coverage with a newly-established national health insurance exchange. The Medicare-like, government-run program would dictate that people with preexisting health conditions could not be denied coverage, but would also dictate what services, medical treatments, and ancillary supplies would have to be included. The Baucus national health-insurance program would be governed by a public/private-funded Health Care Comparative Effectiveness Research Institute, governed by a Board of Governors. The Institute would be responsible for setting national priorities about the most pressing questions and -what medical treatments work and don’t work in addressing the needs in our healthcare system.

While being more market-based than a complete takeover by the federal government, it still has the distinct ring of being a Canadian model with different clothes. Of course, no one knows at this point, and may never know, how much all of this will cost taxpayers. Nor, for that

matter, how much federal taxes would have to be increased to cover the costs not covered by other means of raising funds for a nationally-mandated program.

Senator Edward Kennedy is working on a national health-insurance proposal and intends to have his legislation drafted by Inauguration Day. Another bill from the last Congress, which was sponsored by Senators Ron Wyden (D-OR) and Robert Bennett (R-UT), received the support of eight Democratic and nine Republican Senators then.

On the House side, in the last Congress, there were five national health-insurance bills introduced. Many expect the reintroduction by Representative John Dingell's (D-MI) of his proposed national health insurance plan. The previous Dingell National Health Insurance Bill, H.R.15, would establish a National Health Insurance Board and National Advisory Medical Policy Council. It would establish a National Health Care Trust Fund, funded by a value added tax of five percent. In other words, it would impose a 5% tax on every product and service sold in the United States. Similar to the Baucus plan, the Dingell plan proposed a Medicare-like, government-run program. In November, the Congressman sent a letter to President-elect Obama stating his desire to work closely with the new Administration to enact health-insurance reform. Among other things, the Dingell letter says "I am eager to work with you to make this happen, and I appreciate that your transition team has been in contact with my staff to chart the path forward."

Heretofore, from my perspective, enactment of national health insurance was nothing more than "smoke and mirrors" meant to fool the citizens into thinking that something was actually being done. Who does not remember "Hillary Care"? Hillary Care was never a real threat to anyone. This is no longer the case. The political climate has changed and will continue to change in the new Congress. The health-freedom agenda over the next two years will have to include more than just FDA and FDA-like regulatory issues. Government-run, national health insurance has come to the forefront and must be added to the health-freedom list of important issues.

Challenges and Opportunities

Numerous individuals and organizations are fretting over whom the next FDA Commissioner will be and what that may mean. This is a legitimate concern but it also immeasurably misses the point. Changes in Administration and in the Congressional balance of power will always bring both challenges and opportunities. Unlike other organizations, though, the NHF is not only actively working to keep its members accurately informed but is also actively

lobbying on matters that truly impact your health freedom of choice.

If anything, change brings opportunities to influence Congressional decisions, regardless of the final outcomes. Direct membership participation and lobbying is needed to optimize and profit from opportunities. One cannot influence government decisions if one does not participate in shaping the debate on what policy should be. This is a hallmark of the NHF, which represents in our opinion the best interests of preserving and protecting health freedom of choice from unneeded and unnecessary government intrusion into our lives and individual freedoms. 

CODEX PRESENTATION IN STROUD, ENGLAND

"The roar of the greasepaint, the smell of the crowd!" Or, maybe it was the reverse. At least the presentation given by Ian Crane and NHF president Scott Tips on November 13th in Stroud, England went off without a hitch. The subject was Codex Alimentarius and the crowd numbered some 40 very-interested, very-attentive people. Hosted by Drs. Christopher Hill and Theresa Johnson, local homeopaths, this talk on Codex was announced as the first in a series of events about health and health freedom. Judging by the turnout, there was a lot of interest.

Ian Crane has recently made a name for himself by touring England and speaking out on Codex and related health-freedom issues. His website is chock-full of information on many health-freedom issues, and it does not shy away from controversy. Ian is a fighter.

Ian spoke first and gave a brilliant presentation about a number of health-freedom topics woven around Codex. His speech was then followed by Scott's, which dealt most directly with both the past and recent happenings at Codex meetings and what the future might hold in a Codex-restrictive health world. After Scott finished speaking, Ian wrapped up the evening with closing remarks and then the two of them fielded questions from the audience. It was a jam-packed evening that stretched on longer than expected.

With the success of this event in Western England, Ian and Scott have scheduled follow-on speaking events in the same part of England near the end of January 2009. As health freedom is increasingly threatened, more people are awakening to the threat and starting to act.