It's Not Over Until December 31, 2012

By Lee Bechtel, NHF National Lobbyist

At the time of this writing, Congress is in recess until September 10th for the Democratic National convention. When they return, they will be in session for just seven days, then take a week off, and be back in session for five days the first week in October. Congress will then recess until after the November elections, scheduled not to reconvene on November 13th.

After Congress goes back in session on November 14th, the legislative calendar will get even more politically charged and challenged depending upon the outcomes of the Senate races and the result of the Presidential election. The big issues left undone are passage of a short-term Continuing Resolution for spending by Federal agencies, the expiration of the Bush tax reductions and other taxes – "taxmageddon" – and the "budget sequestration" reductions in defense and Medicare spending in future years. There will be a few other "must pass" bills. This is generally known because Congress cannot get its act together. The House passes bills and Senate Democrats, led by Majority Leader Reid and Barack Obama, have blocked any serious negotiations to compromise and get things done.

Unfortunately, Obama has not and does not lead by example. In a recent interview with a CNN reporter, in case people missed it, when asked why he had not

attempted to work with the Republican leadership in the House on these important issues, Obama said that he felt it was more important to spend time with his family. Seriously. A nice and sympathetic response, without mentioning his 160-plus fundraising trips, let alone golf outings with Bill Clinton. These big issues will eat up the post-election, lame-duck session of Congress; but it is also an opportunity to pass legislation that is far less controversial. In short, lame-duck sessions are, without a doubt, the worst examples of our democratic processes at work.

Some groups in the health-freedom community have been sending warning messages about passage of troubling GMO language contained in the USDA/FDA appropriations bill. In short, with a Continuing Resolution already passed by the House and awaiting Senate passage, this spending bill is dead for this year. NHF members and others in the community, but sadly not all, continue with efforts to get H.R.3380, the Dietary Supplement Protection Act (DSPA), on the legislative agenda in the House and Senate.

As a result of NHF member letters, we continue to get responses back from House members stating positive or neutral positions, but in sporadic fashion. From a lobbyist's perspective, this is the normal response. Some would view this in a not-so-positive light, but professionally not so from the NHF lobbyist's corner. Once introduced, it can be reintroduced next year. Ideas, like seeds, are planted and can persist and grow. Persistence is a virtue, especially when it comes to reforming DSHEA; it always involves a lot of lobbying work and grassroots support from NHF members and others and getting a bill past Nancy Pelosi (D-CA) and Henry Waxman (D-CA), the anti-supplement Congressional leaders. And, of course, Senator Dick Durbin (D-IL) is yet another obstacle and a member of this club of legislators.

NHF members and others already know of H.R.3380, and the importance of taking proactive action against the FDA's draft Guidance for New Dietary Supplement Ingredients and to use this opportunity to amend the DSHEA to move the supplement and dietary-ingredient grandfathering dates forward from 1994 to 2007. Between 1994 and 2006 some 25,000 new supplements were sold to consumers, some with new dietary ingredients and others without. Moving the date forward and exempting these supplements from future FDA regulatory over-reach is the only effective means of putting an end to the FDA's 17-year history of salami-slicing of the DSHEA law and its

double speak on DSHEA. The FDA has blamed industry and sought to penalize supplement consumers via administrative regulations when striving to impose its bureaucratic elitist viewpoint. With the retirements of Congressman Dan Burton (R-IN) and Ron Paul (R-TX), the health-freedom community is losing two great champions.

Where's The Beef? – The NDI Revision

Following a meeting with Senator's Orrin Hatch (R-UT) and Tom Harkin (D-IA) *(NHF News Release, June 22, 2012)*, the FDA supplements division chief Dr. Dan Fabricant sent a note to trade associations informing them that the FDA was "planning on promulgating a revised draft NDI Guidance to clarify and avoid misinterpretations being taken out of statutory context." In August, supplement industry trade association representatives and two representatives of natural health consumer organizations attended a meeting with FDA staffers. One issue of importance to the NHF that was discussed was the creation of an official list of grandfathered ingredients, which currently does not exist due to FDA bureaucratic incompetence over 17 years. One legitimate and universal trade- and consumer-group concern is that the FDA will determine that the list is ***static*** and any ingredient not on the list is by default a new dietary ingredient (NDI) and therefore subject to clinical trial testing also being proposed in the draft Guidance.

We don't want the list to be used as a hammer by the FDA to deny consumers access to safe supplements, which have an exceptional safety record, especially when compared to drugs (and even foods). This is exactly the purpose behind and the issue addressed by H.R.3380. Some health-freedom groups have gotten it, others have not. The industry trade groups are forced to go along with the FDA for fear of regulatory retribution. Unlike other health-freedom groups, the NHF has chosen to aggressively take on the FDA on this issue. Health-freedom advocates have all been here before, the fundamental question is whether some groups have learned anything over the past seventeen years?

The gist of the FDA messages at the meeting was the same – the FDA will keep industry and consumer access concerns in mind as it continues its own single-minded interpretation of DSHEA and pursuit of more regulatory control over supplements. One key question posed by the NHF, which has not been answered yet, is that if the FDA is

formally revising the NDI Industry Guidance, why has it not issued a public notice in the *Federal Register* announcing this action? Where is the beef on this important redrafting of the NDI Industry Guidance? Why hasn't the FDA issued a notice of withdrawal for revisions to the Guidelines? Are the trade groups trumpeting this FDA about-face just being fooled?

There will be different political and legislative dynamics following the November elections. NHF members should rest assured that the NHF will actively monitor and lobby Congress and the FDA on threats to our constitutionally protected rights to make our own health-care choices, which should be freer of elitist government bureaucrats who believe that they know what is best for Americans. The long and checkered history of the FDA in attempting to regulate supplements like drugs, or even like foods, must continue to be challenged. The NHF will be at the forefront of keeping the community accurately informed, and actively lobbying to ensure that health freedoms are represented and protected on Capitol Hill. For more information visit the NHF webpage at www.thenhf.com/government_affairs_federal.html.