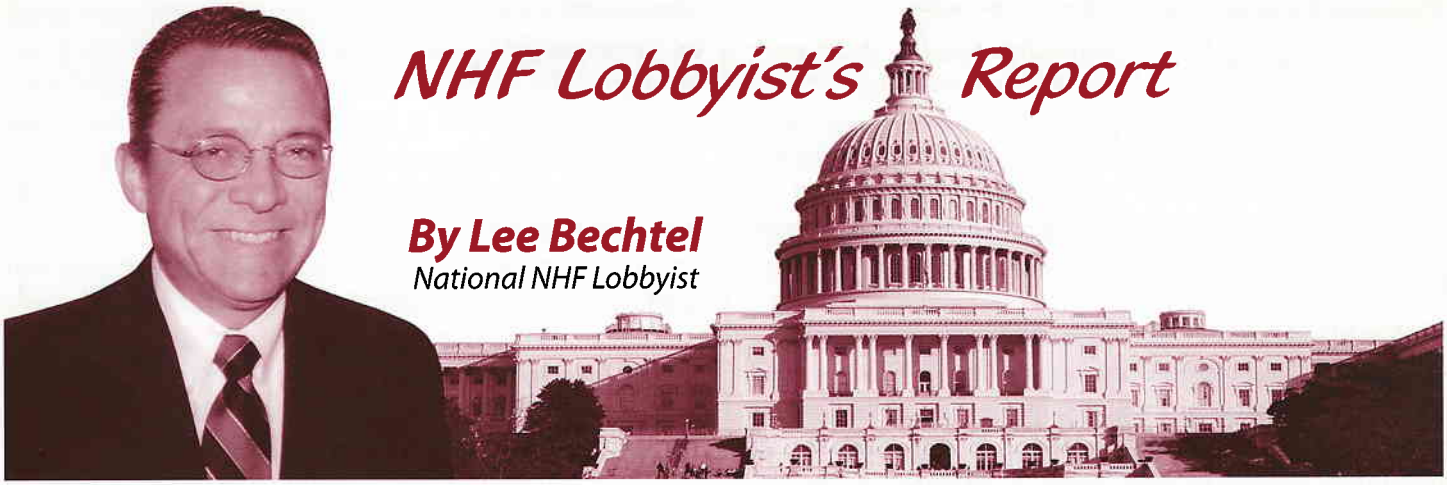

NHF Lobbyist's Report

By Lee Bechtel
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EYE ON THE HEALTH-FREEDOM PRIZE

A prize is not just an award like an Olympic medal. It is also the dedication and significance given to a cause that people treasure and value highly. In this case, NHF members have fought hard over the years to protect against Food and Drug Administration (FDA) interference, and for the prize to have the right to have access to the nutritional foods, supplements, and medical treatments they want.

As continues to be the case with this Congress, Congressional liberals – working closely with health-freedom opponents, FDA bureaucrats, and pharmaceutical companies – maintain their resolve to impose their "more government control" values upon the rest of us. There are four matters before Congress and the FDA currently deserving of NHF member and health-freedom community attention.

"Citizens" Petitions

On the FDA front, the assault upon health freedom comes in the form of two pending pharmaceutical-company backed "Citizens Petitions" (CP) to the Agency. The first is a petition filed by GlaxoSmithKline requesting that dietary-supplement weight-loss claims be classified as "disease claims." This means, in short, that if the petition is approved, then future weight-loss supplements, and who knows how many other supplement products making health-treatment claims, could be regulated as drugs because a "disease claim" is equivalent to a "medical claim" subject to the FDA's lengthy and expensive drug-approval process. In the petition, GlaxoSmithKline admits that it provides unrestricted grants to the four other groups that "joined it" in filing the petition asking the FDA to review its current regulatory thinking on this subject. This is yet another example of a pharmaceutical giant using "front" groups to support its drive to restrict access to natural, healthy products and to impose federal controls on an individual's right to know and sensibly make his or her own health and wellness decisions.

A petition filed by Medicure Pharmaceutical is also on the FDA front. This petition asserts that ***all*** dietary supplements containing pyridoxal 5'-phosphate (the natural form of Vitamin B-6) should be banned from the market. Medicure wants this natural form of Vitamin B-6 banned so as to ensure the exclusivity of its own drug-product ingredient called MC-1. Of course, as we already know, natural substances cannot be patent protected. So, the only way to protect and build market share for Medicure's drug product is for the company to go running to the government and ask it for a coercive monopoly, in this case to have the FDA ban the sale of the natural form of Vitamin B-6. Does this sound familiar? It should. This is the tryptophan and ephedra line of public-policy FDA "regulation" designed to protect one company's drug products at the expense of the competition. It is like an episode from the *Sopranos*. You don't compete with a competitor – you eliminate a competitor's ability to deliver its product to consumers.

Citizen petitions are supposed to be a formal means for a citizen, or more broadly, the public, to ask the FDA to act upon a particular regulatory matter for a company or an industry as a whole. The original intent of petitions, though, has been perverted to facilitate petitions backed by big drug companies to control the choices people have on medical treatments in our country's health-care system. These should be called Big Pharmaceutical Petitions. In both of these cases, the filers of the petitions, and their controlled-interest groups, purport to be protecting consumers. Yet, their true goals are nothing more than the elimination of competition by unleashing the FDA attack dogs on those consumers simply hoping to enjoy their right to dietary supplements. In these cases, this means eliminating the use of natural vitamins and minerals, or at least reclassifying claims for these products so they will be treated like prescription drugs.

Congress Returns, But Not for Long

On the Congressional front, at the time of this writing, Congress is still in its August recess. When its members return in September, there will only be 4 or 5 weeks before the election recess for them to inflict their planned actions – or the unintended consequences of planned actions – upon the citizens of the United States.

The FDA Globalization Act is still in play with the House Energy and Commerce Committee. The NHF is the only consumer-driven, health-freedom group taking the lead on lobbying Congress about this threat to supplements and nutritional foods. The NHF asked its members to petition their Congressional Representatives to amend the current draft bill so as to not burden dietary supplements – which have a tremendous safety record – with even more costly and burdensome rules and regulations that are being applied to less-safe foods. From my own contact with Congress, I can see that NHF members' advocacy efforts have had an impact on Congressional awareness. And although the jury is still out for this session of Congress, rest assured that if this legislation is not acted upon this year, it will be back next year. Information and a petition letter are available on the NHF website at *www.thenhf.com (Government Affairs page)*, and I urge you to sign the letter if you have not already done so.

A newer development on the Congressional legislative front that NHF members and others in the health-freedom community need to be aware of is the creation of a public-privately funded Health Care Comparative Effectiveness Research Institute. Senate Bill 3408 was introduced just prior to the August recess in the Senate. Democratic Senate staff members have said that assurances have been given that this bill will get a full Senate vote in the short session in September. We will see.

This bill could, or could not, be beneficial to the use of complementary and alternative medical treatments for all sorts of medical conditions, and would impact the use of nutritional foods and supplements as part of specific medical-care patient plans. It could very well result in the reduction of conventional medical treatment options for Americans being covered by either publicly-funded (Medicare or Medicaid, Veteran's health care) or privately-funded health insurance.

As proposed, the Institute would function as a not-for-profit private entity, not a federal agency. It would be governed by a public/private Board of Governors. Board members would include 18 appointed members from private insurers, the pharmaceutical industry, health-care consumer groups, physician groups, and from agencies administering Federal health programs. The Institute would be "responsible for setting national priorities" about the most pressing questions about what medical treatments work and do not work in addressing the health-care access needs in our health-care system. The Institute's budget would increase to $300 million by Fiscal Year (FY) 2013, with taxpayers paying $75 million annually, and private insurers paying $1 dollar per insured person per year, and Medicare paying $1 dollar per each beneficiary per year.

The insurance industry supports the legislation and the trade association for the large pharmaceutical companies has stated that it opposes the bill. The latter's concern is that "a research agenda may target the most costly types of treatments and products and shrink demand for treatments, which may not sit well with individual drug and device companies, and the medical professionals affected." From their point of view, the reservations of big drug companies are clearly understandable – their cash cow of treating everything with drugs will be open to the spotlight, beyond their influence over FDA matters. The bill opens the door to quasi-governmental control over the practice of medicine in our country, both conventional and alternative healing arts professions. The American Medical Association has yet to weigh in on its position, not to mention a host of physician medical specialties.

Health-freedom advocates should be concerned about all of these issues. From my perspective, there is no designated representational voice for non-conventional medical professionals – CAM physicians, Naturopathic physicians, alternative healing arts professionals who practice acupuncture and oriental medicine, for example. Decisions would instead be controlled by the insurance industry and drug-company representatives in setting the agenda as to what "comparative research" would be done and on the effectiveness of conventional or alternative medical treatment options.

But those inclined to seriously consider the ramifications of these kinds of bureaucratic institutions can ask the usual range of questions. What about insurance coverage for nutritional foods and/or supplements used in lieu of conventional drugs? What about comparing alternative medical treatments for common medical conditions versus the drug-driven regime that currently exists in our health-care system? What about considering access to safe and cheaper medical treatments currently used in other countries but not FDA-approved for use in the United States? Why shouldn't these modalities be eligible for coverage under Federal health-insurance programs or covered by private insurance companies? Why not include comparative cost-and-treatment-outcome studies on conventional vs. non-

conventional CAM and other modalities? As proposed, there does not appear to be this type of opportunity for alternative thinking among the appointed Institute representatives. If the real goal is to set "national priorities" on treatment options for diseases and medical conditions, why not include all of the options currently on the table and being used in our health-care system? From a Federal health-care policy and FDA regulatory point of view, it is the old Latin saying of "Qui Bono" (*who benefits*) that applies to these matters.

Yet, the real question is why do we need just another bureaucratic overlay burdening our health-care system? And do we especially need a bureaucracy in which views friendly to our own would always be in the minority? The NHF says no. Constant tinkering by the Federal government – our latest "God on Earth" – may satisfy the desires of the average American for someone to do ***something***, but that still does not make it the proper answer. Any bill or program that interferes with natural market mechanisms, and that favors any business at the expense of another, should be opposed in the same way that so many of us oppose artificial drug interventions in our own bodies.

The NHF continues to keep its eye on the prize. And that prize is optimal health and the preservation and enhancement of the health freedom of all individuals to choose their own health-care path, free of coercion.

Health Bits and Pieces
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◆ **MSG and obesity.** The taste enhancer monosodium glutamate (MSG) in foods has long been damned for causing headaches and other undesirable symptoms. If for nothing else, why do we bewail high obesity rates and then permit MSG to be added to baby foods, prepared foods and soups, and even liquid meal replacements for seniors? MSG is widely used in Asia and the obesity epidemic is not as prevalent among Asian populations. So does MSG contribute to overeating problems? Researchers at the Department of Nutrition at the School of Public Health, University of North Carolina at Chapel Hill, investigated. These researchers found 82% of study participants in China added MSG to their foods, with the average intake being 330 milligrams per day. Prevalence of overweight was higher among MSG users. The risk of being overweight more than doubled among high-MSG users. [*Obesity* May 22, 2008, early online]

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