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FEDERAL ACTION UPDATE
Protecting Access to Health Care Choices
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Citizen access to products that promote health, including Dietary Supplements and Organic whole foods that are not genetically engineered or modified, is being challenged on a national and international level by restrictive laws and trade agreements that block access. NHFA is committed to protecting consumer access to products and preserving what health freedom is all about: empowering citizens to make health care decisions with the information they need.

►The following is a table of bills that NHFA has joined other national health freedom organizations in opposing or supporting to protect health freedoms.

Bill Activity as of July, 2012

H.R. 3380, **"Dietary Supplement Protection Act of 2011"**	**Representative Dan Burton / November 4, 2011**	This bill will immediately protect thousands of dietary supplements put in jeopardy by the FDA's recent document outlining their outlandish new expectations of manufacturer of new dietary ingredients. According to the National Health Federation drafters, the bill "*Simply but powerfully, DSPA amends DSHEA by moving forward the grandfathering date to 2007, from 1994, thereby putting many thousands of safe, time-tested products immediately out of range of the NDI Draft Guidance.*"	**Support** Website for writing legislators from NHFA: **http://salsa.democracyinaction.org/o/850/p/dia/action/public/?action_KEY=9598**
Status of Bill H.R. 3380: Still pending, referred to the House Committee on Energy and Commerce: Subcommittee on Health. **Reasons to Support H.R. 3380:**			

H.R. 3380 is a perfect solution to FDA's hostile document, Draft Guidance for New Dietary Ingredients! DSHEA law says that a "dietary supplement" is a supplement marketed "before" 1994, and that a "new dietary ingredient" is a supplement marketed "after" 1994. Of course both dietary supplements and new dietary ingredients must abide by the good manufacturing practices and the adverse event reporting laws. But new dietary ingredients have an added level of regulatory requirements. Now the FDA is trying to say that many of the dietary supplements currently on the market are "new dietary ingredients" and must abide by expansive requirements.

But H.R. 3380 will protect our supplements NOW. And we can also demand Congressional hearings on the misleading and hostile draft guidance! H.R. 3380 simply says, lets amend DSHEA and change the dietary supplement "grandfather" date of 1994, to 2007. This is a common sense solution and will immediately protect supplements. It will quickly protect manufacturers and consumers from the dire threat of FDA's flawed interpretation of existing law which, if applied, would create a loss of thousands of supplements and huge economic consequences for any manufacturer and consumer of a New Dietary Ingredient (NDI)**.** Because the FDA's recent Draft Guidance for NDIs reveals an overbroad interpretation of what an NDI is and when an NDI notification is required**, H.R. 3380 would immediately put thousands of dietary supplement products out of reach of FDA mandates for NDIs by placing products outside of the definition of an NDI.**

H. R. 2908 **"Testimonial Free Speech Act of 2011"**	**Rep. Ron Paul/ September 13, 2011**	This bill will protect the First Amendment free speech rights of individuals to share their experiences and perceptions of the beneficial effects of foods and dietary supplements.	**Support**

Status of Bill H. R. 2908: Still pending, referred to the Committee on Energy and Commerce: Subcommittee on Health.

Reasons to Support H. R. 2908:

The intent of the H.R. 2908 is to restore free speech for those who wish to pass on their nutritional success stories. This bill would get the FDA out of the business of monitoring health testimonials because, under H.R. 2908, the FDA could not "… restrict dissemination of a testimonial containing a consumer's actual perception of the mitigated, preventive, or curative properties of any food or dietary supplement based on the consumer's experience with that food or dietary supplement."

Dietary supplement and other food companies are worried about sharing customer testimonials online because of FDA monitoring. Currently, the government prohibits sellers and supplement producers from publicizing individual consumer testimonials about health improvements resulting from the use of certain foods or dietary supplements, viewing them as marketing violations that render nutritional supplements as drugs, with strict enforcement.

Not only is the FDA's activity destroying the dietary supplement industry with its policy that assumes only drugs cure or treat disease, while claims of health improvement due to nutritional supplements are deemed misbranding and unscientific, it also tramples the right of free speech guaranteed under the First Amendment. H.R. 2908 acknowledges that it is wrong to have a federal regulatory agency such as the FDA monitor and control the free flow sharing of consumer testimonials of foods and dietary supplements.

H. R. 2044 **"Health Freedom Act" aka the Right to Say What Works**	**Rep. Ron Paul/ May 26, 2011**	This bill will amend the Federal Food, Drug, and Cosmetic Act concerning the restrictions on claims about the effects of foods and dietary supplements on health-related	**Support**

		conditions and disease.	

Status of Bill H. R. 2044: Still pending, referred to the Committee on Energy and Commerce: Subcommittee on Health.

Reasons to Support H. R. 2044:

H.R. 2044 prohibits FDA from preventing a disease claim unless it is "false and misleading in a material respect." The bill would amend the Food Drug and Cosmetic Act to say "A food or dietary supplement for which a claim is made . . . is not a drug solely because of such claim."

H. R. 2045 **the "Freedom of Health Speech Act" aka Keep Burden of Proof on Government**	**Rep. Ron Paul/ May 26, 2011**	This bill would amend the Federal Trade Commission Act concerning the improper placement of the burden of proof on manufacturers in false advertising cases involving dietary supplements and dietary ingredients.	**Support**

Status of Bill H. R. 2045: Still pending, referred to the Committee on Energy and Commerce: Subcommittee on Health.

Reasons to Support H. R. 2045:

H.R. 2045 stops the FTC from taking unwarranted actions against advertisers and manufacturers that communicate a health benefit for a dietary supplements or dietary ingredient. Under H.R. 2045, the FTC is prohibited from beginning an investigation of possible false advertising regarding a dietary supplement or a dietary ingredient unless the FTC already possesses clear and convincing evidence that the advertisement is false and misleading. Thus, H.R. 2045 properly places the burden of proof on the FTC to show that an advertisement for a dietary supplement or dietary ingredient is false, that the advertisement actually caused consumers to be misled into believing to be true that which is false, and that, but for the false advertising content, the consumer would not have made the purchase at the price paid.

The bill requires the FTC to prove that a health claim alleged to be false advertising is false based on expert scientific opinion and published peer-reviewed scientific evidence.

H.R. 2045 would also change the law so that excerpted scientific studies will not be considered advertising.

This bill was a re-introduction of H.R. 3394 (111th) from the previous session of Congress.

H. R. 1830, the Free Up Raw Milk Interstate bill	**Rep. Ron Paul/ May 11, 2011**	This bill would authorize the interstate traffic of unpasteurized milk and milk products that are packaged for direct human consumption.	**Support**

Status of Bill H. R. 1830: Still pending, referred to the Committee on Energy and Commerce: Subcommittee on Health.

Reasons to Support H. R. 1830:

H.R. 1830 would reinstate the right to transport raw milk over state lines and authorize the interstate traffic of

unpasteurized milk and milk products that are packaged for direct human consumption. H.R. 1830 allows unpasteurized dairy sales by saying that "notwithstanding the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), section 361 of the Public Health Service Act (42 U.S.C. 264), and any regulations or other guidance issued under such Act or section, **a Federal department, agency, or court may not take any action** (such as administrative, civil, criminal, or other actions) **that would prohibit, interfere with, regulate, or otherwise restrict** the interstate traffic of milk, or a milk product, that is unpasteurized and packaged for direct human consumption, **if such restriction is based on the determination that, solely because such milk or milk product is unpasteurized,** such milk or milk product is adulterated, misbranded, or otherwise in violation of Federal law.

Related bill, S. 1955, was introduced on 12/7/2011 by Sen. Paul, Rand.

H. R. 3553, Label Genetically Modified Foods	**Rep. Dan Kucinich/ December 2, 2011**	To require that food containing, or produced with, genetically engineered materials be labeled accordingly.	**Support**

Status of Bill H. R. 3553: Still pending, referred to the Committee on Agriculture and the Committee on Energy and Commerce: Subcommittee on Health.

Reasons to Support H. R. 3553:

H.R. 3553 would require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly by amending the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act.

H.R. 3553 requires periodic testing of such foods transferred along a chain of distribution to assure accuracy of labels. The bill excludes from the labeling requirement, in all three Acts, food that is: (1) served in restaurants; or (2) prepared primarily in a retail establishment, ready for human consumption, but not offered for sale for immediate consumption in the establishment. Also excluded, for purposes of the FFDCA, is "medical food" as defined in the Orphan Drug Act.

H.R. 3553 subjects violators to civil monetary penalties, but exempts recipients who accept a guarantee of the absence of genetically engineered material in good faith or producers whose food inadvertently becomes contaminated by genetically engineered material. H.R. 3553 also authorizes citizen suits as specified.

This bill was a re-introduction of H.R. 5577 (111th) (Jun 23, 2010).

Citizen Petition To require labeling of genetically modified foods	**Center for Food Safety on behalf of the "Just Label It" campaign/ filed with the FDA on October 19, 2011**	Urges the U.S. Food and Drug Administration to require the labeling of genetically engineered (GE) foods.	**Support** Send supportive comments of Citizen Petition here: **http://salsa3.salsalabs.com/o/1881/p/dia/action/public/?action_KEY=5452**

Status of Citizen Petition: Still pending; this petition continues to draw public support. At the time this is going to print, over 600,000 people have submitted comments supporting the petition and mandatory labeling. Further, a bipartisan group of 55 members of Congress, 45 House members and 10 senators, joined in supporting the petition.

Reasons to Support Citizen Petition:
Citizen Petitions is a formal and legal way to let the voice of the people be heard in government. Quoting from the GMO labeling petition: "*Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution, the Administrative Procedure Act, and the Food and Drug Administration's ("FDA") implementing regulations, the petitioners of the Citizen Petition respectfully request that FDA require that foods that are genetically engineered organisms, or contain ingredients derived from genetically engineered organisms—collectively referred to as "GE foods"—be labeled under the Federal Food Drug and Cosmetic Act ("FFDCA"). The requested actions are necessary to prevent economic fraud, and to protect consumers who are deceived by thinking the absence of labeling means the absence of GE foods.*

Genetic engineering results in changes to foods at the molecular level that have never occurred in traditional varieties. These changes are determinative of consumers' food purchases and, yet, they are not readily apparent. Thus, the absence of mandatory labeling disclosures for GE foods is misleading to consumers. FDA's failure to require labeling for GE foods is an abdication of its statutory mandate to require labeling for foods that are "misbranded" because they are misleading.

This citizen petition also requests that "FDA revisit its interpretation of 'material' facts in light of intervening evidence since the agency enacted its 'Statement of Policy: Foods Derived from New Plant Varieties' in 1992." According to the petition, by failing to label GE foods, FDA has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [and has] offered [] explanation[s] for its decision[s] that run[] counter to the evidence before the agency."

S. 1310 **"Dietary Supplement Labeling Act of 2011"**	**Senator Richard Durbin/ June 30, 2011,**	S. 1310 would require manufacturers of dietary supplements to meet increased pre-market registration requirements of dietary supplement products with the Food and Drug Administration and to expand labeling requirements with respect to dietary supplements.	**Oppose** Website for writing legislators from NHFA: **http://salsa.democracyinaction.org/o/850/p/dia/action/public/?action_KEY=7311**

Status of S. 1310: Still pending, referred to the Committee on Health, Education, Labor, and Pensions.

Reasons to Oppose S. 1310:

The bill will jeopardize access to thousands of dietary supplements. S1310 attempts to impose globalist, EU, drug-like restrictions on supplements above and beyond what 1994 DSHEA called for!

Giving the FDA more police power and regulation over dietary supplements is completely unwarranted. ***FDA already has sufficient authority to regulate dietary supplements*** under its existing requirements for food facility registration, current stringent good manufacturing standards, labeling and adulteration laws, as well as the new dietary ingredient pre-market evaluation and adverse event reporting laws.

S1310 greatly expands FDA authority over new dietary ingredients and dietary supplements, introducing additional burdensome regulations on responsible manufacturers who provide critical supplements to consumers. **S1310's new pre-market registration requirements could virtually eliminate competition in the market-place**, and only allow for the existence of large manufacturers. The proposed requirement would especially imperil small manufacturers who do not have the resources to cope with more burdensome and unnecessary additional regulations.

S1310 is extremely dangerous because it attempts to change the perception of safety of dietary supplements. They are currently deemed food/nutrient products and are heavily regulated under DSHEA. The burden of proof is on the government to show harm before restricting a particular product. This bill, much like the EU globalist approach, which is already harming access to supplements in Europe, would move the US toward perceiving and treating supplements like dangerous drug-like products.

S1310 calls for an onerous process of compiling a pro-active government "danger" list of all ingredients and products that the government, (based on their own agency's conventional science), deems will cause a risk of harm needing further regulation. Creating this type of general broad brush government list, based on government science, is the path to the drug-based EU-type government permission-to-market regulation of EU supplements and **goes far beyond the intent of DSHEA**. **It eliminates** the foundations and principles of dietary supplement food law itself.

H.B. 1364 "Free Speech About Science Act of 2011"	**Reps. Chaffetz and Jason/ April 5, 2011**	This bill concerns the distribution of information on legitimate scientific research in connection with foods and dietary supplements.	**Oppose**

Status of H.R. 1364: Still pending, could go to hearing soon.

Reasons to Oppose H.R. 1364:

The bill's definition of 'legitimate scientific research' is arguable and many health freedom advocates believe it will further entrench conventional medicine's concept of "evidence based medicine" and perpetuate the conventional publication and review politics associated with whether a particular scientific research project or publication is "legitimate". Health freedom advocates would rather support freedom of speech bills, described above.

FDA Draft Guidance Document for New Dietary Ingredients **(Docket No. FDA–2011–D–0376)**	**FDA /issued in Federal Register July 2011**	This agency document provides FDA interpretation of existing laws regarding "New Dietary Ingredients".	**Oppose** Website for writing legislators from NHFA: **http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0376-0002**

Status of FDA Draft Guidance Document: Still pending, could become official Guidance Document. However a number of health freedom leaders have received information that this Draft Guidance Document is going to be amended

and resubmitted by FDA employees.

Reasons to Oppose FDA Draft Guidance Document:

The new FDA Draft Guidance for Industry; "*Dietary Supplements: New Dietary Ingredient Notifications and Related Issues*" is a sweeping and hostile interpretation of existing law as it applies to future FDA enforcement proceedings on dietary supplement manufacturers If adopted, the Draft Guidance for New Dietary Ingredients could result in loss of access by consumers to thousands of dietary supplements already on the market.

The FDA's understanding of what is an NDI is much broader than what DSHEA intended and, if adopted, the FDA's Draft Guidance will cause the loss of up to 239,347 jobs and result in a total economic loss to the U.S. economy of up to $39.8 billion annually, according to Dr. Shepherd-Bailey, Ph.D., of Emory University School of Law. And most importantly, this guidance if adopted, would cause the loss to consumers of their most treasured asset … their health!

The Draft Guidance goes against Congress's specific intent in the 1994 Dietary Supplement Act (DSHEA) that: *"the [FDA] should not take any actions to impose regulatory barriers limiting or slowing the flow of safe products … to consumers;*". Yet the proposed Draft Guidance imposes onerous reporting, safety testing, and evidentiary burdens, and even in some cases animal and human studies, on manufacturers of dietary supplements with new dietary ingredients that go way beyond the current industry standards. If finalized, this guidance will force thousands of supplement manufacturers out of business.

The Draft Guidance goes against Congress's specific intent in DSHEA that: "*dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare;*". Yet this guidance would give the overarching presumption that dietary supplements and new dietary ingredients (NDIs) are inherently dangerous and extensive safety and compliance measures must be required.

Despite DSHEA's clearly stated law that: "*dietary supplements shall be deemed food*" and despite U.S. Senate findings that: "nearly all consumers indicate that dietary supplements should not be regulated as drugs," the proposed evidentiary requirements essentially treat food supplements with new ingredients as if they were toxic drugs, presumed dangerous, when really any new dietary ingredient, even if not marketed before 1994, is still a food: an herb, an amino acid, a vitamin, a mineral, or other ingredient defined in DSHEA.