



February 10, 2010

On February 3, 2010, Sen. John McCain introduced his Dietary Supplement Safety Act of 2010. Please see the attached memorandum for a discussion of how McCain's bill threatens to dramatically change the dietary supplement industry. In addition, because McCain's bill will fundamentally change the way dietary supplements are regulated and force the removal of supplements from the market that have been consumed safely for decades, we urge you to contact your representatives to oppose this bill.

Feel free to contact us if you have any questions.

Steve Wallach
CEO
Youngevity®

11808 WOLF RUN LANE
CLIFTON, VA 20124

4140 E. BASELINE ROAD
SUITE 201
MESA AZ 85206

1050 SEVENTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20036

(202) 466-6937 • FAX (202) 466-6938
WWW.EMORD.COM

MEMORANDUM

TO: ALL CLIENTS
FR: EMORD & ASSOCIATES
RE: JOHN MCCAIN'S DIETARY SUPPLEMENT SAFETY ACT
DA: FEBRUARY 9, 2010

MCCAIN'S DIETARY SUPPLEMENT SAFETY ACT THREATENS TO DRAMATICALLY CHANGE THE DIETARY SUPPLEMENT INDUSTRY

On February 3, Senator John McCain (R-AZ) introduced his Dietary Supplement Safety Act of 2010 ("DSSA"), a bipartisan bill co-sponsored by Senator Byron Dorgan (D-ND).

If DSSA becomes law, it will:

- Require the registration of "dietary supplement facilities," which are defined as "any business or operation engaged in manufacturing, packaging, holding, distributing, labeling, or licensing a dietary supplement for consumption in the United States." The registration would contain information sufficient to notify the Secretary of the name and address of each facility at which, and all trade names under which, the dietary supplement registrant does business. In addition, the registrant would also be required to submit the following: a list of all dietary supplements manufactured, packaged, held, distributed, labeled or licensed by the facility; a full list of the ingredients contained in each dietary ingredient; and a copy of each dietary supplement's labeling. Registration would be updated annually and when there is a new dietary supplement or reformulation of an existing dietary supplement. Thus, under Senator McCain's bill, everyone from a multi-level marketer of supplements

to the local health food store owner to the large national and multi-national supplement manufacturer and distributor must report to FDA their names, addresses, dietary supplement products they hold and sell, and the ingredients of those products, or be in violation of the law. For the first time in American history, every person who distributes supplements will be tracked by the federal Food and Drug Administration, subjecting him or her to inspection and to the panoply of regulatory restraints that the FDA now uses against wholesalers and large retailers.

- Amend the definition of “adulterated” to include dietary supplements that are manufactured, packaged, held, distributed, labeled, or licensed by a dietary supplement facility that is not registered.
- Amend the definition of “new dietary ingredient” to mean a dietary ingredient that “is not included on the list of ‘Accepted Dietary Ingredients’ to be prepared, published, and maintained by the Secretary.” Presently, a “new dietary ingredient” means “a dietary that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.” Under the DSSA, products in circulation prior to 1994 are no longer grandfathered. If a dietary ingredient is not on the accepted list, it will be unlawful to sell in the United States. In other words, all supplements are presumed unlawful unless and until the FDA Commissioner says otherwise. Under McCain’s bill, the FDA Commissioner can ban an ingredient as unsafe without a hearing, without a rulemaking, and without any due process, simply by excluding it from her Accepted Dietary Ingredient list.
- Amend the definition of “adulterated” as it relates to a dietary supplement that contains a new dietary ingredient. Currently, a dietary supplement which contains a new dietary ingredient is adulterated unless: (1) it “contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered”; or (2) “there is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.” The DSSA removes the exception for new dietary ingredients that have been present in the food supply, making it more difficult for new dietary ingredients to be introduced into the market.

- Require persons submitting information in support of use and safety for a dietary supplement that contains a new dietary ingredient to “create and maintain a scientifically reasonable substantiation file relating to the claim that the dietary ingredient or dietary supplement will reasonably be expected to be safe.”
- Require dietary supplement manufacturers and retailers to obtain written evidence that their dietary supplements are registered and that the requirements for new dietary ingredients have been satisfied prior to their manufacturing, packaging, holding, distributing, labeling, or licensing the dietary supplements.
- Impose a civil monetary penalty for non-compliance that is not more than twice the gross profits or other proceeds derived from the manufacture, packaging, holding, distribution, labeling, or license of the non-compliant supplement.
- Require event reporting for *non-serious* adverse events. The bill fails to define what a non-serious adverse event is, making it likely that reporting will be required for everything from a consumer’s dislike of the product’s taste to a consumer’s objection to the color of a label.
- Give the FDA authority to issue a cease distribution and notification order if “there is a reasonable probability that a dietary supplement or a product marketed or sold as a dietary supplement would cause serious, adverse health consequences or death, or is adulterated or misbranded.” This provision is unnecessary since the FDA can already halt the sale of any dietary ingredient that presents a risk of illness or injury, can get an injunction blocking the sale, and can prosecute those responsible. Moreover, under McCain’s bill, there are no safeguards to prevent an abusive use of this new regulatory power; the FDA Commissioner has unbridled discretion to remove any dietary ingredient from the market on a mere suspicion that it causes harm. The ingredient remains off the market while the seller is first required to litigate in a hearing before the FDA Commissioner (thus, no separation of functions) before proceeding to a court of law. Thus, a decision to halt distribution can remain in place for years before there is an independent adjudication on the merits.

Because this bill will fundamentally change the way dietary supplements are regulated and force the removal of supplements from the market that have been consumed safely for decades, we urge you to contact your representatives to oppose this bill. If you have any questions, please feel free to contact us.