

## **OPTION 1 – AMEND S. 3546 TO ESTABLISH A NATIONAL TOLL-FREE NUMBER IN PLACE OF MANDATORY REPORTING TO ELIMINATE BUDENSOME AND INEFFECTIVE REGULATION AND TO REMOVE BASIS FOR “RISK/BENEFIT” STANDARD**

### **1. Establish a Toll-Free Number**

**Issue:** S. 3546 requires that a manufacturer, packer or distributor (and even a retailer in some cases) include on their product labels a phone number or address to permit consumers to report serious adverse events. These parties are then required to collect information on all potential adverse events, serious or not, differentiate serious from non-serious events, and report serious events to FDA within 15 days. This will lead to thousands of different numbers consumers are calling and thousands of parties answering, interpreting, documenting and keeping records and then reporting this same information to FDA, which then in turn has to organize and track this information. The entire process could be simplified and improved with the use of a single, national toll-free number that goes directly to FDA. Dietary supplement companies would not be charged with determining which reports are “serious” and should be sent to FDA. FDA, which has the expertise to assess product risks, would receive more adverse events more quickly. FDA could then determine whether there is a safety issue with greater speed and efficiency, and if there is, also determine whether the safety issue is product specific or applicable to multiple products with the same ingredient, assuring a more rapid and appropriate FDA response.

**Amendment:** See Amended S. 3546 Section 2, attached.

### **2. Amend S. 3546 to Remove Basis for Illegal “Risk/Benefit” Standard.**

**Issue:** The Amendment also includes a provision to remove the word “unreasonable” from Section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, as FDA has used this word as the sole basis for creating and subjecting dietary supplements to a new “risk/benefit” safety standard, the same standard that the agency applies to drugs and devices. As the authors and supporters of DSHEA have recognized, this standard was not intended by Congress, is not authorized under the Dietary Supplement Health and Education Act of 1994 (DSHEA), and, as applied by FDA in its final rule banning ephedra, is a standard that virtually no supplement product could hope to pass.

**Amendment:** See Amended S. 3536 Section 2(d), attached.

## OPTION 1

### **SECTION 1. SHORT TITLE.**

*This Act may be cited as the `Dietary Supplement and Nonprescription Drug Consumer Protection Act'.*

### **SEC. 2. ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS AND DIETARY SUPPLEMENTS.**

*(a) In General- Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:*

#### ***`Subchapter H-- Adverse Event Reports***

#### ***`SEC. 760. ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS AND DIETARY SUPPLEMENTS.***

*`(a) Definitions- In this section:*

*`(1) NONPRESCRIPTION DRUG ADVERSE HEALTH EVENT-*

*The term `nonprescription drug adverse health event' means any health-related event associated with the use of a nonprescription drug that is adverse, including--*

*`(A) an event occurring from an overdose of the drug, whether accidental or intentional;*

*`(B) an event occurring from abuse of the drug;*

*`(C) an event occurring from withdrawal from the drug; and*

*`(D) any failure of expected pharmacological action of the drug.*

*`(2) NONPRESCRIPTION DRUG- The term `nonprescription drug' means a drug that is--*

*`(A) not subject to section 503(b); and*

*`(B) not subject to approval in an application submitted under section 505.*

*`(3) DIETARY SUPPLEMENT ADVERSE HEALTH EVENT- The term `dietary supplement adverse health event' means any health-related event associated with the use of a dietary supplement that is adverse.*

*`(b) Toll-Free FDA Telephone Number Requirement-*

*`(1) IN GENERAL- All Nonprescription drug and dietary supplement labels must include a toll-free number established by FDA. The number must be prominently*

*displayed on the label directly beneath the words "To report any adverse health events to FDA, call the number below:"*

*`(2) FDA shall promulgate regulations to implement the toll-free number requirement, to establish a nationwide telephone number, and to set type size and placement requirements.*

*`(c) Preemption-*

*`(1) IN GENERAL- No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a system for adverse event reports for nonprescription drugs or dietary supplements, that is different from, in addition to, or otherwise not identical to, this section.*

*`(2) EFFECT OF SECTION-*

*`(A) IN GENERAL- Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.*

*`(B) PERSONALLY-IDENTIFIABLE INFORMATION- Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not--*

*`(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or*

*`(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.*

*`(C) USE OF SAFETY REPORTS- Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with section 756.*

*`(d) Authorization of Appropriations- There are authorized to be appropriated to carry out this section such sums as may be necessary.'*

*(b) Modifications- The Secretary of Health and Human Services may modify requirements under the amendments made by this section in accordance with section 553 of title 5, United States Code, to maintain consistency with international harmonization efforts over time.*

*(c) Misbranding-*

*(1) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:*

*`(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes the FDA toll-free telephone number established by FDA regulation.'*

*(2) Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:*

*`(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes the FDA toll-free telephone number established by FDA regulation.'*

*(d) Adulteration- Section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(f)(1)(A)) is amended by striking 'or unreasonable'.*

*(e) Effective Dates-*

*(1) IN GENERAL- Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.*

*(2) MISBRANDING- Sections 502(x) and 403(y) of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall apply to any nonprescription drug (as defined in such section 502(x)) and dietary supplement labeled on or after the date that is 1 year after the date of enactment of this Act.*

### **SEC. 3. PROHIBITION OF FALSIFICATION OF REPORTS.**

*(a) In General- Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:*

*`(ii) The falsification of a report of an adverse event submitted to the Secretary.'*

*(b) Effective Date- The amendment made by this section shall take effect 1 year after the date of enactment of this Act.*