



## **POSITION STATEMENT**

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### **Industry Should Be Required to Report Serious Adverse Events (AEs) to FDA**

#### **Background**

Currently, dietary supplement companies are not required to submit adverse events to FDA, although companies can voluntarily do so. However, if a consumer used a product and believes something went seriously wrong, that report, if submitted to a company, should be provided to the federal agency regulating the product. Therefore, the Council for Responsible Nutrition (CRN) strongly supports the bipartisan efforts of Senators Orrin Hatch (R-UT), Tom Harkin (D-IA), Richard Durbin (D-IL), Mike Enzi (R-WY) and Ted Kennedy (D-MA) to develop legislation that would mandate the reporting to FDA of serious adverse events<sup>1</sup> for dietary supplements and over-the-counter drugs (OTCs).

#### **Consumers have a right to expect that if they report an adverse event to a dietary supplement manufacturer, FDA will know about it**

- Many responsible dietary supplement manufacturers already voluntarily report any serious adverse events associated with their products to FDA. However, all companies should be required by law to report serious adverse events to FDA. Consumers should know that if they call or write to a manufacturer about a serious health event they believe is associated with their use of a dietary supplement, the company will notify FDA. It's a positive step toward building greater consumer confidence in dietary supplements as it demonstrates a company's confidence in the safety of its products.

#### **AERs serve as a signal to FDA and do not prove causation between a product or ingredient and an adverse event**

- In fact, dietary supplement companies receive very few serious Adverse Event Reports (AERs), which demonstrates the wide margins of safety for these products. Requiring manufacturers to report these relatively few incidents will demonstrate to FDA, the medical community and to consumers the safety of this class of FDA-regulated products. In any case, FDA treats adverse event reports as early warning signals that might suggest trends among certain products or safety concerns among the general public that may not show up in a limited clinical trial. FDA clearly advises that adverse event reports do not demonstrate causality between the FDA-regulated product and a reported adverse event.

#### **It's the responsible thing to do**

- AERs provide early warning signals to FDA of potential product problems, like product contamination or adulteration, tampering, bioterrorism and ingredient safety issues. By providing this information to a single source—FDA—manufacturers increase the likelihood that trends indicating a problem will be identified more quickly, and fewer consumers will be affected. By giving consumers more confidence in the industry, everyone benefits.

<sup>1</sup>An event that is associated with the use of a product that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity or a congenital anomaly or birth defect.

**Serious Adverse Event Reporting for Dietary Supplements & OTCs**

## **S. 3546: Dietary Supplement and Nonprescription Drug Consumer Protection Act**

**Sponsors:** Sen. Orrin Hatch (R-UT), Sen. Tom Harkin (D-IA) and Sen. Dick Durbin (D-IL)

**What:** S. 3546 would amend the Food, Drug & Cosmetic Act (FD&CA) to require that the manufacturer, packer or distributor of a dietary supplement or over-the-counter drug (OTC) notify FDA of any serious adverse events it receives—associated with their supplement or OTC—within 15 business days.

The legislation: instructs FDA to consolidate adverse event reports (AERs) if multiple reports of the same incident or duplicates exist; preempts states from creating their own AER systems; requires the manufacturer retain all “records related to” AERs for 6 years (responsible for reporting only serious AERs to FDA); protects these safety reports from being misused in product liability suits; allows for agreements between a manufacturer and a retailer “whose name appears on the label” (i.e. “Distributed by ...” or “Manufactured exclusively for...”) authorizing the manufacturer to report to the FDA; and, includes new language underscoring that reporting a serious AER to the FDA “shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.” The language also makes it illegal to file a false report with the manufacturer or the FDA.

**Background:** Adverse event reporting by the manufacturer is required for other FDA-regulated products (e.g. medical devices, prescription drugs, some OTCs). This legislation would require similar reporting of serious AERs for monographed OTCs and dietary supplements. This legislation would not affect the current regulatory structure for these products, and would not restrict consumer access to any products currently being legally marketed in the United States. FDA has repeatedly stated that AERs are a method to detect early signals of potential problems, and do not provide proof that the product(s) in question (or ingredient associated with the adverse event) actually caused the event. AERs do provide early warning signals to FDA of potential product problems, such as product contamination or adulteration, tampering, bioterrorism and ingredient safety issues.

This legislation would require a manufacturer to submit only “serious” adverse event data (i.e. a health-related event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity or a congenital anomaly or birth defect). Limiting the data to serious reports reduces the reporting burden on manufacturers and does not overwhelm the agency with meaningless consumer complaints and non-serious AERs. Currently, consumers, doctors, hospitals/healthcare providers, and many dietary supplement manufacturers voluntarily report serious adverse events for dietary supplements to FDA through Medwatch and its CFSAN Adverse Events Reporting System (CAERS) program. Prior data and previous experience has shown that there are relatively few such incidents a year—but if such events do occur, a responsible industry should quickly notify FDA.

There are numerous protections in the FD&CA to prevent misuse of the AER data received by FDA. For example, Section 756 of the FD&CA ensures that any submission of a safety report shall not be construed as an admission that the product contributed to an adverse experience; all information that reveals the identity of the person who filed the report must be redacted, as stipulated under the Privacy Act and HIPPA protections for patient privacy. This legislation would permit manufacturers to supplement the report with additional information to negate or refute the relationship of the event to the product or to raise questions about the completeness or validity of the report.

**Requested Action:** Support S. 3546