



## **BACKGROUND**

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### **The Truth About Mandatory Adverse Event Reporting for Dietary Supplements**

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Much misinformation is being disseminated about potential legislation that would require manufacturers of dietary supplements to provide FDA with information about the serious Adverse Event Reports (AERs) they receive. The Council for Responsible Nutrition (CRN) represents the interests of the dietary supplement industry. Consequently we would only support legislation that we believed would have a positive impact for industry and its consumers. We support the current efforts underway in the Senate to develop legislation that would mandate the reporting to FDA of serious AERs. Such legislation would appropriately require that, if a consumer or healthcare professional contacts a manufacturer to report a serious adverse event related to a dietary supplement, then the manufacturer must tell FDA. Don't consumers have a right to expect dietary supplement manufacturers to share this kind of important information with the agency that regulates its products?

#### **Here's what legislation mandating reporting of serious AERs would not do:**

**MYTH:** *Requiring dietary supplement manufacturers to report serious adverse events will ruin Americans' "health freedom," and restrict consumers' access to dietary supplement products.*

**FACT:** Requiring manufacturers to report serious adverse events involving their products to FDA in fact would strengthen the regulatory structure for dietary supplements and build greater consumer confidence in this category of FDA-regulated products—thus ensuring and protecting Americans' continued access to safe, beneficial dietary supplements. In addition, it would provide consumers with more information to make educated choices about the supplements they use.

**MYTH:** *Mandatory AER legislation would treat dietary supplements like prescription drugs and upset the regulation of dietary supplements under the Dietary Supplement Health & Education Act (DSHEA).*

**FACT:** It is true that this legislation would require manufacturers to notify FDA when they receive information about a serious adverse health effect involving one of their products—something already required of prescription drugs, medical devices and many OTC drugs—but that does not change the basics of the way dietary supplements are regulated. Rather, by demonstrating the relatively few serious AERs that are reported, and the wide margin of safety behind our industry's products, such legislation would help to defuse our critics who would otherwise gain support for their call to roll back DSHEA and replace it with drug-like regulation of supplements, including pre-market approval for these products. The Federal Food, Drug and Cosmetic Act (FD&CA) is clear about the distinction between dietary supplements and drugs; serious AER legislation would not alter those definitions or regulatory structures.

**MYTH:** *Mandatory AER legislation would result in hundreds of thousands of reports that would literally overwhelm FDA.*

**FACT:** The legislation under discussion would only require a manufacturer or distributor to submit serious adverse event data (that is, 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). Many dietary supplement manufacturers already report these events voluntarily and they have told their trade associations there are relatively few (maybe 2-3 a year per company). This requirement will help demonstrate the wide margins of safety for this category of FDA-regulated products.

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Moreover, consumers, doctors, hospitals and other healthcare providers already report adverse events for dietary supplements to FDA through its Medwatch and CAERS programs—this legislation would just make the reports mandatory for the manufacturers. If there were going to be a “tidal wave” of reports to FDA, why isn’t it already happening? Additionally, other consumer products, like many OTC medicines, already have mandatory AER reporting and the number of serious reports received don’t come anywhere close to the outlandish predictions of critics opposing AERs. The reality is that there should be very few serious AERs for supplements.

**MYTH:** *Serious adverse event reports submitted to FDA by manufacturers would give plaintiff’s attorneys new ammunition in product liability litigation.*

**FACT:** FDA has repeatedly stated that AERs are simply a method to detect early signals about potential problems, and do not mean that the product or ingredient associated with the adverse event actually caused the event. There are numerous protections in the Food Drug & Cosmetic Act (FD&CA) to prevent misuse of the AER data that FDA receives, and these protections limit the use of AERs by the plaintiff’s bar in product liability litigation. For instance, Section 756 of the FD&CA ensures that any submission of a safety report (AER) shall not be construed as an admission that the product contributed to an adverse experience; all information that reveals the identity of the subject who filed the report must be redacted according to the protections under the Privacy Act; and this legislation expressly permits manufacturers to supplement the report with additional information that tends to negate the relationship of the event to the product or to raise questions about the completeness or validity of the report. Moreover it assures that the supplemental statement must be part of any report released by FDA for public disclosure. And finally, this legislation does not change the public’s access to AERs that are filed directly with FDA through Medwatch and CAERS—access that the public has always had to this data.

**MYTH:** *Mandatory AERs submitted by manufacturers would prevent them from obtaining needed product liability insurance and lead to fewer dietary supplements from which consumers could choose.*

**FACT:** Would insurance carriers provide product liability insurance on a product without asking its manufacturer what kinds of consumer complaints it has received—whether the data is filed with a federal agency or not? Carriers can already ask their insureds for this information to make their underwriting decisions. Several underwriters and risk managers we spoke with said they currently ask about consumer complaint files—even beyond serious adverse events. This legislation only means that carriers have a way to verify the information provided to them. As stated previously, there are relatively few serious AERs for dietary supplements so the impact on coverage and on the range of products offered to consumers will likely be unchanged. In fact, mandatory reporting might actually provide assurance to carriers of the safety of these products and make insurance easier to get.

**MYTH:** *“Big Pharma” is behind this AER legislation in order to drive out dietary supplement companies and to increase their own profits and destroy “health freedom.”*

**FACT:** Responsible dietary supplement manufacturers and their trade associations are supporting this legislation because it is the right thing to do for consumers. AERs provide early warning signals of potential product problems, like product contamination or adulteration, tamperings, bioterrorism and ingredient safety issues. Assuring that these reports go to a single source, FDA, in order to spot trends or “spikes” increases the likelihood that a potential problem will be identified more quickly, and fewer consumers will be affected.

Many responsible dietary supplement firms already voluntarily report to FDA any serious AERs that they receive. This legislation levels the playing field and requires that same responsible behavior of all dietary supplement manufacturers.