

**Talking Points On New Draft Legislation  
On Mandatory Adverse Event Reports  
The Dietary Supplement and Nonprescription Drug Consumer Protection Act (the “Act”)**

**The Act is not needed.** There is already an existing reporting system. The Act does harm to consumers and industry by raising unfounded concerns about the safety of safe supplements and by imposing a significant compliance burden and cost on industry. FDA has not requested the Act. If adopted, the Act creates a risk that FDA will ban certain ingredients because it will view the existence of *any* risk as a reason to cease sales of supplement ingredients.

**If you believe the Act should be adopted in spite of this, here are some important changes that need to be made:**

**Ongoing Reporting Obligation a Major Problem:** Often the first a company learns of an alleged adverse event is when a lawsuit is filed. It has to submit “additional information” which means the complaint filed in the lawsuit, the answer, every brief, and every document produced or discovered in the lawsuit (including depositions) during the first year must be gathered and disseminated to FDA. *The Act should be changed to limit ongoing reporting obligations to respond to specific requests from FDA. Also, once a lawsuit is filed, the reporting obligation should be suspended.*

**Falsification of Reports a Serious Issue:** Many adverse event reports received by manufacturers turn out to be from individuals or plaintiff attorneys merely seeking to extract a settlement and there is no remedy against these parties for filing the false report. The Act does not limit who may submit a report. This is an invitation for abuse. *Section 4(a)(ii) should be amended to read as follows to address this:*

**SEC. 4. PROHIBITION OF FALSE 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 submission, either orally or in writing, of a report that is materially false, fictitious or fraudulent, to a responsible person (as that term is used in section 760 or 761), concerning an adverse event or serious adverse event.”

**Increased Risk of Multiple-Reports for One Event:** The Act does not eliminate the existing CAERS voluntary reporting system under which anyone can submit reports directly to FDA, nor does it require FDA to consolidate multiple reports about a single incident. *The interplay between the Act and the existing CAERS system should be addressed. FDA should be required to develop systems to ensure that it consolidates multiple reports of the same incident into a single report.*

**Act Doesn’t Address if the Person Filing the Initial Report Fails to Provide Adequate Information or to Cooperate:** *The Act should be modified so that a responsible person need not report to FDA unless certain minimum information is provided (such as the complainer’s name, verifiable phone number or address, and correct product and brand name). FDA should not accept reports through any of its systems without this minimum required information.*

**Act Should Limit Reporting and Recordkeeping to a List of Ingredients Identified by FDA:** FDA doesn’t want to hear about or track every supposed stomachache or headache or other minor issue that might be associated with a multivitamin product. Companies don’t want to keep records and file reports for all these things. And yet the Act requires this. *The reporting and recordkeeping obligations under the Act should be limited to products with ingredients identified on a list published by FDA. The list would be created through a notice and comment process and would identify those specific ingredients which FDA has a reasonable scientific basis to conclude that there are concerns about safety. An obvious example would be ephedra.*

**Act Should Include A Sunset Provision:** *The Act should automatically expire within a specified period unless an extension is approved by Congress. This would ensure that if it turns out that the legislation appears to be unnecessary as many predict, its negative impacts will not continue indefinitely.*

**Act Doesn’t Cover All Relevant Products:** *The Act should be modified to cover homeopathic products, chinese medicinals and foods.*

**Recordkeeping Requirement too Vague:** *The Act should be modified to limit the record-keeping requirement to complaint files; otherwise, the recordkeeping requirement potentially covers far too many records: virtually every hard-copy and electronic record a manufacturer generates.*