

March 20, 2006

Re: Review of Mandatory AER Reporting Bill

Dear Nutraceutical:

This letter responds to your request for a detailed assessment of the latest draft of the AER bill. The bill suffers from a series of individual problems that have cascading negative effects.

1. ***Misdirection of Complaints from Local Responders to Federal Authorities; Terrorism Risk Increased.*** The bill directs consumers to complain to dietary supplement manufacturers and retailers rather than to local physicians and health authorities if they believe they have experienced a serious adverse event from ingesting a dietary supplement. The bill pre-empts local systems, including those of poison control centers, to the extent that they are not identical to the bill directing reporting to supplement manufacturers and retailers and then, by them, to the FDA. The combined effect of these measures is to direct consumers who are injured away from health authorities who need the information not only to respond to the medical needs of the person harmed but also to assess whether the harms are due to causal factors other than the ingredients in the supplement, including causal factors that may reveal acts of terrorism. By directing consumers to complain to supplement manufacturers and retailers and, in turn, to have those entities send the complaints along to the FDA in Washington, the bill removes information from local responders that would otherwise aid them in determining ultimate causes. It will then tend to delay response. Rapid response is indispensable, particularly in dealing with terrorist acts (such as injection of a toxic chemical into dietary supplement containers on store shelves).

2. ***Fox in Charge of the Hen House Effect.*** Ironically, the bill depends upon those who may be responsible for adulteration to report adverse effects to the FDA. In instances of harm stemming from purposeful acts of adulteration, it is unlikely that one who violates the law by selling tainted goods will report the law violation by sending the government the complaints received. By directing complaints away from physicians and local authorities, this system will diminish the extent to which serious adverse events caused by intentional wrongdoing will be discovered.

3. ***No Safeguards Against FDA Abuse.*** One of the principal reasons why Congress passed the DSHEA was to arrest instances of abuse of law and process by the FDA due to its historic bias against dietary supplement companies. The bill invites FDA to investigate supplement companies based on unverified complaints of injury. There are no limits on the investigatory process. As we know from experience, FDA has not infrequently used repeated investigations of companies to drive their costs up and interfere with their day to day operations. It has contacted vendors and customers and, by so doing, caused them to distrust the company in question, resulting in lost contracts and sales. Those same effects can be anticipated from this bill. There is nothing in the bill to protect companies from these kinds of abuses.

4. ***Inadequate Safeguards Against Malicious Complaints.*** The bill permits public disclosure of the complaints without prior establishment by HHS that the dietary supplement was likely the cause of the adverse event. FDA presently posts on its web site every AER complaint received by the agency without proof of its validity. This system does not alter that practice but increases the likely number of reports that will be filed. The effect of publishing all complaints is to mask true instances of harm in a sea of unverified complaints. That misleads the public. It also destroys the reputations of firms through defamatory publication without affording the companies any redress. It also invites waste of tax dollars to investigate companies for bogus complaints. While the company is responsible for evaluating the complaints, the bill denies the company the right to review medical information necessary to perform that evaluation. That medical information is kept from the company and, so, the company is not able to determine the cause or defend itself adequately against a false charge. Any person who wishes to impose a burden on a company can simply complain that someone, the complaining party or someone else, was seriously injured by the supplement. The company must then report the complaint to the FDA and then the FDA makes it publicly available, causing a mass defamatory impact.

5. ***Complaints Not Limited to Those Allegedly Injured.*** The bill is poorly drafted such that it does not limit the right to file an adverse event report to those who have suffered the alleged serious event. The definition of serious adverse event in the bill includes any event that results in "a life threatening experience" or "a persistent or significant disability or incapacity." The Reporting Requirement section of the bill makes the "responsible person" (every manufacturer, distributor, and retailer) to submit "any report received." Nowhere in this bill is there a limitation on who may submit the report. Literally anyone can. As a result, I could submit a report if I suspected that any person I saw or heard about in general had suffered what I perceived to be a life threatening experience or a persistent or significant disability or incapacity. There are public interest groups out there that believe virtually every dietary supplement poses a life threatening risk to users or creates a risk of persistent or significant disability or incapacity. There are others who attribute all manner of physical manifestations (whether in fact due to disease, allergy, or other ingested substances) to dietary supplements. Any of them are free to file a complaint with the manufacturer,

retailer, and/or distributor. Under the bill such complaints are treated in an identical manner with those coming directly from health authorities and from consumers who take the supplements. This is a gross invitation for abuse. It will result in the maintenance of false reports along with legitimate ones and it will make it more difficult, not less, to discern the presence of actual adverse events due to the use of certain dietary ingredients in the marketplace.

6. *Proof of Actual Injury Not Required Before Tax Dollars Spent to Investigate.* The bill causes publication of the reported adverse events, invites investigation of the reporting companies, and requires response to inquiries--all without first establishing that the dietary supplement in question is in fact the cause of the harm or harms alleged. There is no requirement that the person allegedly harmed be the one to report, that he or she see a doctor and have a medical verification of suspected cause, or have the government investigate the medical background of the allegedly injured patient to determine, before posting the information publicly or investigating the company, that the harms alleged are likely caused by the dietary supplement. Moreover, the bill invites the worst kind of invalid scientific submission: self-diagnosis. The person who experiences a change in physical status is often not equipped to know with reasonable certainty whether the change is life-threatening or is a significant incapacity or disability. That calls for a medical judgment. Moreover, the person who experiences a change in physical status is not equipped to know whether a dietary supplement, as opposed to a food eaten, a chemical ingested from tainted water, exposure to chemicals, exposure to radiation, or ingestion of a drug is the likely causative factor. At best, local medical authorities are best equipped to make that determination, followed by the Centers for Disease Control and Prevention on the federal level, not FDA bureaucrats. By permitting the posting of medically unverified reports and by imposing on "responsible persons" the reporting, recordkeeping, and investigation burdens without causality, the bill adds grossly to the costs of companies in the industry, wastes tax dollars, and invites confusion rather than clarity about the safety of dietary supplements.

7. *Bill Denies Companies Right of Access to Medical Records Needed for Self-Defense Against False Complaints.* The bill keeps confidential (except to the government) the medical records of the person allegedly harmed. That invites abuse. While the government, in its inspections of a company, may--but is not required to--have reason to believe that the dietary ingredient is the cause of a specific adverse event, the company being inspected lacks the specific information needed to determine cause. The company thus can be investigated without knowing the nature, purpose, and scope of the investigation. It can be required to produce responsive materials without knowing how those materials will be assessed. Information of this kind is time sensitive. Seeing the physical manifestations, performing tests to determine causality, and preserving relevant evidence all necessary to defend a company is prevented by this hiding of the pertinent information. The effect is to permit the government to mount a case against the accused without letting the accused know sufficient information to mount a defense.

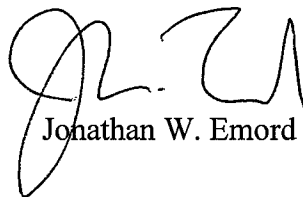
8. *Ineffectual Falsification of Reports Section.* This section of the bill is totally ineffectual. A knowing falsification of a report of a serious adverse event to a responsible person is made a prohibited act under the FDCA. However, because proof of

causation is not required as a condition precedent to filing a report and because medical records are withheld from the party that would be harmed by a false report, there is no basis upon which to establish the "knowing falsity" required to prove a false report to have been filed. So, the accused is left without any real remedy. Moreover, there is still no requirement that the complaining party be the one who allegedly suffered the event, there is no requirement that the report be submitted under penalty of perjury, and there is no requirement that the complaining party have a doctor confirm that the event is likely caused by the supplement. So, because those elements are lacking, "knowing falsity" will be all but impossible to prove. The section is wholly ineffectual and impracticable. The section, as it pertains to knowing falsification of an adverse event report, would also apply to the company submitting the report and to the complaining party. This creates a perverse disincentive for responsible persons to file reports they suspect may be false because if they have a reason to believe the report may be false, they may be making a false report themselves.

This bill appears to have been drafted without due regard for the history of FDA bias against the dietary supplement industry or the history of abusive submissions made under the existing AER reporting system. By magnifying the power of the FDA to inspect and by magnifying the reports that must be filed, the bill results in the imposition of costly regulatory burdens without any real benefit to consumers.

Consumers harmed by dietary supplement ingredients are best directed to physicians for treatment, for diagnosis of the real cause of harm, and for remedial measures. There is presently no proof that FDA lacks sufficient information from local responders to enforce the law against those who sell adulterated dietary supplements. In the apt phrase of others, this appears to me to be a bill in search of a problem. The framers of our Constitution warned against precisely this kind of legislating because it increases federal power at the expense of private rights.

Best regards,



Jonathan W. Emord