

**ADVERSE EVENT REPORTING**

by Leanne Wylet B.A. and Helen Lawler, M.A.

The defeat of the California Bill SB 779 which would have required an adverse event reporting (AER) system for dietary supplements was welcomed. A similar AER system at the federal level could benefit subsidiaries of pharmaceutical companies that produce and/or distribute supplements by eliminating many of their smaller competitors. All independently-owned companies would be at risk due to the pro-pharmaceutical bias of CODES, the FDA and similar agencies in other countries

Recent trends at the FDA, including Good Manufacturing Practices and protocols for the safety of supplements, are well-suited to the harmonization of our dietary supplement laws to the more stringent regulations of other countries such as Germany and Australia. Dosage limits at or near RDA levels for all over-the-counter supplements, and restrictions on permissible ingredients would eliminate the most innovative and most effective products now on the market.

The potential impact of international trends may be hard to grasp when US trade associations such as the National Nutritional Food Association (NNFA) and Citizens for Responsible Nutrition (CRN) continue to tell us that US laws are protecting access to dietary supplements.

Based on PfAM's many years of research we are now strongly urging those who have relied upon these sources to please do some independent research. There is now too much at stake not to. If you choose to do so here are some questions to consider: (1) Do NNFA and CRN (and other) trade associations still truly represent my company and my interest? (2) Who are their board members? Do any board members also represent pharmaceutical interests too? If so does this represent a conflict of interest according to the trade associations By Laws? (3) Even though my interests have been represented in the past is this trade association still doing so? (4) Do I see any inconsistencies in what I'm being told and what is actually happening? (5) Who or what is their source of information? Is the information objective or biased? (6) Will US laws be adequate to protect continued access to dietary supplements even against threats of trade sanctions?

Over the last eight years PfAM has devoted countless volunteer hours to tracking and documenting federal and international trends related to access to dietary supplements. It has taken constant vigilance to keep abreast with the fast moving incremental changes being made which may adversely impact continued access to dietary supplements.