

AMENDMENTS TO S. 3546
“THE DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG
CONSUMER PROTECTION ACT”

The Problem: S. 3546 as currently written imposes enormous burdens on both the Food and Drug Administration (FDA) and the dietary supplement industry, with no promise of any public safety benefit. For decades FDA has collected and currently collects and evaluates thousands of adverse event reports for nonprescription drugs and dietary supplements using a voluntary reporting system. FDA has been diligently upgrading this voluntary system over the years, and this system has a proven track record of identifying safety issues and protecting the public health. It is telling that FDA, the agency charged with the responsibility of assuring the safety of nonprescription drugs and dietary supplements, has not requested additional authority to require mandatory reporting of adverse events for these products.

The large number of reports that FDA received for ephedra products using this voluntary system proves that underreporting of events is not the problem. When product safety issues occur, healthcare professionals and consumers know to report events to FDA.

The Solution: Three options for amending S. 3546 are provided.

- **OPTION 1 – The mandatory reporting requirements of S. 3546 should be abandoned and replaced by a nationwide toll-free number on all nonprescription drug and dietary supplement labels to make the current voluntary system more effective.**
- **OPTION 2 – If congressional supporters of S. 3546 are serious about the need for better consumer protection, then the mandatory reporting requirements of S. 3546 should apply to all foods, not just dietary supplements, since the safety issues relating to allergens and food-borne bacteria are much more common and serious than the safety issues presented by dietary supplements.**
- **OPTION 3 – At a minimum, S. 3546 should be amended to minimize the reporting and recordkeeping burdens, and to include a sunset provision to assure that the need for even the diminished burdens is established and evaluated at a later date.**

Finally, regardless of which option is chosen, S. 3546 should be amended to include a revision to Section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act to remove the word “unreasonable,” thereby removing any argument that FDA should use the a “risk/benefit” standard, the same standard that FDA uses to evaluate drugs and devices, for dietary supplements, rather than a straightforward “risk” standard that FDA has historically applied to all other foods.