

The Honorable [Senator's Full Name]  
United States Senator  
Office Address  
Washington, D.C. 20510

Re: Hatch/Durbin FDA Amendment

Dear Senator [Last Name]:

I understand that Senators Hatch and Durbin may offer an amendment that would significantly change the Dietary Supplement Health and Education Act (DSHEA) by mandating FDA Adverse Event Reporting (AER) for dietary supplement that may be linked to a "Serious Adverse Medical Event"(SAME).

I strongly oppose this "compromise" amendment. The legislation is another foot-in-the-door approach to regulating dietary supplements like prescription drugs, and imposing bureaucratic controls when no further regulation of dietary supplements is needed. This legislation is completely unnecessary and is trying to fix something that is not broken. The safety record of dietary supplements over the last three decades is absolutely impressive. Unlike pharmaceutical drugs where tens of thousands of people die and are killed and injured every year, there are so few serious adverse events associated with dietary supplements that a person is more likely in this country to die from a bee sting or a lightning strike than they are from consuming supplements.

I am not generally supportive of the FDA when it comes to dietary supplements, but even they have testified to Congress twice this year against the need for Congress to make any changes in the existing DSHEA law.

Reasonable-minded people cannot dismiss the importance of having knowledge of serious adverse events. However, consumers, physicians, manufacturers, and distributors can already file, and do file, AERs. Senator Durbin believes that the current voluntary reporting system is not protecting the public. For the reasons stated above, the amendment is an unnecessary change to the DSHEA law. It would open the door to arbitrary interpretation by FDA bureaucrats to eliminate supplements based on information that may not be proven by reliable medical evidence.

Should this amendment be considered, I expect that you will vote against its passage. I would appreciate knowing what your position is on this legislation and will look for your response.

Sincerely,