



May 24, 2012

Dear Senator Hatch and Senator Harkin:

The dietary supplement industry's trade associations—the American Herbal Products Association (AHPA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), the Natural Products Association (NPA), and the United Natural Products Alliance (UNPA) -- oppose both the dietary supplement related amendments to the Food and Drug Administration Safety and Innovation Act (S. 3187 or the FDA User Fee Legislation).

The Durbin amendment would expand the registration requirements by requiring manufacturers to submit a description of each dietary supplement product manufactured by the facility, a list of all ingredients in each dietary supplement product, and a copy of the label and labeling for each product. Facilities would also be required to submit additional registration if the facility begins manufacturing a new product or a reformulated product, or ceases producing a product for which the facility previously submitted a registration. Senator Durbin's amendment creates more bureaucracy for an already resource-challenged agency and more red tape and costs for industry while doing nothing to protect consumers further.

The Paul amendment goes against the very heart of the Food, Drug and Cosmetic Act and the basis of drug regulation in the United States. The amendment also upsets the careful compromise negotiated in 1994 with the Dietary Supplement Health and Education Act that has been maintained to this day. This amendment also raises significant consumer safety hazards. Indeed, under this amendment, there would be little incentive for many pharmaceutical developers to follow the pathways for evaluating the safety and efficacy of their products. It would be easy to envision a system where unscrupulous companies market drugs as foods or supplements.

The dietary supplement industry opposes both Senator Durbin's and Senator Paul's dietary supplement related amendments because both would disturb the careful balance Congress struck with DSHEA.

Sincerely,

American Herbal Products Association
Consumer Healthcare Products Association
Council for Responsible Nutrition
Natural Products Association
United Natural Products Alliance

Cc: Senator Michael Enzi