Dietary Supplement Labeling Act

Action Requested

Please Oppose the Dietary Supplement Labeling Act (DSLA) When Re-Introduced in 114th Congress

Background

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA).

DSHEA amended the Federal Food, Drug, & Cosmetic Act (FFDCA) to (1) authorize the Secretary of Health and Human Services (HHS) to immediately ban any dietary supplement or ingredient that poses an imminent hazard to public health or safety; (2) require pre-market notification, including scientific substantiation of safety for all new dietary ingredients; and (3) mandate stringent good manufacturing practices regulations to prevent the contamination and adulteration of dietary supplements.

In 2006, Congress enacted the Dietary Supplement and Non-Prescription Drug Consumer Protection Act (Public Law 109-462). This law created mandatory adverse event reporting (AER) requirements for dietary supplements and imposed strict guidelines for the prompt reporting of all serious AERs. The HHS Secretary can review and use existing adverse event data to determine whether a dietary supplement or ingredient poses an unreasonable risk.

In 2011, Congress enacted the Food Safety Modernization Act (FSMA). FSMA called for an extensive overhaul of Food and Drug Administration (FDA) safety regulations to update existing regulations to improve FDA's ability to respond to potential threats to the safety of all foods, including dietary supplements. FSMA strengthens registration requirements for entities that manufacturer, process, package, or hold dietary supplements, and requires an assurance from entities that FDA can inspect their facilities at the times and in the manner permitted by the FDCA. FSMA also gives FDA the authority to suspend a dietary supplement entity's registration if FDA determines, or the facility knows, there is a reasonable probability the supplement causes serious adverse events.

Issue

Senator Richard Durbin (D-IL) has introduced his Dietary Supplement Labeling Act (DSLA) legislation in each of the last two Congresses. NPA expects the Senator to re-introduce this Congress.

In previous iterations, the DSLA has proposed amending the FFDCA to create additional registration and labeling requirements for dietary

supplements.

The legislation would (1) require entity registration for dietary supplements, and product registration for all existing, new, reformulated, and discontinued dietary supplements; (2) require the Secretary of HHS to contract with the Institute of Medicine (IOM) to evaluate the safety of supplement ingredients and proprietary blends that IOM determines could pose potential health risks; (3) require the Secretary to publicly list ingredients and proprietary blends the Secretary determines may pose such risk; and (4) require mandatory warning label requirements for listed ingredients and blends.

This legislation would create redundant regulations for dietary supplements that would force industry and the resource-challenged FDA to bear an undue burden to ineffectively serve public health and safety objectives.

DSLA is based on the flawed presumption that current dietary supplement regulations fail to provide the Secretary with adequate means or authority to protect consumers from unsafe or adulterated dietary supplements.

NPA Position

NPA will strongly oppose the DSLA when re-introduced as well as any legislation that seeks to impose unnecessary regulations on the dietary supplement industry.