



POSITION STATEMENT

Reagan-Udall Foundation of *FDA Revitalization Act* (FDARA – S. 1082): *Does Not Negatively Impact Dietary Supplements or Conflict with DSHEA*

Background

The U.S. Senate has considered and passed the Food and Drug Administration Revitalization Act (FDARA—S. 1082), which addresses many critical issues within FDA related to drugs, devices and foods. Matters addressed in the large, omnibus legislation include: the reauthorization of prescription drug user fees (PDUFA); drug safety; medical device user fees (MDUFMA); pediatric medical products; food safety; and drug re-importation. While dietary supplements are potentially affected by several provisions of the bill, CRN believes that nothing in the legislation would negatively affect supplements as the legislation is currently written.

Creation of the Reagan Udall Foundation

Title II of FDARA would create the “Reagan-Udall Foundation for FDA” which would, as described in the legislation, “...advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.” There has been some concern within the industry that this foundation could “overturn” the Dietary Supplement Health and Education Act (DSHEA). This concern is misplaced. DSHEA has been the subject of much debate over the last 14 years since its inception, but nothing in this section would change the statutory and regulatory authority that DSHEA created in 1994.

During the May 2, 2007 Senate debate on FDARA, both Sen. Orrin Hatch (R-UT) and Sen. Tom Harkin (D-IA), driven by concerns in the industry, engaged in a colloquy (available at www.crnusa.org/pdfs/FDARAcolloquy050207.pdf) with the chairman and ranking member of the Health, Education, Labor and Pensions (HELP) Committee, Sen. Edward Kennedy (D-MA) and Sen. Mike Enzi (R-WY) and asked some pointed and in-depth questions about the foundation. Sen. Enzi explained that the foundation’s “simple purpose is to lead collaborations among the FDA, academic research institutions and industry designed to bolster research and development productivity...” Sen. Kennedy confirmed that, “... the Reagan-Udall Foundation will in no way override, overturn or conflict with DSHEA.” Sen. Hatch questioned whether, “...the language could, in fact, help dietary supplement consumers, because it would allow collaboration between government and industry to conduct research on issues that might be helpful to supplement consumers?” Sens. Kennedy and Enzi both said yes and agreed. This discussion satisfied both Sens. Hatch and Harkin and reinforced that DSHEA was not under attack by the creation of this foundation.

Other Dietary Supplement Provisions

Dietary supplements are also referenced in FDARA in Title V, with the “publication of annual reports,” which would require FDA to continue a pesticide monitoring program and publish results from the Ginseng Dietary Supplements Special Survey, and in Title VI with the proposed creation of an “adulterated food registry.” However, with the inclusion of §605(c), dietary supplements would be exempt from the proposed “adulterated food registry” because of the reporting and record keeping requirements that were enacted in the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462). That law, enacted last year, requires manufacturers to report all “serious” adverse events to the FDA and to retain records of “all” adverse events for 6 years. However, dietary supplements would not be exempt from other provisions within the food safety title of FDARA.

Current Status

FDARA—S. 1082—passed the Senate on May 10th, and to date, the House has yet to take action on the Senate’s language.