

Resolution 4A

Dietary Supplement Protection

2012 The U.S. Health Freedom Congress

Schaumburg, IL, June 14, 2012

Referring to H.R. 3380, Sponsored by Representative Burton of Indiana and introduced on November 4, 2011

“ FINDINGS...

(1) Improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government. The importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention are well known and have been documented in scientific studies;

(2) Since enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplements have had an exemplary public health safety record. Based on national surveys, in 1994, 50 percent of the 260,000,000 Americans regularly consumed dietary supplements. In 2006, 232,000,000 adults over the age of 18 alone consumed dietary supplements, 53 percent of the United States adult population;

(3) There were 4,000 dietary supplements in the marketplace in 1994, and in 2006 an estimated 29,000 dietary supplements were being consumed daily by Americans. Since the enactment of DSHEA, there has been 17 years of additional historical use-safety experience conducted by millions of Americans. Over 17 years, approximately 25,000 new supplements with new dietary ingredients have been approved by the Food and Drug Administration (FDA) under DSHEA and have and are being safely consumed by Americans;

(4) Since January 2007, FDA regulations governing dietary supplement manufacturer good manufacturing practices, dietary supplement adverse event reporting, and private sector voluntary testing and auditing for supplement quality and purity have improved post marketing consumer safety. Before DSHEA, these mechanisms did not exist;

(5) There are DSHEA 'grandfathered' supplements, dietary ingredients, and classified products which were on the market before October 15, 1994, and 'generally recognized as safe' for human consumption. FDA regulatory policy, industry practices, and consumer marketplace paradigms have drastically changed over 17 years, but this policy has not; and

(6) The definition of a new dietary ingredient in section 413 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 350b) does not recognize the current safe market in supplements, nor how intensively supplements have been regulated over the 17 years since enactment of DSHEA

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to protect public health and safety, and should be updated to reflect this reality.” (H.R. 3380 2011)

THEREFORE BE IT RESOLVED that the language and recommendations of H.R.3380 The Dietary Supplement Protection Act of 2011 Sponsored by Representative Burton of Indiana and introduced on November 4, 2011, be supported, and when H.R. 3380 changes the date in dietary supplement protection law from 1994 to January 1, 2007, it will, if adopted:

- (i) prohibit the FDA and any other government agent, agency, or entity from interpreting DSHEA and the existing definition of “new dietary ingredient” in a manner that would increase unnecessarily and unfairly regulation and the regulatory burden for manufacturers or distributors of dietary supplements that have been on the market from 1994 to 2007;
- (ii) protect the original intent and findings of the Dietary Supplement Health and Education Act of 1994;
- (iii) protect the presumption that dietary supplements are safe and the legal principle that the burden of proof of harm is on the government to show harm before blocking access to a dietary supplement; and
- (iv) protect the fundamental right of consumers to have access to dietary supplements in order to ensure their ability to make personal food choices and health related choices for their own sustenance, health, and survival,

Be it resolved that the 2012 Health Freedom Congress has considered the following resolutions and hereby adopts the health freedom principles embodied in the resolutions and offers the support of the member organizations to the extent determined by each organization’s governing principles. *

*This statement was adopted to apply to the set of resolutions that the 2012 Health Freedom Congress passed June 14, 2012.