

“(11) the United States will spend over \$1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

“(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

“(B) the industry consistently projects a positive trade balance; and

“(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least \$4,000,000,000;

“(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

“(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

“(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

“(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.”

#### DISSEMINATION OF INFORMATION REGARDING THE DANGERS OF DRUG ABUSE

Pub. L. 90-639, § 5, Oct. 24, 1968, 82 Stat. 1362, provided that: “It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, the highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse.”

#### CONGRESSIONAL FINDINGS AND DECLARATION OF POLICY

Pub. L. 89-74, § 2, July 15, 1965, 79 Stat. 226, provided that: “The Congress hereby finds and declares that there is a widespread illicit traffic in depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act [see Short Title of 1965 Amendment note set out under section 301 of this title], would discriminate against and adversely affect interstate commerce in such drugs.”

#### EFFECT OF DRUG ABUSE CONTROL AMENDMENTS OF 1965 ON STATE LAWS

Pub. L. 89-74, § 10, July 15, 1965, 79 Stat. 235, provided that:

“(a) Nothing in this Act [enacting section 360a of this title, amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321, 352, and 360a of this title] shall be

construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State in contravention of the laws of such State.

“(b) No provision of this Act nor any amendment made by it shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, unless there is a direct and positive conflict between such provision or amendment and such State law so that the two cannot be reconciled or consistently stand together.

“(c) No amendment made by this Act shall be construed to prevent the enforcement in the courts of any State of any statute of such State prescribing any criminal penalty for any act made criminal by any such amendment.”

#### EFFECT OF DRUG AMENDMENTS OF 1962 ON STATE LAWS

Pub. L. 87-781, title II, § 202, Oct. 10, 1962, 76 Stat. 793, provided that: “Nothing in the amendments made by this Act [enacting sections 358 to 360, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 379e, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 360, and 374 of this title] to the Federal Food, Drug, and Cosmetic Act [this chapter] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.”

#### DEFINITIONS

Pub. L. 105-115, § 2, Nov. 21, 1997, 111 Stat. 2297, provided that: “In this Act [see Short Title of 1997 Amendment note set out under section 301 of this title], the terms ‘drug’, ‘device’, ‘food’, and ‘dietary supplement’ have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).”

#### § 321a. “Butter” defined

For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) “butter” shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

(Mar. 4, 1923, ch. 268, 42 Stat. 1500.)

#### REFERENCES IN TEXT

The Food and Drug Act of June 30, 1906, referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, which was classified to subchapter I (§1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, §1002(a), formerly §902(a), 52 Stat. 1059; renumbered §1002(a), Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784, and is covered by this chapter.

#### CODIFICATION

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to section 6 of this title. Section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

#### § 321b. “Package” defined

The word “package” where it occurs the second and last time in the act entitled “An act to