

from North Dakota [Mr. DORGAN], and the Senator from Iowa [Mr. HARKIN] were added as cosponsors of amendment No. 1122 proposed to S. 1061, supra.

SENATE CONCURRENT RESOLUTION 52—RELATIVE TO FTC RULING ON MADE IN USA LABELING

Mr. HOLLINGS (for himself and Mr. ABRAHAM) submitted the following concurrent resolution; which was referred to the Committee on Commerce, Science, and Transportation:

S. CON. RES. 52

Whereas for the past several decades the "Made in USA" label has defined a product as having all or virtually all of its parts and labor originating in the United States;

Whereas the people of the United States depend upon the integrity of this label when purchasing products;

Whereas the label projects a sense of pride for American workmanship and value;

Whereas the Federal Trade Commission has proposed regulations to lower this standard to allow substantial amounts of a product to be of foreign origin;

Whereas lowering this standard will be a misrepresentation to consumers in the United States who presently believe products bearing the "Made in USA" label were all or virtually all made in the United States;

Whereas consumers in the United States are entitled to purchase products with the understanding that the labels on these products reflect consistent definitions; and

Whereas the Federal Trade Commission is responsible for safeguarding the consumer from unfair, deceptive, and fraudulent practices: Now, therefore be it

Resolved by the Senate (the House of Representatives concurring), That the Congress—

(1) maintains that the standard for the "Made in USA" label should continue to be that a product was all or virtually all made in the United States; and

(2) urges the Federal Trade Commission to refrain from lowering this standard at the expense of consumers and jobs in the United States.

Mr. HOLLINGS. Mr. President, today, along with Senator SPENCER ABRAHAM of Michigan, I am pleased to submit a resolution opposing a proposal by the Federal Trade Commission to allow the "Made in the USA" label to be applied by products that are not made in the United States. If the FTC's proposal were to take effect, it would result in misleading and inaccurate claims and could ultimately cause widespread deception and consumer confusion. Moreover, the FTC's proposal would encourage manufacturers to send U.S. jobs abroad.

The FTC's recent proposal would reverse 50 years of precedent by the use of the "Made in USA" label even for products with as much as 25 percent or more, foreign labor or materials if they were substantially transformed in the United States. In some instances this could result in a product being labeled as "Made in the USA", even if all of the product's materials or components were made abroad.

Under current rules, products can only be labeled as made in the USA. If

all or virtually all of the products is made in the United States. This strict rule ensures that American consumers can rely on the assertions made by manufacturers, on U.S. made products. American consumers have come to rely on this label, as insurance that the components, materials, and labor used to make the product are from the United States. To change the standard would invite confusion and undermine the value of the made in the USA label.

The FTC's proposal is opposed by many of the country's leading consumer groups, including the National Consumer's League, the National Council of Senior Citizens, and Citizen Action. Moreover, many leading manufacturers, agriculture groups, and labor unions oppose changes to the current standard. In my State of South Carolina one of our pre-eminent manufacturers, Nucor Steel Corp., is among the corporations opposed to the FTC changes.

In addition, by permitting manufacturers to mislabel their products, the FTC is encouraging American employers to transfer manufacturing of components or materials abroad. Because consumers prefer products made in the United States, the "Made in USA" label is strong incentive for manufacturers to keep jobs in the United States. By permitting manufacturers to shift manufacturing abroad where they can pay lower wages and still maintain the benefits of labeling products as made in the USA, the FTC is explicitly encouraging the transfer of jobs abroad.

AMENDMENTS SUBMITTED

THE FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997 PRESCRIPTION DRUG USERS FEE REAUTHORIZATION ACT OF 1997

JEFFORDS AMENDMENT NO. 1130

Mr. JEFFORDS proposed an amendment to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Administration Modernization and Accountability Act of 1997".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. References.

TITLE I—IMPROVING PATIENT ACCESS

- Sec. 101. Mission of the Food and Drug Administration.
- Sec. 102. Expanded access to investigational therapies.
- Sec. 103. Expanded humanitarian use of devices.

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

- Sec. 201. Interagency collaboration.
- Sec. 202. Sense of the committee regarding mutual recognition agreements and global harmonization efforts.
- Sec. 203. Contracts for expert review.
- Sec. 204. Accredited-party reviews.
- Sec. 205. Device performance standards.

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

- Sec. 301. Collaborative determinations of device data requirements.
- Sec. 302. Collaborative review process.

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

- Sec. 401. Policy statements.
- Sec. 402. Product classification.
- Sec. 403. Use of data relating to premarket approval.
- Sec. 404. Consideration of labeling claims for product review.
- Sec. 405. Certainty of review timeframes.
- Sec. 406. Limitations on initial classification determinations.
- Sec. 407. Clarification with respect to a general use and specific use of a device.
- Sec. 408. Clarification of the number of required clinical investigations for approval.
- Sec. 409. Prohibited acts.

TITLE V—IMPROVING ACCOUNTABILITY

- Sec. 501. Agency plan for statutory compliance and annual report.

TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES

- Sec. 601. Minor modifications.
- Sec. 602. Environmental impact review.
- Sec. 603. Exemption of certain classes of devices from premarket notification requirement.
- Sec. 604. Evaluation of automatic class III designation.
- Sec. 605. Secretary's discretion to track devices.
- Sec. 606. Secretary's discretion to conduct postmarket surveillance.
- Sec. 607. Reporting.
- Sec. 608. Pilot and small-scale manufacture.
- Sec. 609. Requirements for radiopharmaceuticals.
- Sec. 610. Modernization of regulation of biological products.
- Sec. 611. Approval of supplemental applications for approved products.
- Sec. 612. Health care economic information.
- Sec. 613. Expediting study and approval of fast track drugs.
- Sec. 614. Manufacturing changes for drugs and biologics.
- Sec. 615. Data requirements for drugs and biologics.
- Sec. 616. Food contact substances.
- Sec. 617. Health claims for food products.
- Sec. 618. Pediatric studies marketing exclusivity.
- Sec. 619. Positron emission tomography.
- Sec. 620. Disposal.
- Sec. 621. Referral statements relating to food nutrients.

TITLE VII—FEES RELATING TO DRUGS

- Sec. 701. Short title.
- Sec. 702. Findings.
- Sec. 703. Definitions.
- Sec. 704. Authority to assess and use drug fees.
- Sec. 705. Annual reports.
- Sec. 706. Effective date.
- Sec. 707. Termination of effectiveness.

TITLE VIII—MISCELLANEOUS

- Sec. 801. Registration of foreign establishments.