

patients who have failed existing approved therapies.

*Information system (Sec. 407)*

The conferees intend that the information system shall provide access to the information by the applicant under conditions set by the Secretary, except that access shall not be provided under any particular form of information system to any applicant until appropriate safeguards are in place to ensure that integrity and confidentiality of the information for which access is provided.

*Education and training (Sec. 408)*

The conference agreement authorizes the Centers of the FDA that conduct intramural research to provide fellowships and training to appropriate undergraduate, pre-doctoral, and/or post-doctoral candidates. In the past, FDA's Centers provided for a limited number of scientific training positions through Full Time Equivalent programs or interagency agreements with other federal agencies which have the statutory authority to hire trainees through third parties. However, many of the benefits of the training program have been reduced because FDA has not had specific direct authority to conduct and support them. In light of the additional overhead costs, reduced training flexibility, increased paperwork, and hiring delays that have resulted, it is increasingly difficult and impractical for FDA to hire trainees as FTE Service Fellows. As a result, the Intramural Research and Training Authority authorized here is intended to provide the FDA the authority to conduct and support directly the selection and training of fellows, along more efficient use of appropriated funds by reducing overhead and other costs, and permit the training of such candidates as non-FTE positions. The conference agreement also provides similar authority for the Centers for Disease Control and Prevention.

*Centers for education and research on therapeutics (Sec. 409)*

The conference agreement establishes a demonstration program to conduct research and increase awareness of new products and ways to improve their effective use, and to increase awareness of risks of both new uses and combinations of therapies. In carrying out this demonstration program, the Secretary is directed to act through the Agency for Health Care Policy and Research (AHCPR) in consultation with the FDA Commissioner. The conferees designated AHCPR as the lead agency because of its expertise in the evaluation of the effectiveness of clinical care, its non-regulatory role, and its close working relationship with the health care community in the improvement of the quality of care. Accordingly, this section establishes a new Section 928 in Title IX of the Public Health Service Act, the authorizing statute for AHCPR.

To ensure appropriate coordination and to avoid unnecessary duplication, AHCPR is required to consult closely with the FDA in the development and operation of this demonstration program. The conferees expanded the focus of this demonstration to include ways to improve the effective use of drugs, biological products, and devices as well as risks of new combinations of such products and directed that the clinical information gained in the project would be provided to consumers as well as health care practitioners and insurers. Finally, the conferees direct AHCPR also to consider the appropriate use of products in meeting the purposes of this section.

*Environmental impact review (Sec. 411)*

The conferees believe that FDA's new procedures implementing the National Environmental Policy Act (NEPA) appropriately eliminate unnecessary paperwork and delays

associated with prior agency practices. Section 411 makes clear that an environmental impact statement (EIS) prepared in accordance with those regulations will meet the requirements of NEPA. The conferees do not intend this section to preclude judicial review of EISs. The conferees understand that the FDA may modify its regulations periodically, in consultation with the Council on Environmental Quality and the FDA's authorizing committees, as new circumstances or information warrants.

Because the Clean Air Act authorizes production of limited quantities of Class I and Class II substances for use in medical devices, there will be a continuing, but limited, supply of these substances. The EPA shall not dictate, promote or otherwise encourage a policy preference for disposal by incineration of the contents of metered-dose inhalers, but instead allow such contents to be recaptured, recycled or reused consistent with section 608(a)(3) of the Clean Air Act until such time that Congress conducts oversight hearings into the issue.

*National uniformity for nonprescription drugs and cosmetics (Sec. 412)*

*Confidentiality of OTC company self-audits*

Public policy should encourage drug manufacturers to conduct audits of their activities to candidly alert management to potential problems so that they can be addressed quickly and effectively. If FDA were to assert routine access to these audits, it would create serious disincentives to conducting appropriate audits and preparing thorough reports of the results. FDA already has a policy of not ordinarily requesting audit reports, which is set forth in compliance policy guide (#7151.02, Sec. 130.300) that applies to prescription drug firms. It is expected that OTC drug firms would be subject to the same compliance policy guide. Thus, during routine inspections of OTC drug establishments, FDA would not be expected to request or to review or copy reports and records that result from the firm's own audits and inspections of its operations to assure compliance with applicable FDA requirements such as good manufacturing practice (GMP) regulations. FDA would reserve the right to review such audits in certain limited circumstances as outlined in the compliance guide.

*OTC and cosmetics inspection*

The conferees intend that FDA exercise its new records inspection authority fairly and carefully, especially with regard to inspections at facilities that manufacture products that are both cosmetics and over-the-counter drugs. Cosmetic products that are also OTC drugs will, under the provisions of this bill, benefit from full national uniformity relating to all regulatory requirements, including those associated with ingredients, labeling, and packaging. Therefore, under these provisions, manufacturers of such OTC products will be subject to records inspection by FDA. The conferees want to make clear that any records inspection applies only to those products for which there is full national uniformity. This new records inspection authority applies only to products determined to be over-the-counter drugs. It does not apply to products that are solely cosmetics.

In the case of an inspection at a facility which deals both with cosmetic products that are OTC drugs and those that are not, FDA inspectors do not have access to any records relating to the cosmetic products. Further, the conferees want to make clear that there is no records inspection authority under these provisions for facilities dealing exclusively with cosmetics.

Finally, the conferees expect that FDA will provide sufficient time and guidance to the over-the-counter drug industry prior to

initiating any program of records inspection and in the early stages of implementing this new requirement.

*Effect of national uniformity on state enforcement "little FTC" laws*

All states have laws prohibiting false and misleading advertising, modeled on the Federal Trade Commission Act. These laws have been applied to prohibit unsubstantiated claims for nonprescription drugs and cosmetics, and to require corrective advertising. This provision is not intended to preempt the application of these laws under such circumstances.

The Conference Committee intends to make clear that "Little FTC" laws, as they have historically been written and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

*Effect of national uniformity on state food labeling laws*

This provision is not intended to preempt or prohibit States from regulating the labeling of food which derives from animals treated with non-prescription drugs. Nor are these provisions intended to void State regulations on the use of these drugs.

*Product classification (Sec. 416)*

Subsections (b) and (c) have been amended to make clear that FDA may only modify product classifications for public health reasons based on scientific information.

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LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. UNDERWOOD (at the request of Mr. GEPHARDT) for today and the balance of the week, on account of official business.

Mr. YATES (at the request of Mr. GEPHARDT) for November 8 after 12 noon and November 9, on account of personal reasons.

SENATE BILLS AND CONCURRENT RESOLUTION REFERRED

Bills and a concurrent resolution of the Senate of the following titles were taken from the Speaker's table and, under the rule, referred as follows:

S. 508. An act to provide for the relief of Mai Hoa "Jasmin" Salehi; to the Committee on the Judiciary.