

S. 806

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) notwithstanding any other provision of law, the Secretary of the Interior shall reimburse the Okefenokee Rural Electric Membership Corporation for the cost incurred by such corporation in installing transmission lines, transformers, and electric meters which serve the administrative needs of the Federal Government within Cumberland Island National Seashore in the State of Georgia. No such payment shall be made unless—

(1) the Corporation has entered into a written agreement with the Secretary which provides for—

(A) the continued adequate provision of electrical service by the Corporation at reasonable rates to satisfy the administrative needs of the seashore, as determined by the Secretary, and

(B) the prompt repayment of the Secretary of any amounts paid by the Secretary under this Act, plus interest, in the event of the Corporation's future failure to provide electrical service under terms provided pursuant to paragraph (A); and

(2) the Secretary has performed an audit of the Corporation's records to determine the amount appropriately due the Corporation under the terms of this Act, which amount so determined by the Secretary shall constitute the maximum amount to be paid.

The amount so determined by the Secretary shall be reduced by an amount equal to the sum of all reimbursement for such facilities paid to the Corporation by any governmental or nongovernmental source before the date on which payment is made by the Secretary under this Act.

(b) There is authorized to be appropriated to carry out the provisions of subsection (a) not more than \$338,000.

The Senate bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. SEIBERLING. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks on the Senate bill just considered and passed.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

THE SAINT CROIX ISLAND INTERNATIONAL HISTORIC SITE

Mr. SEIBERLING. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the Senate joint resolution (S.J. Res. 25) redesignating the Saint Croix Island National Monument in the State in Maine as the "Saint Croix Island International Historic Site," with a Senate amendment to the House amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the Senate joint resolution.

The Clerk read the Senate amendment to the House amendment, as follows:

Strike out lines 1 to 5, of the House engrossed amendment.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

□ 1140

Mr. McCAIN. Reserving the right to object, Mr. Speaker, will the gentleman explain the Senate amendment?

Mr. SEIBERLING. Mr. Speaker, will the gentleman yield?

Mr. McCAIN. Yes; I will be glad to yield to my colleague, the gentleman from Ohio.

Mr. SEIBERLING. Mr. Speaker, Senate Joint Resolution 25 would redesignate the St. Croix Island National Monument as the St. Croix Island International Historic Site.

St. Croix Island is located on the boundary between Maine and New Brunswick, Canada.

A companion bill (H.J. Res. 106) was introduced on January 27, 1983 by the gentlewoman from Maine [Ms. SNOWE].

Mr. Speaker, St. Croix Island was settled in 1604 by a group of 150 French settlers who later resettled to a more habitable site across the Bay of Fundy at Port Royal.

In recognition of the importance of the site to the history of both Canada and the United States, Congress authorized the St. Croix Island National Monument in 1949. More recently, in 1981, Canada and the United States dedicated an interpretive structure on St. Croix Island at Red Beach, ME, and a similar structure will be built by New Brunswick on the opposite shore. In addition, Canadian and U.S. officials have signed a memorandum of understanding citing the historic significance of this island to both nations.

Senate Joint Resolution 25 would recognize the truly international significance of St. Croix Island by redesignating the area as the St. Croix Island International Historic Site.

Mr. Speaker, I urge passage of this bill.

Mr. McCAIN. Mr. Speaker, I thank the gentleman again for his work on this bill. I would also like to express our appreciation to our colleague, the gentlewoman from Maine [Ms. SNOWE].

● Ms. SNOWE. Mr. Speaker, I rise in support of Senate Joint Resolution 25, legislation which redesignates the St. Croix Island National Monument in the State of Maine as an international historic site. It is a fitting honor for the famous Island of St. Croix that the House is acting to pass legislation making this designation official.

Since 1604 when Samuel de Champlain first brought settlers to the island, St. Croix has set itself apart by

being the first European settlement in Upper North America. The island is situated at the boundary between Maine and New Brunswick, Canada. Both countries have held the island in high esteem, and Congress recognized its proud traditions in 1949 when St. Croix was established as a national monument.

In recent years, the United States and Canada have worked together in support of an island whose traditions are a source of inspiration for both countries. A memorandum of understanding signed by the two nations cites the dual-historic value of St. Croix. Other improvements and the construction of permanent shelters on both shores will help to preserve the island's significance for years to come.

As an established national monument and as a unit of the National Park System, no part of this resolution affects the status of the island. Redesignating St. Croix as an international historic site is a simple but important step we can take to better maintain a common historical bond.

Mr. Speaker, I look forward to the redesignation of St. Croix as an international historic site.●

Mr. McCAIN. Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

A motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. SEIBERLING. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to extend their remarks on the legislation just considered and adopted.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

The SPEAKER pro tempore. Pursuant to House Resolution 569 and rule XXIII, the Chair declares the House in the Committee of the Whole House on the State of the Union for the further consideration of the bill, H.R. 3605.

□ 1142

IN THE COMMITTEE OF THE WHOLE

Accordingly the House resolved itself into the Committee of the Whole House on the State of the Union for the further consideration of the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug ap-

date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce."

SEC. 105. (a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(b) During the period beginning sixty days after the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act."

Mr. WAXMAN (during the reading). Mr. Chairman, I ask unanimous consent that the amendment be considered as read and printed in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. WAXMAN. Mr. Chairman, this amendment makes several changes to title I of the bill to incorporate compromises reached in negotiations between the brand name drug industry and the generic drug industry. While the bill before us has been endorsed by an overwhelming majority of the brand name drug companies as well as the generic drug industry, consumer, senior citizen, and labor groups, several major drugmakers and the Patent and Trademark Office continued to have concerns about some provisions of H.R. 3605.

During the final week of session before the August break, the chairman of the Senate Labor and Human Resources Committee, Senator HATCH, worked tirelessly to address these last remaining concerns. As a result of his

diligence and commitment to making more low-cost generic drugs available for our citizens, a number of changes to the bill were agreed upon by the brand name and generic drug industries and subsequently passed by the Senate on August 10.

With technical and minor modifications, this amendment adds those changes to the bill before us. Let me describe the changes.

First, the amendment provides a 5-year period of exclusive market life for drugs approved for the first time after enactment of the legislation. This provision will give the drug industry the incentives needed to develop new chemical entities whose therapeutic usefulness is discovered late when little or no patent life remains.

Generic drugmakers that wished to challenge the validity of any patent life remaining on such drugs would not be barred from doing so. Such patent litigation could commence at the expiration of the fourth year of the period and the generic drugmaker could begin marketing after a favorable court decision or 7½ years after approval of the brand name drug, whichever occurs first.

Second, the 10-year period of exclusive market life for drugs approved between 1982 and the date of enactment of the bill is supplemented by affording a 2-year period of exclusive market life to drugs which are not new chemical entities approved during that same period.

Third, a 3-year period of exclusive market life is afforded to nonnew chemical entities approved after enactment of the bill which have undergone new clinical studies essential to FDA approval. This provision will encourage drugmakers to obtain FDA approval for significant therapeutic uses of previously approved drugs.

Fourth, the period during which a generic drugmaker may not market pending the judicial resolution of a challenge to patent validity is expanded from the 18 months currently in the bill to 30 months. Some of the brand name drug companies felt this change increases the likelihood that such patent litigation will be concluded before the generic drugmaker begins marketing.

Fifth, the bill clarifies the authority of the Food and Drug Administration [FDA] to reject a petition filed by a generic drugmaker for consideration of a combination product that differs from the approved product of the brand name manufacturer.

Last, the authority of the FDA to disapprove generic copies of brand name drugs when the agency is seeking to remove the brand name drug from the market due to safety or effectiveness concerns is clarified.

While there was some discussion on amending section 104 of the bill dealing with the confidentiality of safety

and effectiveness data and information submitted in a new drug application, no change is made in that section by this amendment. With the exception of subsection (1)(5), the provision in section 104 statutorily codifies the current FDA regulation pertaining to disclosure of this type of information. FDA's current approach to release of the data and to its policies regarding the extraordinary circumstances when the data would not be released are explained in the preamble to FDA's Freedom of Information Act regulations—39 Federal Register 44602-44642 (December 24, 1974). Section 104 adopts this same approach.

These changes to H.R. 3605 do not upset the fundamental balance of the bill that assures consumers of more low-cost generic drugs when a valid patent expires and the drug industry of sufficient incentive to develop innovative pharmaceutical therapies. I urge my colleagues to support the amendment.

□ 1150

Mr. MADIGAN. Mr. Chairman, I rise in strong support of the amendment offered by the gentleman from California, which takes care of one of the two administration objections to this bill. I understand that their second objection will be addressed in an amendment to be offered later by the gentleman from California.

The amendment now under consideration adopts the compromise proposals agreed to by Senator HATCH and the chief executive officers of the domestic drug companies that previously were not supporting this bill. These changes are fair and reasonable; they do not alter the basic thrust of H.R. 3605, and they do bring the bill in line with the Senate-passed bill, so that this important measure can be quickly signed into law.

I urge my colleagues to support the amendment of the gentleman from California [Mr. WAXMAN].

Mr. KASTENMEIER. Mr. Chairman, I reluctantly rise in opposition to the amendment offered by the gentleman from California to express strong reservations about the amendment.

The bill before us, H.R. 3605, represents a far from perfect compromise which—on balance—further the public interest. This amendment, on the other hand, undoes that balance and tilts too heavily toward unwarranted rewards for private economic interests. Moreover, the various changes suggested by this amendment constitute fundamentally wrong-headed public policy. The proposed changes in the bill include four different types of monopoly or exclusive marketing authority. These changes do little to further the interests of consumers, nor do they strengthen our