

which has already passed in the House of Representatives, designating this month, August 1984, as "Ostomy Awareness Month"; 1.5 million people have undergone an ostomy due to the loss of the normal function of their bowel or bladder. Fortunately, all of these people are able to resume their previous lifestyles after the surgery.

The United Ostomy Association has 50,000 members whom the association counsels through the trauma of surgery and the readjustment that is necessary after surgery. Not only does the association help ostomates, but they also assist the families and friends in gaining understanding and support for their friend or family member.

Many well-known people have had one of the three types of ostomies, a colostomy, an urostomy or an ileostomy, and have become spokespersons for ostomates. We can do our part too by designating this month as "Ostomy Awareness Month" and thereby promoting the education of the American population and commending the people who have had an ostomy and continue to live as they had before the surgery. I urge you to support this important resolution.

The PRESIDING OFFICER. The joint resolution is open to amendment. If there be no amendment to be proposed, the question is on the engrossment and the third reading of the joint resolution.

The joint resolution was ordered to be engrossed for a third reading and was read the third time.

Mr. BAKER. Mr. President, I ask unanimous consent that the pending measure be laid aside and the Senate turn to the consideration of House Joint Resolution 587, Calendar Order No. 1132.

The PRESIDING OFFICER. The joint resolution will be stated by title.

The assistant legislative clerk read as follows:

A joint resolution (H.J. Res. 587) designating the month of August 1984 as "Ostomy Awareness Month."

There being no objection, the Senate proceeded to the consideration of the joint resolution.

Mr. MATSUNAGA. Mr. President, inasmuch as the language of the House joint resolution is exactly the same as that of the Senate Joint Resolution 330, I rise in full support of the measure and ask for its immediate passage.

The PRESIDING OFFICER. The joint resolution is before the Senate and open to amendment. If there be no amendment to be offered, the question is on the third reading and passage of the joint resolution.

The joint resolution (H.J. Res. 587) was ordered to a third reading, was read the third time, and passed.

The preamble was agreed to.

Mr. BAKER. Mr. President, I move to reconsider the vote by which the joint resolution was passed.

Mr. MATSUNAGA. Mr. President, I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. BAKER. Mr. President, I ask unanimous consent that Senate Joint Resolution 330 be indefinitely postponed.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENT

Mr. BAKER. Mr. President, could I inquire next of the minority leader if it is possible for him to clear for action by unanimous consent Calendar Order No. 1115, S. 2926, the drug bill.

Mr. METZENBAUM. Mr. President, reserving the right to object, and I shall not object, I wish to address myself for one moment to the minority leader.

Mr. BAKER. Mr. President, I am advised now that it may take a few additional moments to get that in shape.

I withdraw my request of the minority leader.

Mr. President, I believe now that the earlier matter may be cleared.

Let me renew my inquiry of the minority leader.

I wish now to go to Calendar No. 1115, S. 2926, if the minority leader can clear that.

Mr. BYRD. Mr. President, the matter has been cleared on this side, and there is no objection.

Mr. BAKER. I thank the minority leader.

Mr. President, I ask the Chair to lay before the Senate Calendar Order No. 1115, S. 2926.

The PRESIDING OFFICER. The bill will be stated by title.

The assistant legislative clerk read as follows:

A bill (S. 2926) to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. HATCH. Mr. President, we have before us the most important pharmaceutical legislation to come before Congress in many years. This bill, S. 2926, is the final version of S. 2748, the Drug Price Competition and Patent Term Restoration Act of 1984. This is a groundbreaking compromise in the public interest. It reconciles the opposing, competitive interests of two segments of the pharmaceutical industry which have often stymied each other's attempts to improve the law. The research-based drug industry obtains an extension of patents for new

drug discoveries to compensate them for the time spent off-market in Food and Drug Administration review. The generic drug industry gets the ability to bring generic copies of off-patent drugs to market as soon as the patent expires, without the needless reduplication of studies and tests already in FDA's files.

The public receives the best of both worlds—cheaper drugs today and better drugs tomorrow. The proliferation of new generics for some of the most important drugs on the market will save consumers an estimated \$1 billion or more over the next decade. The added patent life will restore to our domestic drug companies some of the incentive for innovation which has weakened as Federal premarket approval requirements have become more expensive and time-consuming. That incentive will produce both the investment and commitment to research and development that will again place the United States in unquestioned leadership in the field. And it will generate an increase in the number of important new drugs, among the most vital causes for this century's dramatic increase in the length and quality of life.

Now, those who have been following this bill know this is a vastly simplified account of the bill and its effect. It is involved and is carefully balanced at a number of points in ways only lawyers could have devised. But it is a good bill, one which I have heartily endorsed and promoted in the Senate. It is backed by a wide range of organizations including the Pharmaceutical Manufacturers' Association, the AFL-CIO and numerous individual unions, the American Association of Retired Persons, and the National Council of Senior Citizens.

As you are probably also aware, several research-based pharmaceutical companies have felt that the compromise embodied in S. 2748 was not adequate and have pressed for changes in the bill. During the past 3 months I have met with many of these companies to discuss their concerns as has Congressman HENRY WAXMAN, the bill's House sponsor, and indeed as have many members of my committee. While I believe S. 2748 enjoys overwhelming support in the Senate, it has certainly been my belief that it is preferable to accommodate requests for changes which do not disturb balances essential to the bill.

As the time remaining during this session has decreased, discussions over these concerns have intensified. Hoping that I could catalyze a final agreement among the interested parties, we met Tuesday and Wednesday and conducted many hours of intense negotiation. We discussed and placed on the table issues relating both to the abbreviated new drug application

[ANDA] and patent portions of the bill.

Further negotiations ensued yesterday with Congressman WAXMAN, the House sponsor, in an attempt to develop a final position which would be satisfactory to everyone. I am pleased to report that these negotiations bore fruit and that a compromise set of amendments has been incorporated into this new bill and into the technical amendment I am proposing today. The bill, S. 2926, as amended has drawn the support of almost all of the companies opposing S. 2748, and has been accepted by Congressman WAXMAN and by the administration.

Before continuing my remarks, let me acknowledge the good offices of the many people who assisted in these negotiations, especially Mr. Joe Williams, president of Warner-Lambert and chairman of the Pharmaceutical Manufacturers Association; Mr. Jack Stafford, chief executive officer of American Home Products; Mr. Bill Haddad, president of the Generic Pharmaceutical Industry Association; Mr. William Greif, vice president of Bristol Myers; and Mr. William Ryan, assistant general counsel of Johnson & Johnson. Above all, I express my appreciation for the flexibility and leadership of Chairman WAXMAN. We have enjoyed a close and amicable working relationship during the progress of this legislation through the Congress.

The elements of the compromise are:

There is to be a prospective 5-year waiting period for filing of ANDA's following approval by FDA of a new chemical entity new drug application [NDA]. For all other NDA's involving new clinical tests, there will be a 3-year period during which no ANDA approval may be made effective. This protects products whose development has taken much time and money in FDA testing and review, but which have little for no patent life left when they are finally allowed on the market.

Further, the 10-year ANDA moratorium for products approved between January 1, 1982, and the date of enactment is supplemented by a similar provision for 2 years for non-new-chemical-entity drugs.

The period of time during which an abbreviated new drug application is not to be made effective, during the pendency of a patent challenge under the statute, is extended from 18 to 30 months from the date of submission of an ANDA application containing bioequivalency data. This increases the likelihood that the litigation will be concluded within the time period during which ANDA's are not allowed.

Some of the complicated current restrictions on the nature of patents which can be extended are removed, with the provision that one patent on a product, not necessarily the first, can be extended but that total exclu-

sive market life of the product cannot exceed 14 years.

The authority of the Secretary of Health and Human Services to deny a petition for filing an ANDA for a product not exactly similar to the original drug will be expanded to include cases where the proposed generic is a combination drug, one of whose active ingredients is different from those of the original combination drug. This will make sure that FDA retains the authority to prevent drugs from coming to market without proper tests to establish the unforeseen interactions that substituted active ingredients may have on each other.

The concern was raised that FDA might be forced under the bill to approve an ANDA, even if FDA had started proceedings to remove the original drug from the market but had not completed the process. Language was adopted which would remedy this loophole.

The treatment of animal drugs contained in S. 2748 is deleted in this bill.

I would also like to address a comment to one issue which arose during the discussion of the bill. The Patent Commissioner has expressed concern that he is required to verify the contents of applications for patent extension. This was not intended, and a wording change in the bill clarifies that he may rely wholly on the required information as represented by the applicant.

Mr. President, the United States waits for this bill.

Mr. THURMOND, Mr. President, I express my strong endorsement of S. 2926, the Drug Price Competition and Patent Term Restoration Act of 1984. This important compromise measure builds upon legislation which was reported by the Judiciary Committee and passed by the Senate in the 97th Congress. I was a cosponsor of that bill and its successors, and I am pleased to join the distinguished chairman of the Labor and Human Resources Committee, Senator ORRIN HATCH, in cosponsoring this measure.

Mr. President, patent term restoration makes eminently good sense and is fair to business and consumers alike. It encourages inventiveness by making the patent term a real and useful one. This bill adds an additional feature relating to approval procedures for drugs coming off patent, which will expedite the availability of generic drugs. This is a balanced package which addresses legitimate needs in a reasonable manner.

Mr. President, after a long delay, we are finally able to bring this important legislation before the Senate. I want to commend Senator HATCH for his persistence in this matter. I also want to express my congratulations to representatives of the various interested groups who worked together to resolve their differences so that the public in-

terest would be served. Although, as with any compromise, everyone did not get everything that he wanted, this package represents a fair balance of interests.

I urge my colleagues to support S. 2926 so that we can enact patent term restoration and ANDA provisions without further delay.

AMENDMENT NO. 3707

(Purpose: To make certain technical changes to the bills)

Mr. HATCH, Mr. President, I now send to the desk a technical amendment to S. 2926 on behalf of myself and the other cosponsors and Senator METZENBAUM.

The PRESIDING OFFICER. The amendment will be stated.

The legislative clerk read as follows:

The Senator from Utah [Mr. HATCH], for himself and Mr. METZENBAUM, Mr. DeCONCINI, Mrs. HAWKINS, Mr. KENNEDY, Mr. DENTON, and Mr. THURMOND proposes amendment numbered 3707.

Mr. HATCH, Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

Clause (iii) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the bill, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)", and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

Clause (iv) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the bill, redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

Clause (iii) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the bill, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)" and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

Clause (iv) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the bill, is redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than