as a small entity. Such a verified statement need only be filed once in an application or patent and remains in effect until changed.

(b) Any verified statement filed pursuant to paragraph (a) of this section on behalf of an independent inventor must be signed by the independent inventor except as provided in §§ 1.42, 1.43, or 1.47 of this part, and must aver that the inventor qualifies as an independent inventor in accordance with § 1.9(c) of this part. Where there are joint inventors in an application, each inventor must file a verified statement establishing status as an independent inventor in order to qualify as a small entity. Where any rights have been assigned, granted, conveyed, or licensed, or there is an obligation to assign, grant, convey, or license, any rights to a small business concern, a nonprofit organization, or any other individual, a verified statement must be filed by the individual, the owner of the small business concern, or an official of the small business concern or nonprofit organization empowered to act on behalf of the small business concern or nonprofit organization averring to their status.

(c) [Reserved]

(d) Any verified statement filed pursuant to paragraph (a) of this section on behalf of a nonprofit organization must (1) be signed by an official of the nonprofit organization empowered to act on behalf of the organization; (2) aver that the organization qualifies as a nonprofit organization as defined in § 1.9(e) of this part specifying under which one of § 1.9(e)(1), (e)(2), (e)(3), or (e)(4) of this part the organization qualifies; and (3) aver that exclusive rights to the invention have been conveyed to and remain with the organization or if the rights are not exclusive, that all other rights belong to small entities as defined in § 1.9 of this part. Where the rights of the nonprofit organization as a small entity are not exclusive, a verified statement must also be filed by the other small entities having rights averring to their status as such.

3. Section 1.28 is added to read as follows:

§ 1.28 Effect on fees of failure to establish status, or change status, as a small entity.

(a) The failure to establish status as a small entity (§§ 1.9(f) and 1.27 of this part) in any application or patent prior to paying, or at the time of paying, any fee (1) precludes payment of the fee in the amount established for small entities; and (2) precludes a refund, pursuant to § 1.26 of this part of any portions of fees paid prior to establishing status as a small entity. Status as a small entity is waived for any fee by the failure to establish the status prior to paying, or at the time of paying, the fee. Status as a small entity must be specifically established by a verified statement filed in each application or patent in which the status is available and desired, except those applications filed under § 1.60 of this part where the status as a small entity has been established in a parent application and is still proper. Once status as a small entity has been established in an application or patent, the status remains in that application or patent without the filing of a further verified statement pursuant to § 1.27 of this part unless the Office is notified of a change in status. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established, except those filed under § 1.60 of this part. Applications filed under § 1.60 of this part must include a reference to a verified statement in a parent application if status as a small entity is still proper and desired.

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to § 1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to § 1.34(a) of this part.

(c) If status as a small entity is established in good faith, and fees as a small entity are paid in good faith, in any application or patent, and it is later discovered that such status as a small entity was established in error or that through error the Office was not notified of a change in status as required by paragraph (b) of this section, the error will be excused (1) if any deficiency between the amount paid and the amount due is paid within three months after the date the error occurred or (2) if any deficiency between the amount paid and the amount due is paid more than three months after the date the error occurred and the payment is accompanied by a verified statement explaining how the error in good faith occurred and how and when it was discovered.

(d)(1) Any attempt to fraudulently (i) establish status as a small entity or (ii) pay fees as a small entity shall be considered as a fraud practiced or attempted on the Office. (2) Improperly and through gross negligence (i) establishing status as a small entity or (ii) paying fees as a small entity shall be considered as a fraud practiced or attempted on the Office. See §§ 1.56(d) and 1.555 of this part.

§ 1.451 [Amended]

4. In § 1.451, paragraph (b) is amended by removing the reference "§ 1.19(a)(4)" and inserting in its place the reference "§ 1.19(a)(3)".

PART 3—FORMS FOR PATENT CASES [Removed]

5. Part 3 is removed.

PART 4—FORMS FOR TRADEMARK CASES [Removed]

6. Part 4 is removed.

Dated: August 26, 1982.

Gerald J. Mossinghoff,

Commissioner of Patents and Trademarks.

[FR Doc. 82-24877 Filed 9-9-82; 8:45 am]

BILLING CODE 3510-16-M

FLOOR REMARKS AND TEXT OF H.R. 6444, "PATENT TERM RESTORATION ACT OF 1982"

PATENT TERM RESTORATION ACT OF 1982

Mr. KASTENMEIER. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6444), to amend the patent law to restore the term of the patent grant for the period of time that nonpatent regulatory requirements prevent the marketing of a patented product, as amended.

The Clerk read as follows:

H.R. 6444

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Patent Term Restoration Act of 1982".

SEC. 2. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 154:

"§ 155. Restoration of patent term

"(a)(1) Except as provided in paragraphs (3) and (4), the term of a patent which encompasses within its scope a product subject to a regulatory review, or a method for using such a product or a method for producing such a product, shall be extended from the original expiration date of the patent if—

"(A) the product sponsor gives notice to the Commissioner in compliance with the provisions of subsection (b)(1);

"(B) the product has been subjected to a regulatory review pursuant to statute before its commercial marketing or use;

"(C) the patent to be extended has not expired prior to notice to the Commissioner under subsection (b)(1); and

"(D) the patent to be extended was issued on or subsequent to the date of enactment of the Patent Term Restoration Act of 1982.

"(2) The rights derived from any claim of any patent extended under paragraph (1) shall be limited.

"(A) in the case of any patent, to the scope of such claim which relates to the product subject to regulatory review, and

"(B) in the case of patent which encompasses within its scope a product—

"(i) which is subject to regulatory review under the Federal Food, Drug, and Cosmetic Act, to the uses of the product which may be regulated by the chapter of such Act under which the regulatory review occurred, or

"(ii) which is subject to regulatory review under any other statute, to the uses of the product which may be regulated by the statute under which the regulatory review occurred.

"(3)(A) Subject to subparagraph (B), the term of the patent shall be extended by the time equal to the regulatory review period for such product for the period up to ten years after the date of filing of the earliest application for the patent and the time equal to one-half the regulatory review period for the period between ten and twenty years from the filing date of the earliest patent application.

"(B) In no event shall the term of any patent be extended for more than seven years. No term of any extended patent may exceed twenty-seven years from the date of filing of the earliest patent application for the patent. If the term that the patent would be extended is less than one year, no extension shall be granted.

"(C) In no event shall more than one patent be extended for the same regulatory review period for the product.

(4) The term of a patent which encompasses within its scope a method for producing a product may not be extended under this section if—

"(A) the owner of record of such patent is also the owner of record of another patent which encompasses within its scope the same product; and

"(B) such patent on such product has been extended under this section.

"(b)(1) To obtain an extension of the term of a patent under subsection (a), the product sponsor shall notify the Commissioner under oath, within ninety days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended. If the product sponsor is not the owner of record of the patent, the notification shall include the written consent of the owner of record of the patent to the extension. Such notification shall be writing and shall—

"(A) identify the Federal statute under which regulatory review occurred or, if the regulatory review occurred under the Federal Food, Drug, and Cosmetic Act, the chapter of the Act under which the review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

"(C) identify the product for which regulatory review was required;

"(D) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(1)(B) occurred have been satisfied and commercial marketing or use of the product is not prohibited; and

"(E) identify the patent and any claim thereof to which the extension is applicable; the date of filing of the earliest application for the patent; and the length of time of the regulatory review period for which the term of such patent is to be extended; and state that no other patent has been extended for the regulatory review period for the product.

"(2) Upon receipt of the notice required by paragraph (1), the Commissioner shall promptly publish in the Official Gazette of the Patent and Trademark Office the information contained in such notice. Unless the requirements of this section have not been met, the Commissioner shall issue to the owner of the record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the product and the statute under which regulatory review occurred and specifying any claim to which such extension is applicable. Such certificate shall be recorded in the official file of the patent so extended and shall be considered as part of the original patent.

"(c) As used in this section:

"(1) The term 'product' means any machine, manufacture, or composition of matter for which a patent may be obtained and includes the following:

"(A) Any new drug, antibiotic drug, new animal drug, device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(B) Any Human or veterinary biological product subject to regulation under section 351 of the Public Health Service Act or under the virus, serum, toxin, and analogous products provisions of the Act of March 4, 1913 (21 U.S.C. 151-158).

"(C) Any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act.

"(D) Any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) The term 'major health or environmental effects text' means an experiment to determine or evaluate health or environmental effects which requires at least six months to conduct, not including any period for analysis or conclusions.

"(3) The term 'earliest application for the patent' means the patent application providing the earliest benefit of filing date to the patent and includes patent applications under sections 119 and 120.

"(4) The term 'product sponsor' means any person who initiates testing or investigations, claims an exemption, or submits an application, petition, protocol, request, or notice described in paragraph (5) of this subsection.

"(5) The term 'regulatory review period' means—

"(A) with respect to a product which is a drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the first product sponsor (i) initiates a clinical investigation on humans, or (ii) submits an application or petition with respect to such product the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, or the Act of March 4, 1913, and ending on the date such application or petition with respect to such product is approved or the product is licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(B) with respect to a product which is a food additive or color additive, a period commencing on the earliest of the date the first product sponsor (i) initiates a major health or environmental effects test on the product, but only if the data from such test is submitted in a petition referred to in clause (iii) of this subparagraph, (ii) claims an exemption for an investigation with respect to such product, or (iii) submits a petition with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation for use of the product, and ending on the date such regulation becomes effective or, if objections are filed to such regulation, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(C) with respect to a product which is an animal drug or veterinary bilogical product, a period commencing on the earliest of the date the first product sponsor (i) claims an exemption for investigation of the product or requests authority to prepare an experimental product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913, or (ii) submits an application or petition with respect to the product under such statutes, and ending on the date such application or petition with respect to the product is approved or the product is licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(D) with respect to a product which is a device, a period commencing on the earlier of the date the first product sponsor (i) submitted a proposed product development protocol with respect to the product under the Federal Food, Drug, and Cosmetic Act, (ii) initiates a clinical investigation on humans, or (iii) submitted an application with respect to the product under such statute, and ending on the date such application with respect to the product is approved under such statute;

"(E) with respect to a product which is a pesticide, a period commencing on the earliest of the date the first product sponsor (i) initiates a major health or environmental effects test on such pesticide, but only if the data from such test is submitted in a request for registration of such pesticide under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, (ii) requests the grant of an experimental use permit for the pesticide under section 5 of such Act, or (iii) submits an application for registration of such pesticide pursuant to section 3 of such Act, and ending on the date such pesticide is first registered, either conditionally or fully; and

"(F) with respect to a product which is a chemical substance or mixture for which

notification is required under section 5(a) of the Toxic Substances Control Act—

"(i) which is subject to a rule requiring testing under section 4(a) of such Act, a period commencing on the date the first product sponsor has initiated the testing required in such rule and ending on the expiration of the premanufacture notification period for such chemical substance or mixture, of if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or injunction is dissolved or set aside;

"(ii) which is not subject to a testing rule under section 4 of such Act, a period commencing on the earlier of the date the first product sponsor—

"(I) submit a premanufacture notice, or

"(II) initiates a major health or environmental effects test on such chemical substance or mixture, but only if the data from such test is included in the premanufacture notice for such substance or mixture,

and ending on the expiration of the premanufacture notification period for such substance or mixture or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction is dissolved or set aside;

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the product which is subject to regulatory review, for the method for using such product, or for the method for producing such product.

"(d)(1) Notwithstanding subsection (a)(1)(D), in the event the regulatory review period has commenced prior to the date of enactment of this section, then the period of patent extension for such product or a method of using such product shall be measured from the date of enactment of this section. In the event that prior to the date of enactment of this section a new drug product was approved on a date more than seven years after the commencement of the regulatory review period and during such regulatory review period the patentee was notified that such product's application was not approvable under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act and as a result of which the patentee caused a major health or environmental effects test to be conducted to evaluate carcinogenic potential, then the period of patent extension for such product or the method of use of such product shall be seven years, if the filing required by subsection (b)(1) of this Act is made within ninety days of the date of enactment of this section.

"(2) Notwithstanding subsection (a)(1)(D), in the case of products approved and for which a stay of regulation granting approval pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act was in effect as of January 1, 1981, the period of such patent extensions shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted, if the filing required by subsection (b)(1) is made within ninety days of the termination of the regulatory review period or of the date of enactment of this section, whichever is later.".

(b) The analysis for chapter 14 of title 35, United States Code, is amended by adding at the end the following:

"155. Restoration of patent term.".

The SPEAKER pro tempore. Pursuant to the rule, a second is not required on this motion.

The gentleman from Wisconsin (Mr. KASTENMEIER) will be recognized for 20 minutes, and the gentleman from Illinois (Mr. RAILSBACK) will be recognized for 20 minutes.

PARLIAMENTARY INQUIRY

Mr. SHAW. Mr. Speaker, I have a parliamentary inquiry.

The SPEAKER pro tempore. The gentleman will state it.

Mr. SHAW. Mr. Speaker, is the gentleman from Illinois opposed to the bill?

Mr. RAILSBACK. I am not. I favor the bill, Mr. Speaker.

Mr. SHAW. Mr. Speaker, I do oppose the bill, and I make demand for the time on this side of the aisle.

The SPEAKER pro tempore. The gentleman from Florida (Mr. SHAW) will be recognized for 20 minutes.

The Chair recognizes the gentleman from Wisconsin (Mr. KASTENMEIER).

Mr. KASTENMEIER. Mr. Speaker, I yield myself 10 minutes.

(Mr. KASTENMEIER asked and was given permission to revise and extend his remarks.)

Mr. KASTENMEIER. Mr. Speaker, H.R. 6444 is the product of over 4 years of study of ways in which Government patent policy can be changed to stimulate industrial innovation in the United States. The genesis of the legislation was a call by President Jimmy Carter in May 1978 for a domestic policy review of industrial innovation. President Carter's directive lead to the creation of an Advisory Committee on Industrial Innovation composed of more than 150 senior representatives from the industrial, public interest, labor, scientific, and academic communities. This committee made several recommendations for changes in Federal law with the goal of an improved patent system. Several of these changes were enacted by the 96th and 97th Congress, but a key recommendation of the Advisory Committee which remains to be implemented is that calling for "an adequate extension of the Patern term * * * when commercialization of patented inventions is delayed due to Federal regulations." It is this recommendation which is embodied in H.R. 6444.

In view of the economic crisis our country is now experiencing and the obvious need for constructive ways to deal with it, we on the Judiciary Committee took the recommendation for patent term restoration very seriously and commissioned a more detailed analysis of the issue by the congressional Office of Technology Assessment which, after a year of independent study, presented the Congress with a 74-page report on the issue focusing on the pharmaceutical industry as an example.

The OTA report found that—

The drug develpment process is time consuming and is characterized by a high probability of failure. A decade or more may elapse between the time a chemical having promising biological activity is identified and the time it is marketed as a new drug. The odds against developing a marketable pharmaceutical are great . . . only one out of 7,000 to 10,000 newly synthesized chemicals will be found to have promising biological acitivity. Only one out of 10 promising chemicals will survive to marketing.

The report estimates that direct costs, in 1976 dollars, of developing a new pharmaceutical average $33 million. In addition to finding that the new drug-development process is extraordinarily costly and lengthy, the Office of Technology Assessement also found that the average effective patent term for drugs approved in 1979 was less than 10 years.

It is the extraordinarily long development time required by the testing needed to meet regulatory requirements which causes significant loss of effective patent term and underlies the need for H.R. 6444.

The testimony before the subcommittee and the information contained in the report of the Office of Technology Assessment confirms the link between effective commercial patent term and innovation and supports the recommendation of President Carter's Advisory Committee for remedial legislation.

It is important to keep in mind that the issue involved is not simply the growth of the economy, it is encouraging future investment of large sums of private capital in the high-risk area of breakthrough pharmaceutical and chemical technology. Such investments pay off not only in economic growth, but even more importantly in improvements to the health and well being of our people, especially those most likely to need new medical technology such as senior citizens. And, frequently, new pharmaceutical technology can be more cost effective than preexisting theraples which involve often costly hospitalization. I believe firmly that the generic pharmaceutical industry should be encouraged. But it is important to keep in mind that generic companies, by definition, do not develop new and better drugs—they simply copy existing therapies. We must look to the research intensive, patent dependent companies for new cures for disease. The goal of H.R. 6444 is simply to encourage these companies to produce more and better therapies.

Although the general thrust of the testimony presented to my subcommittee was supportive of the concept of patent term restoration, important criticisms were made. The committee was sensitive to those criticisms and adopted a number of amendments to the original proposal which were designed to respond to them. The modifications were so significant that an entirely new bill was drafted and approved by my subcommittee and the full Judiciary Committee. This new bill, H.R. 6444, is vastly different from the original House bill H.R. 1937, or the Senate passed bill, S.255.

The most important amendment restricts the bill to patents issued after the date of enactment. Therefore, generic companies will not experience any delay in access to patented tech-

nology until the year 2000. By the time the first patent is extended by the bill, the advantages of the new products induced by it will far outweigh any delay in generic reproductions coming to the market.

Further, the amendments deny any benefit under the legislation to companies which procrastinate in obtaining their patents and greatly limit any extension of patent to companies which fail to expedite the testing and regulatory approval process. Further, the bill applies to only one patent on any product to avoid pyramiding of patent protection.

H.R. 6444, as reported by the Judiciary Committee, is a balanced bill which will assure more rapid technological innovation in the pharmaceutical and chemical industries, resulting in a stronger economy and the development of less costly and more competitive new therapies and chemicals. At the same time, the interests of consumers have been protected.

The bill is sponsored by over 100 Members. S. 255, a Senate counterpart, passed the Senate last year by a unanimous voice vote.

Mr. Speaker, I urge Members to vote for H.R. 6444.

Mr. Speaker, with my remarks I include a letter received by me Today from the gentleman from Tennessee (Mr. FORD) as follows:

WASHINGTON, D.C.,
September 13, 1982.

Re H.R. 6444—Patent Restoration Act.

Mr. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties and Administration of Justice, Committee on the Judiciary, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I write to support the Patent Term Restoration Act (H.R. 6444) from my perspective as a member of the Subcommittee on Health of the Committee on Ways and Means.

We regard soaring health care costs as a major problem which, to date, has eluded any pervasive legislative or marketplace solution. Health care costs have increased sixfold over the past twenty years, and skyrocketing hospitalization and surgical costs have accounted for a substantial portion of the increase. Health care costs as a percentage of our GNP continues to increase at an alarming rate. Many families have been wiped out because of illnesses that have required protracted and costly hospitalization, and the Medicare and Medicaid programs—which are esssential to the elderly and the poor—have become prime targets for the Administration's budget cutters.

One component of our health care system—medicines—has provided an efficient, effective and humanitarian counterweight to an otherwise bleak health care picture. Prescription drug prices have increased only 34% over the past 20 years. Perhaps even more importantly, however, new drugs have alleviated human suffering and saved billions of dollars by providing effective alternatives to costly surgical procedures and hospitalization. The past two years alone has witnessed the introduction of new or improved drugs to treat or prevent ulcers, glaucoma, pneumococcal pneumonia, second heart attacks, epilepsy, hepatitis, arthritis and hypertension, to name some of our more common and costly illnesses.

New medicines, Mr. Chairman, represent the most compassionate and cost effective means of preventing and treating disease. It is in our national interest, and particularly in the interest of the poor and the elderly, to assure adequate incentives to encourage the introduction of new and better medicines. The stakes are too big to be penny wise and pound foolish.

An average 6.8 year patent term for drugs is grossly unfair and inequitable when better mousetraps receive 17 years of exclusivity. Continuation of this inequity is bound to reduce the flow of funds into R&D for new medicines and the number of new medicines that will be forthcoming in the 1990's.

H.R. 6444 both redresses this inequity and protects consumers and generic manufacturers by excluding products already marketed and patents already issued. It should be supported by all who are prepared to critically examine the importance of new medicines to the poor, the elderly and to our health care delivery system. Feel free to use this letter during floor debate on the bill if it will help secure its passage.

With best regards.

Sincerely,

HAROLD FORD,
Member of Congress.

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

Mr. KASTENMEIER. I yield to the gentleman from Illinois.

Mr. RAILSBACK. Mr. Speaker, I think that the point that the gentleman makes is very, very important, and I would only add to that that one recent amendment that was adopted made it very clear that we did not want any pyramiding or we did not want extensions for one patent that may be discovered to have a new product or a new nature. We really limit it to one extension, and even that extension is limited to a period of 7 years, which may not cover the regulatory review period.

Mr. KASTENMEIER. The gentleman from Illinois is correct, and I thank him for that comment and would like to take this time to thank the subcommittee—the gentleman from Illinois (Mr. RAILSBACK), the gentleman from Michigan (Mr. SAWYER), as well as other members of the subcommittee, including the gentleman from Massachusetts (Mr. FRANK), although he disagrees with this bill. Nonetheless, I think he was of enormous help in the dialog attendant to producing what we have on the floor.

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

Mr. KASTENMEIER. I yield to the gentleman from Ohio.

Mr. SEIBERLING. Mr. Speaker, the gentleman from Wisconsin has done his usual scholarly and lawyer-like job of exploring this subject, and it is a very important one. He has made a very careful and thoughtful presentation. The only thing that concerns me is that we have here a bill that is controversial. There were some amendments offered in the committee which were not adopted. I supported some of them. I did not support others. It does seem to me that it ought to be taken up under a rule so that we can debate those amendments and decide what we want to do instead of doing it under suspension of the rules.

I just wonder if the gentleman can comment on that.

Mr. KASTENMEIER. I am afraid that I have more or less the same answer for the gentleman as was given during the last bill.

□ 1330

The SPEAKER pro tempore. The time of the gentleman from Wisconsin (Mr. KASTENMEIER) has expired.

Mr. KASTENMEIER. Mr. Speaker, I yield myself 1 additional minute.

Mr. Speaker, in view of the period of time that we have remaining in this Congress, in view of what appeared to be overwhelming support for this bill—and I do exclude the gentleman from Tennessee (Mr. GORE), the gentleman from California (Mr. WAXMAN), and the gentleman from Massachusetts (Mr. FRANK) who are in opposition to the bill—and considering what appears to be the numbers in support of this bill, it seemed to be the wisest, most prudent course of action to try to pass this under suspension.

Now, of course, we can go to the Committee on Rules and try to get a rule and open this bill up, but I would think that those who are interested in finding a plausible solution to the problem would think that we would like to test this bill, and I believe this body will approve it by a two-thirds margin or more.

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

Mr. KASTENMEIER. I yield to the gentleman from California.

(Mr. MOORHEAD asked and was given permission to revise and extend his remarks).

Mr. MOORHEAD. Mr. Speaker, I rise in support of H.R. 6444. This bill would amend the patent law by restoring that portion of the patent term during which the marketing or use of a patented invention was prevented due to Federal regulatory review. I am a cosponsor and strong supporter of this legislation.

For far too many years American industrial innovation has not kept pace with our foreign competitors. Analysis of our economic problems reveals that America's preeminence in the creation, possession, and use of advanced high technology has all but gone. Today, there is scarcely an American industrial sector which does not face stiff foreign competition in the sale of high technology products. The Europeans and Japanese are challenging and surpassing us in electronics, communications, and aviation, where in the past we had no peers.

The rate of new drug development is declining and will continue to decline unless there are adequate R. & D. incentives.

In 1960, 50 chemically new drugs came onto the market. In 1979, only 12 such drugs were introduced.

Other data submitted before the Subcommittee on Courts, Civil Liberties and the Administration of Justice support the conclusion that there is a real decline in U.S. pharmaceutical innovation. Studies conducted at the University of Rochester show that there has been a decline in the number of new drug compounds being studied in humans by U.S. companies. These studies show that after an initial rise to a high of 34 new drugs in 1964, the number dropped to a plateau of around 50 for the decade between 1965-1974. However, there was a 40-45 percent decline in new drugs in 1975 to 1976. A preliminary update of this data presented at the March 1980 meeting of the American Society of Clinical Pharmacology and Therapeutics indicates that this low level of new drug productivity has not changed.

There are other indications that R. & D. by U.S. pharmaceutical companies is declining. In 1964, U.S. firms asked FDA for permission to do research on 70 chemicals developed by their own research. In 1976, only 20 such applications were filed with FDA. Moreover, U.S. firms are becoming increasingly dependent upon licenses from foreign companies to provide them with research candidates. Testimony before the subcommittee projected that of the new drugs anticipated to be approved in the period 1981-1985, about 50 percent will have originated outside the United States.

A bill similar to H.R. 6444, S. 255 has already passed the other body and is also pending before our committee. This legislation is very important and will benefit all Americans, particularly the sick and the elderly by encouraging the development of important new medicines—and I urge the Members to vote favorably for the enactment of H.R. 6444.

Mr. SHAW. Mr. Speaker, I yield myself 5 minutes.

Mr. Speaker, I think that what we have to look at here when we are discussing this bill is exactly what it does. It extends the potential that a company is protected from any competition whatsoever in the field to 24 years. That is exactly what the bill does.

This means that we are simply guaranteeing, with the elimination of competition, a continuation of the high price of drugs which has now lasted for 17 years. We would now extend that for 24 years, and the people who are bitten are the consumers. Twenty-five percent of the drugs that are consumed today are consumed by the elderly, those people who can no longer support themselves and have limited means in which to do so. I think this is the important thing that we must consider and that we must keep in mind during this discussion.

Exactly what we are trying to do today is not to kill the bill but to open it up for the amendment process so that we can offer some technical amendments in this particular area, some amendments that are very important to the consumers at this time, particularly to the elderly population.

We are looking now at two time periods that basically extend the life of a patent. One is the time period during which the Government is doing its work. This is the time period over which the company has no control. I have no problem in extending that time in addition to the time the patent would last.

However, the other period of time we are talking about is the time that the companies themselves are controlling. This is the period of time between applying for the patent and the time they finish their experiments and what not with the drug. This can go on to extend to the full 7 years, together with the time consumed by the Government.

Mr. Speaker, I reserve the balance of my time.

Mr. KASTENMEIER. Mr. Speaker, I yield 2 minutes to the distinguished chairman of the Committee on the Judiciary, the gentleman from New Jersey (Mr. RODINO).

(Mr. RODINO asked and was given permission to revise and extend his remarks.)

Mr. RODINO. Mr. Speaker, I thank the chairman of the subcommittee for yielding this time to me.

Mr. Speaker, I am pleased to rise in support of this important compromise legislation, the Patent Term Restoration Act, which provides a limited patent term extension for pharmaceutical and chemical inventions, the primary class of inventions which loses commercial patent life due to regulatory testing and paperwork requirements.

I compliment the gentleman from Wisconsin and his able subcommittee, who have studied this issue for over 4 years, with the expert assistance of the Office of Technology Assessment and the Patent and Trademark Office.

Mr. Speaker, I would like to use my time to carefully respond to some of the criticism which has been leveled against this bill.

First, it has been suggested that H.R. 6444 will simply enrich already prosperous drug companies. In response, I would only say that the purpose of H.R. 6444 is not to enhance profits of anyone. Rather, the purpose of the bill is to channel existing profits into further research by insuring adequate patent term to amortize investments in research. Since 1966, effective patent life has declined from 14.6 years to 6.8 years. Unless a remedy such as this legislation is passed, pharmaceutical companies may not continue to invest in research, a situation which will not be in the public interest.

Further, it has been claimed that decline in patent term will have no effect on the level of investments in research. The committee record shows to the contrary, that pharmaceutical research as a percentage of sales fell almost 35 percent from 1966 to 1980. During the same period, average effective patent term declined from 14.6 years to 7.4 years—46 percent. In 1981, it declined further to 6.8 years.

Also, it has been claimed that patent owners can already extend patent life by obtaining more than one patent on a product, so-called patent pyramiding.

This is the most erroneous charge against this bill, because these subsequent patents are virtually always "process patents" which simply protect a new method of manufacture, they do not extend the patent on the invention itself. They in no way limit generic companies from using an off-patent chemical formula and manufacturing the product.

It is recognized by many that the issue involved is not simply the growth of the economy, it is encouraging future investment of large sums of private capital in the high risk area of breakthrough pharmaceutical technology. Such investments pay off not only in economic growth but even more importantly in improvements to the health and well being of our people, especially those most likely to need new medical technology, such as senior citizens.

That is why such nonprofit groups as the National Alliance of Senior Citizens, the American Cancer Society, the American Heart Association, the American Medical Association, the American Bar Association and dozens of researh hospitals and universities support the legislation.

The committee has reported a measure that neither side is totally happy about. That is a mark of its fairness. It will, I believe, provide some impetus for development of the myriad drugs necessary to the continued health needs of our Nation.

Mr. SHAW. Mr. Speaker, I yield 5 minutes to the ranking minority member of the subcommittee, the gentleman from Illinois (Mr. RAILSBACK).

(Mr. RAILSBACK asked and was given permission to revise and extend his remarks.)

Mr. RAILSBACK. Mr. Speaker, I rise in very strong support of this bill.

I simply want to agree and concur with the remarks both of the chairman of the full committee as well as of the chairman of the subcommittee, the gentleman from Wisconsin (Mr. KASTENMEIER), and I want to begin by saying that in my opinion this is a case where Government regulation has once more impacted tremendously on American business.

I want to make a point in response to an earlier remark that we are somehow extending patent life for 24 years. Let me make it very clear that that 24 years that was mentioned is not really a useful patent life because it would include the regulatory review before the product was even marketed. In other words, what we are doing is recognizing the problems of this one American industry. Actually there are

two, because we have the agricultural chemical industry, as well as the pharmaceutical industry, both of which undergo very extended, prolonged regulatory testing, and the net effect is that our American pharmaceutical industry and our American agricultural chemical industry simply are not afforded the protection that is afforded to virtually every other American industry that is entitled to patent protection.

What we are trying to do is to encourage these companies which are research intensive and very risky by their nature to plow money into research and development for effective new drugs. That is the purpose of the bill, and it is in my opinion sorely needed.

I want to mention something from a competitive standpoint as it relates to foreign competiton, and I want to make this point so that all of my colleagues are aware of it. Foreign competition has increased dramatically over the past 10 years. Approximately 40 percent of new drugs introduced were developed by foreign companies, primarily Japanese and West German. Fifty percent of the drugs scheduled for introduction in the period, 1981-85, we believe, will be foreign originated.

Of perhaps greater significance is the fact that the Japanese Government has now targeted the Japanese pharmaceutical industry as a priority growth industry for the 1980's and the 1990's. What that means, then, is that we are now going to have the Japanese Government, as it does, working in concert with its pharmaceutical industry to try to really develop almost a monopoly in that industry. We have already seen the establishment in the United States of several subsidiaries of Japanese pharmaceutical companies, and the number is expected to increase dramatically over the next 2 to 3 years.

I want to cite an editorial that I think summarizes at least my view, and this comes from the Chicago Tribune of May 1, 1981, which said this:

Some objections have been raised to the proposed legislation because it would lengthen the time until a drug could be copied by the developer's competitors and marketed as a generic product, presumably at a lower price. But in the long run, we all stand to benefit much more from the discovery and availability of new medications. It is far less expensive to treat patients with drugs than with surgery or long hospitalization, which may be the only alternatives. And one of the most effective ways to cut health care costs is to develop new medications. Enormous savings, for example, could be made if we had more effective drugs for heart disease, cancer, genetic disorders, respiratory diseases, and a long list of other ailments for which better treatment is urgently needed.

Mr. Speaker, I want to mention, too, that we have support from the American Cancer Society, the American Medical Association, the National Alliance of Senior Citizens, the Johns Hopkins University, the Association of American Medical Colleges, and the Health Industry Manufacturers Association, which are very much aware of the need for further plowing money into research and development. That is just mentioning a few of the 38 letters of endorsement that we have received. There are more than 50 editorials from newspapers all over the country that endorse this legislation.

Mr. Speaker, I strongly urge my colleagues to support the legislation.

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

Mr. RAILSBACK. I am happy to yield to the gentleman from Ohio.

(Mr. KINDNESS asked and was given permission to revise and extend his remarks.)

Mr. KINDNESS. Mr. Speaker, I thank the gentleman for yielding, and I wish to associate myself with his remarks in strong support of the bill.

Mr. Speaker, in recent years, the average patent life for new drugs introduced into the marketplace has declined significantly. It has been shown that our stringent regulatory requirements take 7 to 10 years to complete, almost half of the 17-year period that Congress has specified for exclusive patent protection on other products. No one wants to return to allowing the sale of any concoction off of the back of a wagon, without the public having any idea whether it is safe to take, or effective as a medicine. But, if the agencies of Government are going to demand costly and extensive development and testing procedures before any product can be marketed, it is only fair that the time required to obtain that approval is not taken off the patent life.

The average cost of marketing a new medicine is now about 470 million, and the number of such new medicines has declined dramatically in the last 20 years, at the same time that the regulatory approval process has been demanding increased resources of time and money.

This bill would simply restore part of the patent life not available, because the Federal Government delays marketing until appropriate clinical and animal tests have satisfied the Food and Drug Administration scientists that a drug is safe and effective. No patent would be extended unless such regulatory delay had actually occurred, and in no case could the term be extended more than 7 years.

Opposition to this idea has come from some who complain that restoring this part of the patent protection will result in higher prices for drugs, a particular concern of the elderly. They overlook the fact that research and development of new products are essential as an alternative to more costly forms of therapy, such as hospitalization or surgery. Besides being less costly, drug therapy is safer for elderly patients. They have certainly benefited from our superior technology in the past. In fact, out of every dollar spent on health care in the United States, only about 8 cents is paid for medicine. While the Consumer Price Index has risen 178 percent, and health care costs have increased 629 percent, the cost of prescription drugs has increased only 34 percent in the past 20 years.

Patent restoration will provide more incentive for research and development of new products, as well as promoting price competition between old and new medicines. Drug manufacturers who do not do research and development are very shortsighted to oppose this incentive, because if the basic research is not done and the testing and approval process not completed, there will be substantially fewer products brought to the market, and both they and the public will be the losers.

This extension of the patent term to compensate for time required by our regulatory procedures is a matter of equity, and will not affect the patent life of any drug or chemical currently being marketed. I urge the passage of this legislation.

Mr. KASTENMEIER. Mr. Speaker, I yield such time as he may consume to the gentleman from New Jersey (Mr. HUGHES).

(Mr. HUGHES asked and was given permission to revise and extend his remarks.)

Mr. HUGHES. Mr. Speaker, I rise in support of H.R. 6444, the Patent Term Restoration Act, and urge my colleagues to adopt this important bill which provides for an extension of the patent term lost due to Federal agency review periods.

As a cosponsor of H.R. 6444, and as a member of the Judiciary Committee which favorably reported the patent term restoration bill in early August, I believe that enactment of this legislation will go a long way in stimulating industrial innovation and would reduce the inequities resulting from delays in bringing patented products to market due to Federal regulations and agency reviews.

Despite the fact that enactment of the patent term extension bill promises to improve the quality of health care by bringing more—and much improved—pharmaceutical products to the marketplace, some concern has been raised by those who fear that the extended patent term will result in slowing the process by which generic drugs come to the marketplace. The Judiciary Committee, however, mindful of the important role that generics play, limited the application of the legislation to patents issued after the date of enactment. The legislation also provides that no patent can be extended under the bill for more than 7 years.

I believe that the patent term bill is a fair and equitable approach to assure that American companies remain competitive while at the same time encouraging the developing of new products to meet our health needs. As Congressmen RODINO and

KASTENMEIER have clearly indicated, this legislation will encourage the investment of the large sums of private capital needed to achieve new breakthroughs in the high-risk fields of pharmaceutical innovation and technology.

I urge you to join with us in supporting this important and well-balanced legislative proposal.

Mr. KASTENMEIER. Mr. Speaker, I yield 7 minutes to a member of the subcommittee, the gentleman from Massachusetts (Mr. FRANK), in the belief that he will yield to those colleagues who support his point of view.

Mr. FRANK. Mr. Speaker, I thank the chairman of my subcommittee for yielding to me.

Mr. Speaker, I want to acknowledge the significant work that the gentleman did to improve this bill, but I think in part that is one of the reasons why we ought not to be doing this on suspension.

There are two levels of discussion on this bill. One is whether or not any relief is needed for this industry, and Members differ about that. But there is another level which is even more important for those who agree that some relief would be required, and that is how best to structure it in a fairly difficult area.

In committee there were several amendments which were debated at some length and defeated. Allusion was made to the fact that opponents to the bill in its present bill were overwhelmed. Mr. Speaker, we were "whelmed," but I am not sure that we were overwhelmed. We got better than a third of the committee that supported some fairly substantial amendments, and we lost by votes of 16 to 10 and 16 to 9. That seems to me to justify a chance to deal with the bill in a form that allows amendment. This really is not the kind of legislation for which the suspension calendar was intended, since there is a substantial bipartisan section of the committee which seeks amendments and since there are subcommittees and chairmen having related jurisdiction which support amendments.

Mr. Speaker, the fundamental amendments are two in number. First, the question is, if some patent term as this is necessary, when should it begin? In its current form the patent term is extended for that period during which experimentation is being done on the drug. That is not in my judgment the requirement that the Federal Government imposes on the companies. It is something that common sense and common decency and a respect for human life imposes on the companies. I do not think they ought to be compensated in extra time for the time they use in testing this drug for efficacy and for safety.

Moreover, the FDA itself has no control over what happens during that period. That is in the control of the companies themselves.

One amendment proposed by the gentleman from Florida (Mr. SHAW), and supported by many of us in the subcommittee would have begun adding on to the patent process at that moment at which the Food and Drug Administration was given a completed application. It is at that point that the jurisdiction of the regulatory agency is engaged. It is during that period that any bureaucratic delay would occur.

Many of us were prepared to support an amendment that would say that the day the companies hand in a completed application to the FDA, from that moment forward they would get extra time.

Another amendment we wanted to have is related, because as the bill now stands, there is no mechanism for deciding who was at fault for the delay. Under the current bill a company which suffers delay because of its own ineptitude or its own shortcutting in not properly testing this drug would be rewarded with an extension of its patent term. I would like the opportunity to offer an amendment, supported by a substantial partisan minority of the subcommittee, to allow someone to intervene in that process and say, "wait, this is not the problem of bureaucratic delay."

□ 1345

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

Mr. FRANK. I yield to the gentleman from Illinois.

Mr. RAILSBACK. I thank the gentleman for yielding.

I wanted to point out that there is, as the gentleman knows, a great deal of testing before it actually goes into the chemical testing stage, before they ever even apply for a patent. There are all kinds of testing before it ever reaches that stage.

Mr. FRANK. I thank the gentleman. I am glad there is. But I do not regard that as a favor at any point that the companies are doing for us. I regard that as an integral part of the process by which one determines the fitness of the drugs to go forward.

Let me say further I agree with the gentleman that this is a fit subject for debate. What we are asking for today is not defeat of the whole bill but defeat of the suspension process so that the gentleman from Illinois and I could in fact conduct this debate for the benefit of the Members in a somewhat more open fashion, not constrained as we are by the time.

I do not think, given the kinds of issues the gentleman from Illinois would like further to discuss, that the suspension process adequately contains this.

The cost of this is that generic drugs, a means of saving money for consumers and for the Government, a means of effective cost control that does not sacrifice the quality of care, will be put further out of the reach of consumers. I think that would be a mistake.

Mr. Speaker, I yield such time as I have remaining to the gentleman from Tennessee (Mr. GORE).

Mr. GORE. I want to thank by colleague and pay my respects to the chairman of the subcommittee and the full committee.

I respectfully oppose this bill as strongly as I possibly can as an unnecessary giveaway for which nothing will be given in return. It proceeds from false premises and I want to outline them one by one.

No. 1, the impression is given that this industry is in distress. That is false. This industry is the third most profitable industry in the United States. This fact comes not from the debate of the chairman of the subcommittee this morning, but in the arguments and the general presentation of the industry. The profits of this industry are going up and up and up.

No. 2, that there is some problem with R. &. D. expenditure. Research and development spending has been skyrocketing and it has been going up in real terms, deflated dollars year after year after year. Let me read you a recent quote from Fortune magazine within the past year.

> Merck is pouring a colossal $280 million into R&D this year, nearly four times more than ten years ago, while Eli Lilly's $210 million for 1980 was three times more than in 1971. Pfizer's research expenditure, which quintupled from 1970 to 1980, will grow by nearly 16% this year, to around $180 million, while Squibb has boosted spending 84% in the last five years to $91 million.

Where is the problem with incentive for research and development? And as if there was a problem, we already gave them just this past year a new 25-percent tax credit to stimulate them even more. How much encouragement do they need?

The second false premise is that innovation has been declining, it is said. Innovation has not been declining.

The statement has been made that there are half as many drugs approved this year as in 1960. That is misleading because 1962 was the year the modern era of drug regulation began. There were fewer new drugs approved in 1962 than there were this year.

The third false premise, that there is a problem with the effective patent life. Let us look at the effective patent life for not just the ones that the drug industry averages in but let us look at the top selling drugs for this year.

An average number of years of patent monopoly protection after FDA approval is not 17 years but 18½ years, more than the 17 years.

How could that be? It is because they use the patent system, they pyramid patents, and they evergreen patents. Even after the patent period expires they still control the market.

Take the example of librium.

I urge my colleagues to vote no when the occasion arises.

Mr. SHAW. Mr. Speaker, I yield 1 minute to the gentleman from Kansas (Mr. GLICKMAN).

(Mr. GLICKMAN asked and was given permission to revise and extend his remarks.)

Mr. GLICKMAN. Mr. Speaker, I cosponsored this legislation and I still believe that there are many more changes in the law that need to be made.

But I would urge my colleagues, as a cosponsor, to vote against this bill on the Suspension Calendar.

This is a very serious piece of legislation. One of the amendments that was offered in committee, the Shaw-Frank amendment, would have provided that the extension period for patents be counted as to the various products covered from the time of the application to the Federal agency until it is approved. That is a critical amendment. The length of the patent term as it is to be extended under this bill would be modified significantly by a very important amendment that should have the opportunity to be offered.

While it is true many of the things that have been said about the nature of this industry and the need for innovation, I think the length of the time of the patent extension is one that demands the attention of this House under a separate floor vote and, therefore, I would urge a no vote under suspension of the rules.

Mr. SHAW. Mr. Speaker, I yield 5 minutes to the gentleman from Michigan (Mr. SAWYER).

Mr. SAWYER. Mr. Speaker, I rise in support of this legislation.

Right at the outset I want to make a correction or two in some of the statements made by the gentleman from Tennessee; namely, if you adjust for inflation the pharmaceutical research as a percentage of sales fell by almost 35 percent from 1966 to 1980.

During the same period of time the effective patent term declined from 14.6 years to 7.4 years. Then in 1981 the effective patent term declined to 6.8 years.

I would also suggest that the gentleman from Tennessee published an article not too long ago wherein he attributed this bill to the Reagan administration. This bill actually, if the gentleman had done his homework, had its genesis in the Carter administration. President Carter appointed a blue ribbon panel to get into this subject, to find out why innovation and patent applications were declining in the United States and in particular in this industry; namely, the pharmaceutical and chemical industries where they had declined by over 50 percent since 1960.

This panel came up with some four major recommendations. One was that we computerize and data process the Patent Office to make it more efficient. Second, that we get a review and restudy process and increase the patent examiners. Third, that we set up a new Patent Court of Appeals called the Court of Federal Circuit. Fourth, that we do something to correct this intrusion on the patent term that this process of Federal examination and licensing before it could be marketed that applied in both the pharmaceutical and chemical industries.

The first three of those have been accomplished by the Congress, and this is the fourth one that is being implemented to try and get some life back in our innovation and our patent applicatons and in our progress.

This bill has been endorsed by approximately 50 of the major newspapers in the country, including the New York Times and the Washington Post, which are certainly liberal and consumer-oriented newspapers.

Not only has it been endorsed by these major newspapers on the basis of fairness, but by every one of the major medical and health care organizations, including the American Medical Association, the American Bar Association, the Patent Division, and the American Association of University and American Association of Medical Schools, the Heart Association, the Cancer Association, who are all behind this legislation.

May I say that when we have a patent term for 17 years for the inventor of a toy, to say that the inventor of an important pharmaceutical can only have 6.8 years of patent protection is just a question of plain fairness. All of them had 17 years historically as indicated by the Constitution. Then in 1962 we started this Federal process of a patent, but before marketing, that has gradually chewed up that patent life as to pharmaceuticals and pesticides and certain chemicals.

In just plain fairness it is merely giving back that time or a portion of it.

Also, the pyramiding and evergreening has been alluded to and would be prevented by this bill which wipes that out.

So it is just in plain fairness to this industry and to reencourage the investment of research and development money.

Incidentally, we are getting very little for it. There is no effect on the patent life for almost 20-years down the pike from today if we do adopt the bill. Nothing will change except the encouragement of R. & D. money going into the development of pharmaceuticals and drugs.

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

Mr. SAWYER. I yield to the gentleman from Illinois.

Mr. RAILSBACK. I thank the gentleman for yielding.

I wanted to make one point, which is that the New York Times and the Washington Post I think have now come out with a subsequent editorial that calls for an amendment.

But the gentleman is absolutely right, originally they were very strong for the bill.

I think the gentleman has made some excellent points. I think the gentleman from Texas (Mr. BROOKS) is also for the bill.

Mr. SHAW. Mr. Speaker, I yield 1 minute to the gentleman from Texas (Mr. BROOKS).

(Mr. BROOKS asked and was given permission to revise and extend his remarks.)

Mr. BROOKS. Mr. Speaker, I rise in support of H.R. 6444, the Patent Term Restoration Act of 1982. This bill would allow the extension of the term of a patent for products which are subject to review by Federal agencies when the owners of those patents are prevented from marketing their inventions during the agency approval process.

Mr. Speaker, this bill has the important purpose of encouraging innovation by restoring full value to patents on inventions subject to agency review. It would grant patent owners an extension of their rights for up to 7 years beyond the traditional 17-year patent term. The knowledge that the regulatory review and approval process will not diminish the value of their patents is certain to encourage research and development in these regulated fields.

Mr. Speaker, under the able leadership of my friend, Chairman BOB KASTENMEIER, the Judiciary Subcommittee on Courts, Civil Liberties, and the Administration of Justice has made several changes to the original patent term bill, H.R. 1937. These amendments insure that the original purpose of the legislation will be carried out and that there will be minimum negative impact from the bill on the generic drug industry and on consumers.

I urge support of H.R. 6444.

Mr. SHAW. Mr. Speaker, I yield 4 minutes to the gentleman from California (Mr. WAXMAN).

(Mr. WAXMAN asked and was given permission to revise and extend his remarks.)

Mr. WAXMAN. Mr. Speaker, there is one proposition that I think both the proponents and opponents of this bill would agree upon that is the fact that when we give an extension of the patent interest period it is going to lead to a longer period of time in which there will be higher prices for drugs. That is logical, because a patent means you have a monopoly over the production and sale of a drug.

That monopoly means that there cannot be a competitor who can produce the same drug and sell it at a cheaper price.

What this bill will do will be to insist on the highest price for drugs to be paid by those people who need to buy drugs.

Who are the people who need to buy drugs? Primarily the elderly and certainly the sick. Eighty-four percent of drug purchases in this Nation are paid for out of the pockets of the people who must buy medications.

This bill will add a shift and it will add to the cost of drugs billions which will mean a shift out of the pockets of the elderly primarily into the pockets of the pharmaceutical manufacturers. We are told that we ought to support this shift of billions of dollars from those who are on limited, fixed incomes to those who are some of the wealthiest corporations in this Nation because it is going to be fair and it is going to bring about innovation.

But if we look at those claims, they just do not hold up because what we see with the pharmaceutical industry was, according to the Wall Street Journal, a 25-percent increase in profits in 1981. For 1982, a 20-percent increase in profits. And at a time when everyone else in this Nation is suffering from recession.

What we have seen in expenditures for research and development is a continuous increase year after year.

When the drug manufacturers manufacture drugs they get their investment back and they get a tremendous profit. I do not begrudge them that but what I do begrudge them is to come to Congress a year after we passed the tax break for them for research and development of 25 percent, and to ask us to help them out by giving them a longer period of time over which they are going to ask the elderly of this Nation to pay higher prices for drugs.

I do not think that is fair and a number of my colleagues agree that it is not fair who originally thought this idea of this bill seemed right.

□ 1400

A number of my colleagues joined in even coauthoring the bill, who accepted that superficial argument that is advanced for it; and then later, when they looked at the legislation more carefully, they decided to oppose it.

Two of the leading newpapers in this Nation originally supported the bill when they heard from the pharmaceutical industry. But when they looked at it a little more carefully, they backed away from it. The New York Times and the Washington Post both told us to support this legislation, and then later came out with editorials asking us to either oppose it or to severely curtail it.

Now, this legislation is different from that which the other body has proposed, and it is still not legislation that the drug industry will support because the drug industry wants the bill passed by the other body—because that is a much more generous bill for them. And this compromise which we are being urged to vote for is a compromise which they still do not accept.

I urge that on this suspension vote we defeat this bill, that we defeat it because as it stands today before us we have only one choice to vote up or down, and I say let us vote down this bill. I urge my colleagues to join me in doing so.

Mr. SHAW. Mr. Speaker, I yield 1 minute to the gentleman from Tennessee (Mr. GORE).

Mr. GORE. I thank my colleague for his courtesy.

Mr. Speaker, just to correct the record once and for all, the Post changed its position, the New York Times changed its position, too, and the Times did not just ask for amendments. I say to my colleagues; it came out flat, foursquare against the whole thing. Let me read to my colleagues what they said:

> The pharmaceutical industry is efficient, profitable and healthy. It has no demonstrable need for any special break. The patent system as a whole may need reform, but that is a different issue. Monopoly rights should not be doled out to anyone with a hard-luck story, as Congress seems to believe. The proposed extension is unjustified, unsuited to the stated purpose of increasing research and offensive to the basic principle of a free economy.

To sum up, research and development spending is increasing. Profits are increasing. Innovation is stable. The industry does not need this bill. The only thing it will accomplish is to raise the price of medicine by an estimated $3 billion to $5 billion each year.

Mr. Speaker, I urge my colleauges to vote "no."

Mr. SHAW. Mr. Speaker, I yield myself the balance of my time.

The SPEAKER pro tempore. The gentleman from Florida (Mr. SHAW) is recognized for 1 minute.

Mr. SHAW. Mr. Speaker, I think in our desire to finish up the legislative business of this Congress, we are probably going to be doing a lot of things and voting on a lot of things that we have no business doing. In looking around this hall today, we see that most of the Members are apparently not here. I think that if we would check, we would find that they were not in their offices, that they are in their home districts doing important business. But this is important business. What we must do is to vote this bill down under suspension, get it here on the floor, with an open rule, so that we can present amendments to take the bad part out of this bill and pass it in a preferred form.

What we are talking about is the pocketbooks of the elderly. And for us to go running out of this hall so that we can get home to campaign and tripping over the limited earnings of the elderly in doing so, I think it would be a tragedy. We must take out of the bill the portion that would allow the extention of the patent, the period of time the prices are set without competition, to take out that portion which the company has complete control of, and come up with a good bill that all of us can support.

● Mr. CORRADA. Mr. Speaker, I rise in support of H.R. 6444, the Patent Term Restoration Act, which would restore the period of useful life of patents lost hurdling over Federal regulations. Currently, manufacturers of such products as drugs, medical devices, and chemicals, use more than half of the 17 years of their patents exclusivity period complying with FDA's premarketing requirements.

It is only fair play that we correct this inequity in the law. It is ironic that medical breakthroughs be penalized for having to meet Federal regulatory requirements directed to protect the public health.

With this kind of disincentive, it comes as no surprise that in the past 20 years there has been a dramatic decline in the number of new medicines introduced in the United States. Our research intensive industries feel betrayed when Congress incentives are diminished by subsequent regulations and nothing is done about it.

The future well-being of our citizens and the economic situation of our Nation demands the drafting of incentives for economic investment in high-risk areas that could bring about economic growth and new lifesaving products. This bill provides a simple, equitable, and uncostly way of stimulating this capital investment in areas that could lead us to a new era of economic stability and a healthier life for our people.

I urge my colleagues to vote for the passage of this legislation.●

The SPEAKER pro tempore. The question is one the motion offered by the gentleman from Wisconsin (Mr. KASTENMEIER) that the House suspend the rules and pass the bill, H.R. 6444, as amended.

The question was taken.

Mr. FRANK. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to the provisions of clause 5, rule I, and the Chair's prior announcement, further proceedings of this motion will be postponed.

GENERAL LEAVE

Mr. KASTENMEIER. Mr. Speaker, I ask unanimous consent that all Members may have 3 legislative days in which to revise and extend their remarks on the bill, H.R. 6444, just considered.

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

There was no objection.
