OISS FORM 52 (12/80)

CONGRESSIONAL RECORD
PROCEEDINGS AND DEBATES OF THE 97TH CONGRESS

HOUSE

| BILL | DATE | PAGE(S) |
|---|---|---|
| H.R. 6444 | Sept. 16, 1982 | H7158-59 |

ACTION
Correction of Record

## CORRECTIONS OF THE RECORD

Mr. RAILSBACK. Mr. Speaker, I ask unanimous consent that my remarks on H.R. 6444 in the RECORD of September 13 at pages H6920 and H6921 and of September 14 at page E4158 be corrected.

My remarks on those days are incorrectly printed and I wish them to be corrected with the following statement.

Also, in the RECORD of September 14, my remarks on H.R. 6444 at page E4158 are attributed incorrectly to my colleague from Illinois, Mrs. COLLINS.

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

Large and small businesses must be encouraged to channel a larger share of profits, manpower, and investment capital into research and the development of commercial products; the pharmaceutical and agricultural chemical industries are research-intensive and risky. They are particularly dependent on the patent system and they face stiff foreign competition. Ironically, these industries while especially needing the patent system, do not receive its full benefits. The effective term of pharmaceutical patents as a consequence of regulatory review, dropped from 16 years in 1960 to 13 years in 1970, to about 9.5 years in 1979, to 6.8 years today. The agricultural chemical industry today can expect an effective patent term of only about 12 years. This is just unacceptable!

Given the fact that today, upward of 10 years of patent life out of a total of 17 years, can be (and often is) lost because of Government-required testing the drug company has less than 7 years of patent life to try and recover its initial investment. This bill would

provide that if a company did lose a number of years of its patent life because of Government-mandated review, then it could recover a maximum of 7 years. This would give that company more years to recover its investment, and this should mean cheaper prices to the consumer. I also believe this legislation could mean more and better medications, resulting in better and earlier therapy. This point was well made by a Chicago Tribune Editorial of May 1, 1981, which said:

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 durgs for heart disease, cancer, genetic disorders, respiratory diseases, and a long list of other ailments for which better treatment is urgently needed.

In addition to the support of the Chicago Tribune, this bill enjoys the editorial support of over 25 newspapers from around the country. It is also cosponsored by 103 Members of this body.

Although the National Council of Senior Citizens has sent you a letter in opposition, I would like to point out that the National Retired Teachers Association and the American Association of Retired Persons have decided not to take a position on this legislation. It also has the support of the American Medical Association, the National Alliance of Senior Citizens, the Johns Hopkins University, the Association of American Medical Colleges, the Health Industry Manufacturers Association, to mention just a few of the 38 letters of endorsement we have received from health, medical organizations, and universities around the country.

Mr. Speaker, at this time I would like to further clarify, for the purpose of legislative history, the amendments I offer and which were adopted by the Judiciary Committee.

Under section 155(a)(2), the rights derived from restoration of a patent term are limited to the scope of the claims which cover the product undergoing regulatory review. Because a single patent can also encompass a product with several uses subject to different regulatory review requirements, or subject to no regulatory review requirements at all, a patent extension for a product approved, that is, as a human drug, covers all human drug uses but not pesticidal, photographic, or other uses.

Under section 155(a)(3), any patent extension must be calculated from the original expiration date of the patent. Thus, if it would happen that two regulatory review periods for two different products under the same patent occurred, the resultant extensions would run concurrently, both dated from the original patent expiration date and not consecutively.

Under section 155(c)(2), acute and subchronic toxicity testing is ordinarily completed in less than 6 months. In that case, it would not be included within the definition of a "major health and environmental effects test." However, if acute and subchronic toxicity testing took longer than 6 months, it would be included within such definition.

Section 155(c)(4) defines product sponsor in a way to assure that any person or persons responsible for any part of the regulatory review process for a product qualifies as a product sponsor to obtain the restoration benefits provided under the bill. The term "first product sponsor" is used throughout section 155(c)(5) and is intended to assure that if there is more than one product sponsor (as is usually the case when a university or other inventor licenses a product), the period of patent extension includes the combined regulatory review period of the first and subsequent product sponsors even if the extension is obtained by a subsequent sponsor.

The clinical investigation referred to in section 155(c)(5)(A) is intended to permit the calculation of the period of patent extension for a drug or human biological product to commence with the first safety testing of the drug in humans. Normally, this testing will occur at the beginning of phase 1 of the IND phase of FDA review.

Mr. Speaker, in conclusion, I would like to mention that during our subcommittee hearings and markup, a hardship case was brought to our attention by Senator GRASSLEY which this bill presently omits, and the case involved a company, Impro Products, Inc., an animal health products firm. I am advised that a district court, on September 2, 1982, issued a permanent injunction against the agency involved preventing them from further distribution of the false test results as the company wages a larger antitrust suit. If appropriate, this case may be considered when we meet with the other body in conference.

I urge the Members to vote in favor of H.R. 6444.

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

There was no objection.