97TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { No. 97-696

PATENT TERM RESTORATION ACT OF 1982

AUGUST 4, 1982.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. KASTENMEIER, from the Committee on the Judiciary, submitted the following

REPORT

together with

ADDITIONAL AND DISSENTING VIEWS

[To accompany H.R. 6444]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred 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, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

The amendments (stated in terms of the page and line numbers of the introduced bill) are as follows:

Page 2, line 2, strike out "paragraphs (2) and (3)" and insert in lieu thereof "paragraphs (3) and (4)".

Page 2, line 4, strike out "a regulatory review period" and insert in lieu thereof "regulatory review".

Page 2, line 6, strike out "subject to a regulatory review period".

Page 2, insert at the end of line 6 the following: "from the original expiration date of the patent".

Page 2, line 8, strike out "recipient of marketing approval" and insert in lieu thereof "product sponsor".

Page 2, strike out lines 11 through 13 and insert in lieu thereof the following:

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

Page 2, strike out lines 20 through 24 and insert in lieu thereof the following:

(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 a 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.

Page 2, line 25, strike out "(2)" and insert in lieu thereof "(3)".

Page 3, line 1, strike out "or method".

Page 3, line 7, strike out "extension of a" and insert in lieu thereof "term of any extended".

Page 3, beginning in line 13, strike out "or method".

Page 3, line 15, strike out "(3)" and insert in lieu thereof "(4)".

Page 3, strike out line 23 and all that follows through "has ended." on line 1 on page 4, and insert in lieu thereof the following:

(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.

Page 4, beginning in line 1, strike out "recipient of marketing approval" and insert in lieu thereof "product sponsor"; and in line 6 on that page, strike out "or regulation".

Page 4, insert before the semicolon in line 7 the following: "or, if the regulatory review occurred under the Federal Food, Drug, and Cosmetic Act, the chapter of the Act under which the review occurred"; and in line 10 of that page strike out "and the statutory use".

Page 4, strike out lines 12 and 13 and insert in lieu thereof the following:

(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

Page 4, line 14, strike out "the claim or claims of the patent" and insert in lieu thereof "the patent and any claim thereof".

Page 4, line 20, strike out "or method".

Page 4, line 22, strike out "(A) publish the information noticed" and insert in lieu thereof "publish"; and in line 24 on that page, strike out ", and (B)" and insert in lieu thereof the following: "the information contained in such notice. Unless the requirements of this section have not been met, the Commissioner shall".

Page 5, line 2, strike out "statutory use and the claim or claims" and insert in lieu thereof the following "statute under which regulatory review occurred and specifying any claim".

Page 5, line 4, strike out "each patent" and insert in lieu thereof "the patent so"; and in that line strike out "such certificate".

Page 5, strike out lines 7 through 11 and insert in lieu thereof the following:

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

Page 5, line 20, strike out "155" and insert in lieu thereof "151".

Page 5, line 21, strike out "any" and insert in lieu thereof "Any".

Page 6, line 1, strike out "any" and insert in lieu thereof "Any".

Page 6, strike out lines 13 through 16 and insert in lieu thereof the following:

> (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.

Page 6, line 18, insert after "a" the following: "product which is a".

Page 6, beginning on line 20, strike out "recipient of marketing approval" and insert in lieu thereof "first product sponsor".

Page 6, line 21, strike out "initiated" and insert in lieu thereof "initiates"".

Page 6, beginning on line 22, strike out "for the specific method for use for which such product is approved or licensed under such statutes".

Page 6, beginning in line 25, strike out "or a method for using or of producing such product"; and beginning in line 3 on page 7, strike out "or a method for using or of producing such product".

Page 7, beginning on line 1, strike out "such statutes" and insert in lieu thereof "the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, or the Act of March 4, 1913".

Page 7, line 5, strike out "or licensees" and insert in lieu thereof "or the product is licensed"; and beginning in line 5, strike out "the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913," and insert in lieu thereof "such statutes".

Page 7, line 16, insert after "a" the following: "product which is a".

Page 7, strike out lines 18 through 25 and insert in lieu thereof the following:

> 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;

Page 8, line 1, after "to" insert the following: "a product which is".

Page 8, strike out lines 3 through 18 and insert in lieu thereof the following:

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;

Page 8, line 19, insert after "to a" the following: "product which is a".

Page 8, beginning in line 20, strike out "recipient of marketing approval" and insert in lieu thereof "first product sponsor"; beginning in line 22 on that page, strike out "such product or method for using such product" and insert in lieu thereof "the product"; in line 24, strike out "or (ii)" and insert in lieu thereof "(ii) initiates a clinical investigation on humans, or (iii)"; and in line 25, strike out "such" and insert in lieu thereof "the".

Page 9, line 1, strike out "or method for using such product"; and beginning in line 3, strike out "such product or a method for using such product" and insert in lieu thereof "the product".

Page 9, line 6, insert after "a" the following: "product which is a"; beginning in line 7 on that page, strike out "recipient of marketing approval" and insert in lieu thereof "first product sponsor"; and in line 10, strike out "the data from which" and insert in lieu thereof "but only if the data from such test".

Page 9, line 14, insert "for the pesticide" after "permit".

Page 9, line 19, insert after "a" the following: "product which is a"; and beginning in line 25 on that page, strike out "recipient of marketing approval" and insert in lieu thereof "first product sponsor".

Page 10, line 12, strike out "recipient of marketing approval" and insert in lieu thereof "first product sponsor"; in line 16 on that page, insert "chemical" after "such"; and in line 17 on that page, strike out "the data from which" and insert in lieu thereof "but only if the data from such test".

Page 11, beginning in line 3, strike out "or the method of use of such product subject to the regulatory review period." and insert in lieu

thereof "which is subject to regulatory review, for the method for using such product, or for the method for producing such product".

Page 11, line 5, strike out "In" and insert in lieu thereof "Notwithstanding subsection (a) (1) (D), in".

BACKGROUND

H.R. 6444 is the product of over four 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 led to the creation of a cabinet-level coordinating committee chaired by Secretary of Commerce, Juanita Kreps, which supervised the activities of a team of experts under the direction of Dr. Jordan J. Baruch, Assistant Secretary of Commerce for Science and Technology. Dr. Baruch organized more than 150 senior representatives from the industrial, public interest, labor, scientific and academic communities into the Advisory Committee on Industrial Innovation. The deliberations of the Advisory Committee encompassed five areas of investigation: economic and trade policy; environmental, health and safety regulations; regulation of industry structure and competition; federal procurement policy; and federal patent and information policy. Members of the Advisory Committee were asked to prepare specific recommendations for changing existing policies or initiating new ones to enhance the state of industrial innovation in our country.

The Advisory Committee was especially productive in recommending modifications in patent policy as a means of enhancing the climate for innovation. Among the recommendations of the Committee were: upgrading the Patent Office by increasing the examination staff and providing modern data-processing research tools to patent examiners; providing a reexamination procedure to increase the reliability of patents whose initial examination may have been incomplete; and creating a central court to hear all patent appeals. President Carter eventually accepted all three of these recommendations and requested that Congress enact implementing legislation.

Public Law 96–517, signed into law on December 12, 1980, provided for computerization of the Patent Office and a system of reexamination of patents. It also expedited the transfer of patent rights derived from government-funded research and development to the academic and small business communities as a way of stimulating private-sector initiative.

On April 2, 1982, President Reagan signed into law Public Law 97–164, the proposal to create a Court of Appeals for the Federal Circuit, a central forum for all patent appeals originally recommended by the Advisory Committee. On June 8, of this year, the House passed H.R. 6260, which by enhancing fee revenue available to the Patent and Trademark Office, will permit for the first time the full complement of patent examiners necessary to comply with the Advisory Committee's request for an adequate examining staff.

A key recommendation of the Advisory Committee which remains to be implemented, however, is that calling for "an adequate extension of the patent term . . . when commercialization of patented inven-

tions is delayed due to Federal regulations." [1] It is this recommendation which is embodied in H.R. 6444.

H.R. 6444 constitutes one of the most significant changes in the patent laws since the 1952 revision of the code, because it grants to certain patent owners extension of their exclusive rights for up to seven years beyond the traditional 17-year term. Given the far-reaching implications of the proposal to competitors and consumers, the Subcommittee on Courts, Civil Liberties and the Administration of Justice proceeded to examine the issue with exceptional scrutiny.

Originally, it had been suggested that the patent term restoration issue should be pursued in the context of the 96th Congress legislation, embodying many of the recommendations of President Carter which eventually became Public Law 96–517. During the course of subcommittee markup on that legislation, Congressman Harold Sawyer of Michigan offered an amendment embodying the concept of patent term restoration to compensate for regulatory delay. Mr. Sawyer graciously withdrew his amendment with the understanding that the matter would be taken up in the 97th Congress after an opportunity for thorough education and study.

In the First Session of the 97th Congress, the Subcommittee proceeded to examine the subject, embodied in a new bill, H.R. 1937, in great detail. Several days of hearings were held, with witnesses from the industrial community, the public sector and the public interest community being heard. In addition, a study by the Congressional Office of Technology Assessment was commissioned. This led to a 74-page report on the issue, focusing on the pharmaceutical industry as an example.[2]

The OTA report provided the Subcommittee with a great deal of information, in addition to that provided by the testimony of witnesses at the hearings, about the research process and the relationship of the patent system to the development of the fruits of commercial scientific research.

The OTA report found that, "Although important pharmactutical innovations may result from new therapeutic applications of existing chemicals . . . many of the pharmaceutical breakthroughs that have occurred have resulted from NCE (new chemical entity) research and the development of NCEs generally has required more time and money than other types of innovation and has involved greater risks." The report concluded, "The drug development process for NCEs 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 7000 to 10,000 newly-synthesized chemicals will be found to have promising biological activity. Only one out of 10 promising chemicals will survive to marketing." [3] The report estimates the 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 Assessment also found that "an early patent

[1] Advisory Committee on Industrial Innovation, Final Report, September 1979, p. 149.
[2] Patent Term Extension and the Pharmaceutical Industry, Congress of the United States, Office of Technology Assessment. Washington, D.C., 1982.
[3] Patent Term Extension and the Pharmaceutical Industry, pp. 12 and 13.

application is encouraged by the patent laws of the United States and most foreign countries, since, when two or more investigators independently arrive at the same discovery, the investigator who first files a patent application generally has an advantage in obtaining the patent."[4] Further, it is necessary to file a patent application prior to publication of information about a new invention because of the risk that it would otherwise fall into the public domain.

Because early publication of research is a significant factor of the ethics of medical and pharmaceutical research, patent applications on new pharmaceutical inventions tend to be filed very early in the research and development process. The result is that the 17-year term of a patent begins to run long before the invention ever reaches the marketplace and begins returning the revenue necessary to recoup development costs and finance further research.

The OTA report cited a study of patented drugs indicating that the average effective patent term for drugs approved in 1979 was less than 10 years.[5]

It is this extraordinarily long development time, required in large measure by the testing required to meet regulatory requirements associated with significant loss of effective patent terms, which underlies the need for H.R. 6444.

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

Subcommittee Modifications to the Original Bill

Although the general thrust of the testimony presented to the subcommittee was supportive of the bill, significant criticisms were set forth by representatives of the generic pharmaceutical industry and Public Citizen, Inc. Specifically, generic industry representatives expressed concern that the legislation would prevent the growth of their industry with the result that consumers would be deprived the option of less expensive generic products. These sentiments were echoed by representatives of Public Citizen, Inc. who argued that the burden of higher prices would be felt most seriously by those who require pharmaceuticals the most and yet have fewer financial resources, namely the elderly. This was confirmed by the finding of the Office of Technology Assessment that, "the price of drugs whose patents are extended will be higher during the extended period than they would have been if patent protection ended." The O.T.A. concludes, "the magnitude of the additional cost to the consumer will be significantly influenced by the extent to which generic competition would have existed had the patent term not been extended."

In view of these findings the subcommittee modified the legislation as introduced, H.R. 1937, with a number of amendments designed to deal with criticisms of the bill. A clean bill, H.R. 6444, was then reported incorporating the amendments. The amendments, incorporated into H.R. 6444 are as follows:

[4] Ibid., p. 14.
[5] M. Eisman and W. Wardell, "The Decline in Effective Patent Life of New Drugs," *Research Management* January 1981, cited in Patent Term Extension and the Pharmaceutical Industry, Supra, p. 20.

1. Patent extension is granted only to the 'recipient of market' approval who is the actual domestic U.S. developer rather than the patent owner, who may be only a licensor who has not committed any resources to the development and final regulatory approval of the patented product.

2. The maximum period of extension of any patent is limited so that no patent may be extended more than 27 years from the date of first filing anywhere in the world. In addition, full credit for patent extension is given only for regulatory delay experienced within the first 10 years following the patent application. This amendment was designed to encourage companies to file and process U.S. patent applications expeditiously and to complete regulatory related testing as rapidly as possible.

3. The definition of what constitutes regulatory related delay, in the case of pharmaceuticals, is changed to provide a shorter extension.

4. The legislation is made to apply only to pharmaceuticals, medical devices, food additives and chemicals on the ground that no evidence was presented including that other calsses of inventions experienced comparable regulatory delay.

5. The legislation is made prospective only in application. This constitutes a significant response to the concerns of the generic industry and public interest groups because it would delay any impact on either the generic industry or consumer prices for nearly 20 years. However, the incentive effect of the certainty of full patent term would provide an immediate incentive to invest in and develop new patented technology. Thus, technological innovation can be stimulated with minimum negative impact on the generic industry and consumers. By the time the first patent is actually extended by the legislation the greater number of new products which will have been generated, frequently selling at lower cost then earlier therapies or products, will outweigh any negative impact associated with a delay of availability to generic concerns.

6. The legislation is modified to include a very limited class of so-called "process patents" where the process involves the making of a product for which there is no underlying "product patent". This is designed to deal with the very special situation of recombinant DNA technology where the process constitutes the invention, not the product, even though the invention is subject to very extensive testing and regulatory review.

7. Two additional amendments were adopted which were designed to deal with limited and special situations involving unusual regulatory difficulty.

The legislation is sponsored by 103 members. S255, a Senate counterpart, passed the Senate last year by a voice vote.

ORGANIZATIONS SUPPORTING H.R. 6444

Albert Einstein College of Medicine.
American Academy of Dermatology.
American Association of Colleges of Podiatric Medicine.
American Bar Association.
American Chemical Society.
American College of Cardiology.

American College of Chest Physicians.
American Health Industries Institute.
American Heart Association.
American Medical Association.
American Patent Law Association.
American Pharmaceutical Association.
American Society of Hematology.
Associated Medical Schools of New York.
Association for Advanced Technology in the Biomedical Sciences.
Association of American Medical Colleges.
Association of Independent Research Institutes.
Association of Schools and Colleges of Optometry.
Chemical Manufacturers Association.
Citizens for the Treatment of High Blood Pressure.
Department of Health and Human Services.
Environmental Protection Agency.
Food and Drug Administration.
Fox Chase Cancer Center.
Health Industry Manufacturers Association.
The Johns Hopkins University.
Massachusetts General Hospital.
Massachusetts Institute of Technology.
National Alliance of Senior Citizens.
National Agricultural Chemical Association.
National Association of Chain Drug Stores.
National Association of Manufacturers.
National Council on Synthetic Fuels Production.
National Drug Trade Conference.
National Wholesale Druggists Association.
Patent and Trademark Office.
Pharmaceutical Manufacturers Association.
Society of University Patent Administrators.
U.S. Chamber of Comerce.
University of Cincinnati Medical Center.
The University of Texas System Cancer Center.
University of Delaware (Office of Research and Patents).
University of Wisconsin Medical School.
Wisconsin Alumni Research Foundation.
Worcester Foundation.

Conclusion

H.R. 6444, as reported by the 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 adequately protected.

Section-by-Section Analysis

SECTION 1

This section provides that the Act may be cited as the "Patent Term Restoration Act of 1982."

SECTION 2

This section adds a new Section 155 to Title 35 of the United States Code to provide for the restoration of a patent term that is diminished because of federal regulatory review requirements.

Section 155(a)(1) provides that the term of a product patent, a use patent, or a process patent, that includes within its scope a product that is subject to regulatory review by a federal agency, shall be extended if the product sponsor gives the required notice to the Commissioner of the Patent and Trademark Office and if the patent to be extended has not expired prior to such notice and was issued on or subsequent to the date of enactment of the Patent Term Restoration Act of 1982. This provision makes the legislation prospective in its application and leaves existing patented products under the protection only of present patent law, with two limited hardship exceptions set out in Section 155(d). It encourages industry to invest necessary resources in the development of new technology that is not yet subject to a patent, but denies an extension of the patent term for investment decisions previously made under existing law.

Section 155(a)(2) provides that the rights to be derived from the restoration of a patent term are limited in scope to the product or method subject to the regulatory review period and to the specific use for which regulatory review was required by federal statute. Thus, if a chemical is subjected to regulatory review for new drug uses, but is also marketed for other commercial uses, the patent term extension would apply only to the new drug uses for which regulatory review was required.

Section 155(a)(3) establishes the length of patent term restoration. The beginning point for calculating patent term restoration is the filing of the earliest patent application anywhere in the world. The term of the patent is extended by the time equal to the regulatory review period for the product or method for up to 10 years after the date of filing of the earliest application, and the time equal to one-half the regulatory review period for the product or method for the period between 10 and 20 years from that earliest filing date. This provision gives firms an incentive to submit products for regulatory review in the United States as soon as possible after the first patent application is filed anywhere in the world, since any regulatory review time incurred more than 10 years after that date will be compensated only at the rate of six months of patent term extension for each year of regulatory review. It thus promotes the prompt availability of useful products in this country and decreases the potential for a United States "lag" in such products as new drugs.

No patent may be extended for more than seven years, nor may any extension result in a patent term of more than 27 years from the date of filing of the earliest patent application anywhere in the world. If the patent term would be extended less than one year, no extension is granted. These provisions also encourage early submission of new products for regulatory review in the United States by preventing lengthy patent term extensions that could result if such review were delayed until after foreign marketing has already begun.

No more than one patent may be extended for the same regulatory review period for any product or method. Thus, if there is a product

patent and a process patent, both of which were subject to the same regulatory review period, the patent holder must choose which of the two patents is to be extended.

Section 155(a)(4) limits the circumstances under which a process patent may be extended. No process patent may be extended if the owner of the patent also owns another patent for the same product that has already been extended under the terms of the bill. This provision prevents firms from abusing the legislation by obtaining extensions of successive new process patents for a product that has already been the subject of a patent term extension.

Section 155(b)(1) establishes the procedure for patent term restoration. Within 90 days after the regulatory review period is terminated, the product sponsor is required to notify the Commissioner of the Patent and Trademark Office that the period has ended. Such notification must be in writing and provide specified information about the regulatory review involved, the claims to be extended, and information that will determine the length of the extension.

Section 155(b)(2) establishes the action to be taken by the Commissioner upon receipt of such a notice. The Commissioner must publish the information contained in the notice in the Official Gazette of the Patent and Trademark Office and issue to the owner of record of the patent a certificate of extension, which must also be recorded in the official file of the patent.

Section 155(c) defines five important words and phrases used in the bill.

Section 155(c)(1) defines the term "product" to include any machine, manufacture, or composition of matter for which a patent may be obtained. The bill identifies a number of specific kinds of products that are encompassed by this term, including human and veterinary drugs, medical devices, food and color additives, pesticides, and chemical substances.

Section 155(c)(2) defines the phrase "major health or environmental effects test" to mean an experiment which requires at least six months to conduct, not including any period for analysis or conclusions. Such testing includes, for example, chronic toxicity testing in animals, which may take two or three years to complete. It excludes acute and subchronic toxicity testing that ordinarily is completed in less than six months.

Section 155(c)(3) defines the phrase "earliest application for the patent" to mean the patent application that provides the earliest benefit of filing date anywhere in the world.

Section 155(c)(4) defines the term "product sponsor" to mean any person who initiates testing, claims an exemption, or submits an application or petition under the regulatory statutes set out in Section 155(c)(5).

Section 155(c)(5) defines the critical term "regulatory review period," which determines the maximum potential period of patent term restoration (subject to the further limitations established in Section 155(a)(2)). The regulatory review period is defined precisely for each of six categories of products that are subject to regulatory review under specified federal statutes.

Subparagraph (A) defines the regulatory review period for human drugs to commence on the earliest of the date the first product sponsor

initiates a clinical investigation on humans for the drug, or submits an application or petition for approval for licensing, under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act. The regulatory review period ends on the date the application or petition is approved or, if objections are filed, on the date those objections are resolved and commercial marketing is permitted. If commercial marketing is initially permitted and later revowed pending further proceedings as a result of objections, the regulatory review period ends on the date such proceedings are finally resolved and commercial marketing is permitted.

Subparagraph (B) provides that the regulatory review period for a food additive or color additive commences on the earliest of the date the first product sponsor claims an exemption for investigation, or initiates a major health or environmental effects test that is subsequently submitted as part of the petition for a regulation, or submits a petition for a regulation, under the Federal Food, Drug, and Cosmetic Act. The regulatory review period ends when the petition is granted or, if objections are filed, when such objections are resolved and commercial marketing is permitted. If commercial marketing is initially permitted and later revoked pending further proceedings, the regulatory review period ends on the date such proceedings are finally resolved and commercial marketing is permitted.

Subparagraph (C) provides that the regulatory review period for an animal drug or veterinary biological product commences on the earlier of the date the first product sponsor 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 submits an application or petition for approval or licensing under such statutes. The regulatory review period ends on the date such application or petition is approved or, if objections are filed, when such objections are resolved and commercial marketing is permitted. If commercial marketing is initially permitted and later revoked pending further proceedings, the regulatory review period ends on the date such proceedings are finally resolved and commercial marketing is permitted.

Subparagraph (D) provides that the regulatory review period for a medical device commences on the earlier of the date the first product sponsor submits a proposed product development protocol, initiates a clinical investigation in humans on the device, or submits an application for approval under the Federal Food, Drug, and Cosmetic Act. The regulatory review period ends on the date such application is approved.

Subparagraph (E) provides that the regulatory review period for a pesticide commences on the earliest of the date the first product sponsor initiates a major health or environmental effects test, requests the grant of an experimental use permit, or submits an application for registration, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. The regulatory review period ends when the pesticide is first registered, either conditionally or fully.

Subparagraph (F) provides that the regulatory review period for a chemical substance or mixture for which notification is required under Section 5(a) of the Toxic Substances Control Act and which is subject to a rule requiring testing under Section 4(a) of that Act com-

mences on the date the first product sponsor initiates such testing. If no such testing is required, the regulatory view period commences on the earlier of the date the first product sponsor submits a premanufacture notice or initiates a major health or environmental effects test. The regulatory review period ends on the expiration of the premanufacture notification period or, if an order or injunction is issued under the Act, the date on which such order or injunction is dissolved or set aside.

Under all six of these subparagraphs, the regulatory review period does not commence until a patent has been granted for the product, use, or process that is subject to regulatory review. Thus, if the regulatory review period ends before the patent is granted, there will be no extension of the patent term.

Section 155(d) provides for two exceptions to the general rules established in the bill, to deal with hardship cases.

Section 155(d)(1) states that, where a new drug was approved more than seven years after the commencement of the regulatory review period and the application was determined by the Food and Drug Administration not to be approvable until a lengthy carcinogenicity bioassay was conducted, then the period of patent extension is seven years. Under these circumstances, public health considerations required additional testing that justifies a full seven-year patent extension.

Section 155(d)(2) states that, where a flood additive approval was stayed prior to 1981 pending proceedings concerning the safety of an ingredient that were ultimately resolved by permitting its marketing, the period of patent extension is measured from the date the stay was imposed until the proceedings were resolved and commercial marketing permitted. Once again, such lengthy proceedings to assure public safety justify extension of the patent term.

Oversight Statement

The Committee on the Judiciary has oversight responsibility over the operations of the patent system and the Patent and Trademark Office in the Department of Commerce. In addition to its ongoing oversight, the Committee's Subcommittee on Courts, Civil Liberties and the Administration of Justice held an oversight hearing with respect to the Patent and Trademark Office on March 4, 1981, published as Oversight Hearings Before the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the Committee on the Judiciary, House of Representatives, Ninety-Seventh Congress, First Session on the Copyright Office, The U.S. Patent and Trademark Office, and the Copyright Royalty Tribunal, Serial No. 17.

The Committee expects to continue its oversight activities in this area.

Statement of the Budget Committee

No statement has been received on H.R. 6444 from the House Committee on the Budget.

Estimate Cost of the Legislation

The Committee concurs in the estimate of the Congressional Budget Office that no net additional cost is likely to be incurred by the federal government as a result of enactment of H.R. 6444.

STATEMENT OF THE CONGRESSIONAL BUDGET OFFICE

Pursuant to clause 7, rule XIII of the Rules of the House of Representatives and section 403 of the Congressional Budget Act of 1974, the following is the cost estimate of H.R. 6444, as amended, prepared by the Congressional Budget Office.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., July 29, 1982.

Hon. PETER W. RODINO, Jr.,
Chairman, Committee on the Judiciary, U.S. House of Representatives, Rayburn House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has reviewed H.R. 6444, the Patent Term Restoration Act of 1982, as ordered reported by the House Committee on the Judiciary, July 28, 1982.

H.R. 6444 would amend the patent law to adjust the term of certain patent grants when delays occur as a result of regulatory processes. While some additional publishing costs would be required by the Patent and Trademark Office to implement this bill, such costs are not expected to be significant and it is likely that they would be covered by additional fee income. Thus, no net additional cost is likely to be incurred by the federal government as a result of enactment of this bill.

Should the Committee so desire, we would be pleased to provide further details on this estimate.

Sincerely,

ALICE M. RIVLIN,
Director.

NEW BUDGET AUTHORITY

In regard to clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, H.R. 6444 creates no new budget authority or increased tax expenditures for the Federal Government.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause (l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill will have no foreseeable inflationary impact on prices or costs in the operation of the national economy.

FEDERAL ADVISORY COMMITTEE ACT OF 1972

The Committee finds that this legislation does not create any new advisory committees within the meaning of the Federal Advisory Committee Act of 1972.

COMMITTEE VOTE

The Committee on the Judiciary ordered reported H.R. 6444, as amended, by voice vote with a quorum of members being present.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of Rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows new matter is printed in italic existing law in which no change is proposed is shown in roman):

TITLE 35, UNITED STATES CODE

* * * * * * *

PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

* * * * * * *

CHAPTER 14—ISSUE OF PATENT

Sec.
151. Issue of patent.
152. Issue of patent to assignee.
153. How issued.
154. Contents and term of patent.
155. Restoration of patent term.

§ 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 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 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 a 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 10 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 10 and 20 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 27 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 in 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 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 test" 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 under 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 regualtion, 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 biological 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 marekting 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 Substance 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, or if an order or injunction is issued under section 5(c) 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) submits 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(c) 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 90 days of the termination of the regulatory review period or of the date of enactment of this section, whichever is later.

* * * * * * *

ADDITIONAL REMARKS OF HON. BARNEY FRANK, HON. DON EDWARDS, HON. PATRICIA SCHROEDER, HON. GEORGE W. CROCKETT, JR., AND HON. JOHN CONYERS, JR.

In passing H.R. 6444, we believe the Committee should have adopted amendments offered by E. Clay Shaw and Barney Frank.

As reported by the Committee, H.R. 6444 determines the amount of time which will be extended when the original patent expires. As to each product covered by the bill, the time to be extended is counted in general from the submission by the patent holder of the application, petition, etc., to the relevant federal agency, or the initiation of major testing for the product; it ends when final approval or license is given by the agency. Specifically as to new drugs, the period to be extended begins with human testing or the submission of an application (an "IND") to the Food and Drug Administration. It ends with the approval of a New Drug Application (NDA) by FDA.

What is critical here with new drug procedures as an example, is that it is the filing of the NDA well after testing has started, which begins the governmental review process. Any time taken by the patentee prior to the filing of an NDA would be taken even in the absence of a governmental review to satisfy the patentee's own concerns about safety and effectiveness and to avoid product liability judgments. To the extent that it is equitable to restore the time lost to governmental regulatory procedures, it is logical to count only the time actually taken by the government. What H.R. 6444 has done is to begin counting time years prior to governmental review. In fact, as found by the Office of Technology Assessment study, this pre-NDA period of time can easily run up to five or six years.

The Shaw Amendment would have rectified this overly generous restoration. It provided that the extension period be counted as to the various products covered from the filing of the application to the federal agency until its approval. The amendment would have focused upon the only time which the government can reasonably be charged with having consumed in regulating the product involved. To award further time is, we believe, unnecessary and unfair to the public.

The Frank Amendment would have placed necessary safeguards into the system as it relates to new drugs. Under H.R. 6444, a patentee need not demonstrate that he acted with reasonable diligence in pursuing regulatory approval. While we understand that the Committee, in reporting the bill, would not condone nor knowingly encourage delay, there is not now any way of making such a determination. After all, it would often be to the patentee's advantage to have patent time extended as much as possible while the product is being marketed and returning the investment made in it. If the testing period is slowed down, the developer will know that this time will be restored when it

is most valuable to him—while it's selling. There is quite clearly, therefore, a built-in incentive for dilatoriness by the patent holder which we feel is not adequately addressed by the bill.

Mr. Frank's proposal would have simply established a proceeding before the Commissioner of Patents and Trademarks to determine whether the patent holder had acted with reasonable diligence in securing regulatory approval. If the Commissioner had determined that the holder did not act diligently for a certain period of time, that time would have been subtracted from the extension period. In addition, the Commissioner would have been charged with determining the filing and approval dates for the product. This finding is necessary because the patent holder is the only private party with knowledge of the length of the review process. Such information is not otherwise made public.

The Frank Amendment, in our view, should have been added to ensure the public that the patent restoration system is not abused. Given the incentive for delay, the lack of public information as to the length of the regulatory process, and the absence in the bill of any other enforcement mechanism to guard against abuse, this modest proposal was reasonable, necessary and not overly burdensome.

The Committee erred, we believe, in not adopting these amendments: the Shaw Amendment, to focus more precisely the time period which could be extended and the Frank Amendment, to safeguard the public's very substantial interests in this process.

Dissenting Remarks of the Honorable Barney Frank

Although I must respectfully dissent from the Committee's action in reporting H.R. 6444 without substantive amendments, I wish to commend our able and distinguished Subcommittee Chairman, Bob Kastenmeier. As reported by the Subcommittee on Courts, Civil Liberties and the Administration of Justice, H.R. 6444 is markedly improved over its predecessor, H.R. 1937. The Subcommittee added, among other items, an important provision making the legislation prospective only in its application and it cut down the scope of the bill to apply only to the specific products listed.

However, I still believe the legislation to be unnecessary in pursuit of the purpose stated for it and harmful to the consuming public, particularly those who because of age or illness must rely on medications.

For the reasons detailed in the Additional Remarks joined in by several of my colleagues on the Committee, I believe the Committee should have adopted amendments offered by the gentleman from Florida, E. Clay Shaw, and by myself. The Shaw Amendment would have focused more appropriately the time to be extended at the end of the patent term; it would have restored only the time actually taken by the agency review process. In fact, as former Food and Drug Administration Chairman Donald Kennedy has observed, even in the absence of a new drug approval process, patentees would require substantial time to test their new products prior to marketing, which time is not the fault of the federal government. Delays, Mr. Kennedy has noted, are often the responsibility of the manufacturer. Unfortunately, H.R. 6444 restores time which is not consumed by the federal

government in regulating these products. In this respect, the bill is overly generous.

As for the amendment I offered during Committee deliberations, I believe it was necessary to guard against the possibility that the patent restoration system would be misused. As pointed out in the Additional Remarks, there is a built-in incentive for delay during the regulatory review period by the patentee and there is no public accountability as to the actual length of that period. My amendment would have instituted a fair and relatively simple proceeding before the Commissioner of Patents and Trademarks at which these matters could have been determined.

If the goal of the bill is to spur additional research and development, particularly regarding new drugs, it is not necessary. As found by the Office of Technology Assessment (OTA) study, the number of new chemical entities (NCEs) approved, which demonstrates pharmaceutical innovation, has remained relatively constant since 1963. Approvals of NCEs offering important or modest therapeutic value has remained relatively stable over this period. Moreover, OTA found that revenues in the pharmaceutical industry have increased steadily and the relationship between revenues and research and development expenditures has also remained stable. Finally, the Congress has already given research-intensive industries, including the drug industry, ample incentive to increase R&D spending by passing the provision of the 1981 Tax bill allowing a 25 percent tax credit for increased R&D expenditures, a measure which I cosponsored.

To the extent that it is equitable to restore time lost because of regulatory review, the Shaw Amendment would have dealt with that matter much more fairly. But there are other equities at work here which are not adequately served by H.R. 6444. The most important is the impact that this bill will have on our most vulnerable citizens—the elderly, ill, and disabled. Without doubt, the longer a manufacturer is able to maintain a non-competitive monopoly over his product, the longer prices for that product will remain higher than if competition were allowed. It is only through the introduction of generically-equivalent drugs, at the close of the patent period, that price competition can exist. In fact, OTA went even further by declaring that patent term extension may in some cases even prevent any competitive pressure from being exerted since generic drugs may not even be introduced at all.

Surely, it is not equitable to expect the elderly and ill, who are often already in severe financial straights, to pay the price for patent extension, especially where the extension is not even necessary in order to promote the development of new drugs.

The severe impact the bill will have on these groups and working families in general has been recognized by a wide variety of organizations. For example, the American Association of Retired Persons/National Retired Teachers Association, the National Council of Senior Citizens, the United Auto Workers, the Service Employees International Union, the American Federation of State, County, and Municipal Employees, the International Association of Machinists and Aerospace Workers. Public Citizen, and Consumer Federation of America have all expressed opposition to or criticism of H.R. 6444 as reported by the Committee.

There were two related matters, dealing with post-patent barriers to effective competition which I was unable to raise before the Committee but which I believe should be dealt with by the Congress as soon as possible. The first is a trademark issue relating to whether generic drugs can be manufactured in the same size, shape, and color as the original drug, an issue which was before the Supreme Court this year. However, in that case, *Inwood Laboratories* v. *Ives Laboratories*, the issue was not finally resolved. To those whose lives depend on the taking of medications, allowing generic drugs to be sold in the same size, shape, and color as the original product is critical. Many patients associate appearance with therapeutic effect; many patients co-mingle prescriptions in a single container and rely on appearance to differentiate one from another; appearance can be of great value during emergencies; and the appearance of a drug can help avoid mistakes by those who dispense them. In fact, these were the findings of the District Court, quoted by the Supreme Court in *Inwood*.

I am hopeful that the Courts Subcommittee will be able to move forward on a bill, H.R. 6840, which I filed to make clear that manufacturing medications with the same appearance does not violate the trademark laws. It would be, I might suggest, wise to withhold further consideration of H.R. 6444 until the Judiciary Committee has had an opportunity to act on this very closely related matter.

A second issue, which serves to make difficult effective competition once a patent has expired, is the so-called Abbreviated New Drug Application (ANDA) procedures employed by the FDA in approving generically-equivalent drugs. Under present FDA practice, with respect to original drugs approved after 1962 for which generic approval is being sought, approval will only be given if studies which demonstrate safety and effectiveness are filed with the generic application or are referred to by FDA. These studies often are not publicly available and are a closely guarded secret of the original manufacturer. If I had had the opportunity, I would have offered an amendment which would have required FDA to rely upon proof that the generic is in fact fully equivalent. I am hopeful that the Energy and Commerce Committee, which has jurisdiction over the FDA, will have an opportunity to review this aspect of the legislation, since it so clearly relates to matters within that Committee's expertise. The questions of patent extension and post-patent market barriers are very closely entwined.

Together, these two issues, the "size-shape-color" and ANDA matters, serve to prevent or diminish meaningful post-patent competition in the drug industry. Since the effect of H.R. 6444 will be to erode competition further, these related issues must be dealt with by the Congress if fair and comprehensive legislation is to be passed.

H.R. 6444 does not, in my view, deal appropriately with the equities involved, and it will have a severe impact on the elderly and ill. I must therefore respectfully dissent, despite my commendation for the fine work of Chairman Kastenmeier in improving this bill over its predecessor.

BARNEY FRANK.
DON EDWARDS.
PATRICIA SCHROEDER.
GEORGE W. CROCKETT.
JOHN CONYERS.

O