

PIPELINE DRUGS: PROPOSED REMEDIES FOR RELIEF IN THE DRUG PATENT TERM RESTORATION REVIEW PROCEDURE ACT OF 1999

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

ON

S. 1172

A BILL TO PROVIDE A PATENT TERM RESTORATION REVIEW PROCEDURE FOR CERTAIN DRUG PRODUCTS

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AUGUST 4, 1999
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**PIPELINE DRUGS: PROPOSED REMEDIES FOR
RELIEF IN THE DRUG PATENT TERM RES-
Toration REVIEW PROCEDURE ACT OF
1999**

WEDNESDAY, AUGUST 4, 1999

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The committee met, pursuant to notice, at 10:30 a.m., in room SD-628, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Also present: Senators Specter, Ashcroft, Sessions, Leahy, Kennedy, Feinstein, Torricelli, and Schumer.

**OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S.
SENATOR FROM THE STATE OF UTAH**

The CHAIRMAN. I want them to get everyone in they can. This is standing room only. This is not the biggest room in the Senate, but I hope I can get everybody in. This is a very important hearing. These are very complicated issues. There are very important people testifying here today and I would like to have as many people from outside get in here as we can.

Today, the Judiciary Committee will examine remedies proposed in S. 1172, the Drug Patent Term Restoration Review Procedure Act of 1999, sponsored by Senators Torricelli and Sessions. This hearing will help us gauge what legislative action is warranted.

Article I, section 8, clause 8, of the U.S. Constitution reads,

The Congress shall have the power * * * to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

Congress' exercise of a constitutionally based patent power has important consequences for society and has led to occasional controversies between various business, consumer, and inventor interests. Yet, few would argue with the basic premise that people will be encouraged to produce inventions if there is some reward as an incentive.

The fundamental question S. 1172 asks of this committee is, are there instances where, through regulatory delay or inefficiencies, Congress' constitutional responsibility to, "promote the progress of science," is undermined to a level which warrants remedial action and, if so, should an objective mechanism be established for the

consideration of such claims. Assuming the answer to these questions is yes, the sponsors of S. 1172 have proposed a mechanism for pipeline drugs.

S. 1172 would establish a review process within the Patent and Trademark Office to assess the treatment of certain pipeline drugs that lost patent protection due to exceedingly lengthy regulatory reviews at FDA. Similar bipartisan legislation introduced by Congressmen Ed Bryant and Jim McDermott has also been introduced in the House of Representatives. The House bill was the subject of a hearing in the House Judiciary Committee on July 1, 1999.

Proponents of S. 1172 believe that proper patent protection for pharmaceutical products is crucial for the discovery of new potentially life-saving drugs. I agree with this premise, and S. 1172 establishes a mechanism to determine if such protection has been provided for individual drugs or whether the dictates of Federal drug law and regulations undeservedly eat into this protection.

The review process established in S. 1172 is one which supporters believe is fair and impartial because an independent body will employ specified, objective standards to determine whether or not to restore lost patent life. It is argued that a process-based solution is preferable to Congress acting on an ad hoc case-by-case basis, which certainly has been the case over the last number of years.

Under the bill, only pipeline drugs that were involved in an FDA review process that took more than 60 months would be eligible for review. There is no doubt that the protections afforded a patent holder were significantly reduced and this delay may have been due to circumstances that were beyond the control of the applicant.

On the other hand, critics of S. 1172 will argue that this legislation is unwarranted because the resulting additional period of exclusivity will result in additional costs to consumers. Opponents have suggested that inequities of the past should be given little consideration and that as a matter of public policy Congress' constitutional responsibility to promote the progress of science should be prospective in approach. Our focus, they argue, should be given exclusively to advancing policies which rely on innovation to replace products whose patents have expired.

Finally, critics argue that S. 1172 creates a procedure for granting partial patent restoration through an entity, the Patent and Trademark Office, that may inherently favor a patentholder. There is some question about whether the PTO is the appropriate forum to make decisions relating to the details of an agency review.

As we examine this important issue, I hope we can examine some of the following questions. Is legislation of this sort in the interest of the American public? Many believe that it is, and they may be right. Was the type of delay suffered by these drug manufacturers one that warrants legislative action, and will such action benefit others? What impact will S. 1172 have on the generic drug industry? Should the committee only be reviewing administrative delays affecting pipeline drugs, or is it a much broader problem which warrants a broader, more comprehensive solution?

Now, I look forward to exploring these and other questions with our panel of distinguished witnesses. In the end, we must be mindful of the fact that Congress at one point in its recent history passed product-specific private relief bills which granted those

products patent term extensions. In fact, Congress has enacted product-specific patent extensions for pipeline drugs.

At the time, critics then argued that such product-specific legislation did not benefit the public or the institution. Instead, it was suggested that an objective process be put in place, a process that subjected the claims for equitable relief to a set of objective criteria and public scrutiny. S. 1172 appears to be an effort to rise to this challenge.

Therefore, it is appropriate that this committee closely examine the merits of this legislation, with an eye on Congress' constitutional obligation to promote the progress of science, and balance them with what is in the best interest of the American public. I believe that a fair and equitable solution is possible, and I look forward to hearing the recommendations of our witnesses on what they believe is the appropriate solution to this critical issue.

106TH CONGRESS
1ST SESSION

S. 1172

To provide a patent term restoration review procedure for certain drug products.

IN THE SENATE OF THE UNITED STATES

MAY 27, 1999

Mr. TORRICELLI introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To provide a patent term restoration review procedure for certain drug products.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. PATENT TERM RESTORATION REVIEW PROCE-**
4 **DURE FOR CERTAIN DRUG PRODUCTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Drug Patent Term Restoration Review Procedure Act of
7 1999”.

8 (b) PATENT TERM RESTORATION.—

1 (1) IN GENERAL.—Chapter 14 of title 35,
2 United States Code, is amended by inserting after
3 section 155A the following new section:

4 **“§ 155B. Patent term restoration review procedure**
5 **for certain drug products**

6 “(a) DEFINITIONS.—For purposes of this section—

7 “(1) the term ‘Commissioner’ means the Com-
8 missioner of Patents and Trademarks; and

9 “(2) the term ‘drug product’ has the meaning
10 given that term under section 156(f)(2)(A), but does
11 not include drugs or products described under sec-
12 tion 156(f)(2)(B).

13 “(b) SPECIAL PATENT TERM REVIEW PROCE-
14 DURE.—

15 “(1) IN GENERAL.—

16 “(A) PATENT RESTORED.—The term of
17 any patent described under subparagraph (B)
18 shall be restored under paragraph (3) from the
19 expiration date determined under section 154
20 (including any extension granted under section
21 156), if the Commissioner determines that the
22 standards under paragraph (2) have been met.

23 “(B) PATENT.—Subparagraph (A) refers
24 to any patent that—

1 “(i) has been extended under section
2 156, subject to the 2-year limitation de-
3 scribed under section 156(g)(6)(c);

4 “(ii) is in force on—

5 “(I) September 24, 1984;

6 “(II) the date of enactment of
7 this section; and

8 “(III) the date of filing an appli-
9 cation under this section; and

10 “(iii) claims a drug product, a method
11 of using a drug product, or a method of
12 manufacturing a drug product.

13 “(2) STANDARDS.—

14 “(A) IN GENERAL.—Upon application by
15 the owner of record of the patent or its agent
16 under paragraph (5) and consideration of the
17 application and all materials submitted by par-
18 ties that would be aggrieved by grant of the
19 restoration of a patent, the term of a patent de-
20 scribed in paragraph (1) shall be restored if the
21 Commissioner determines that—

22 “(i) the period set forth in section
23 156(g)(1)(B)(ii) for the drug product ex-
24 ceeded 60 months;

1 “(ii) the owner of record of the patent
2 or its agent has established by clear and
3 convincing evidence that the patent owner
4 acted with due diligence (as such term is
5 defined in section 156(d)(3) and applied in
6 section 156(d)(2)) during the regulatory
7 review period referred to in section
8 156(g)(1)(B); and

9 “(iii) granting the patent restoration
10 would not be detrimental to the public in-
11 terest and the interest of fairness, as de-
12 fined by the factors set forth in paragraph
13 (7).

14 “(B) DETERMINATION.—

15 “(i) DEDUCTION OF TIME.—If the
16 Commissioner determines there is substan-
17 tial evidence that the patent owner did not
18 act with due diligence during a part of the
19 regulatory review period, that part shall be
20 deducted from the total amount of time in
21 the applicable regulatory review period re-
22 ferred to in section 156(g)(1)(B), and the
23 resulting period, shall be the basis for cal-
24 culating the patent restoration term under
25 paragraph (3) of this subsection.

1 “(ii) FDA CONSULTATION.—The
2 Food and Drug Administration shall be
3 consulted with respect to the Commis-
4 sioner’s determinations under subpara-
5 graph (A) (i), (ii), and (iii). If there is a
6 dispute concerning the underlying facts be-
7 tween the patent owner and the Food and
8 Drug Administration, the Food and Drug
9 Administration shall make the relevant
10 records of the Administration available to
11 the Commissioner.

12 “(3) RESTORATION TERM.—If the Commis-
13 sioner determines that the standards in paragraph
14 (2) have been met for a patent, the term of such
15 patent shall be restored for a period equal to the
16 regulatory review period as defined in section
17 156(g)(1)(B) (taking into account any deduction
18 under paragraph (2)(B)(i)), without taking into ac-
19 count the 2-year limitation described in section
20 156(g)(6)(C), except that—

21 “(A) the total of the period of the patent
22 term restoration granted under this section and
23 any patent term extension previously granted
24 under section 156 shall be subject to the time

1 period limitations described in section
2 156(e)(2)–156 (e)(4) and (g)(6)(A); and

3 “(B) any patent term extension previously
4 granted under section 156 shall be subtracted
5 from the period of the patent term restoration
6 granted under this subsection.

7 “(4) INFRINGEMENT.—During the period of
8 any restoration granted under this subsection, the
9 rights derived from a patent the term of which is re-
10 stored shall be determined in accordance with sec-
11 tions 156(b) and 271.

12 “(5) PROCEDURE.—

13 “(A) TIME FOR FILING.—Any application
14 under this section shall be filed with the Com-
15 missioner within 90 days after the date of en-
16 actment of this section.

17 “(B) FILING.—Upon submission of an ap-
18 plication to the Commissioner by the owner of
19 record of a patent referred to in paragraph (1)
20 or its agent for a determination in accordance
21 with paragraph (3)—

22 “(i) the Commissioner shall publish
23 within 30 days after the submission in the
24 Federal Register a notice of receipt of an

1 application and make the application avail-
2 able to the public upon request;

3 “(ii) any interested party may submit
4 comments on the application within the 60-
5 day period beginning on the date of publi-
6 cation of the notice;

7 “(iii) within 7 days following the expi-
8 ration of that 60-day period, the Commis-
9 sioner shall forward a copy of all com-
10 ments received to the applicant, who shall
11 be entitled to submit a response to such
12 comments to the Commissioner within 45
13 days after receipt of such comments;

14 “(iv) within 30 days following receipt
15 of the applicant’s response to comments or,
16 if there are no such comments, within 30
17 days following expiration of the 60-day
18 comment period, the Commissioner shall,
19 in writing—

20 “(I) determine whether to grant
21 the application; and

22 “(II) make specific findings re-
23 garding the criteria set forth in para-
24 graph (2) (including, where appro-
25 priate, findings regarding the public

1 interest and fairness factors set forth
2 in paragraph (7)); and

3 “(v) if the Commissioner determines
4 that the standards set forth in paragraph
5 (2) have been met, the Commissioner
6 shall—

7 “(I) issue to the applicant a cer-
8 tificate of restoration, under seal, for
9 the period prescribed under paragraph
10 (3); and

11 “(II) record the certificate in the
12 official file of the patent, which cer-
13 tificate shall be in effect from the date
14 it issues and shall be considered a
15 part of the original patent.

16 “(C) PATENT TERM DURING REVIEW.—If
17 the term of a patent for which an application
18 has been submitted under this section would ex-
19 pire before a determination to issue a certificate
20 of restoration is made under subparagraph (B),
21 the Commissioner may extend, until such deter-
22 mination is made (but not to exceed 1 year) the
23 term of the patent if the Commissioner deter-
24 mines that the patent likely would be eligible
25 for restoration.

1 “(D) RECORD AND REVIEW.—The Com-
2 missioner’s determination under subparagraph
3 (B)(iv) shall be based solely on the record devel-
4 oped under this subsection. Except as provided
5 in section 141, the Commissioner’s determina-
6 tion shall not be reviewable in any court.

7 “(6) APPLICATION FEE.—The applicant shall
8 pay a fee for an application made under this sub-
9 section which shall be determined in accordance with
10 the same criteria as the fees established under sec-
11 tion 156(h).

12 “(7) PUBLIC INTEREST AND FAIRNESS.—When
13 required to make a determination under paragraph
14 (2)(A)(iii), the Commissioner shall consider each of
15 the following factors and shall not rely solely on any
16 single factor:

17 “(A) Whether grant of the application
18 would result in the public having no other com-
19 mercially available alternatives to treat the
20 same disease or condition as the drug claimed
21 in the patent that is the subject of the patent
22 term restoration request.

23 “(B) Whether grant of the application
24 would disserve society’s interest in the avail-
25 ability of innovative drugs at competitive prices.

1 “(C) Whether denial of the application
2 would disserve society’s interest in encouraging
3 and rewarding pharmaceutical research and in-
4 novation.

5 “(D) Whether denial of the application
6 would be unfair to the applicant, in comparison
7 to others who have experienced the benefits of
8 a 5-year patent restoration under section 156
9 while experiencing similar regulatory review
10 delays.

11 “(E) Whether other manufacturers, before
12 the date of enactment of this section, have sub-
13 mitted applications under sections 505(b)(2) or
14 (j) of the Federal Food, Drug, and Cosmetic
15 Act that are sufficiently complete to permit
16 substantive review and have made substantial
17 investments to manufacture a generic version of
18 the particular drug that is the subject of the
19 patent term restoration application, which
20 would not receive the compensation specified
21 under subsection (e) of the Drug Patent Term
22 Restoration Review Procedure Act of 1999.”.

23 (2) TECHNICAL AND CONFORMING AMEND-
24 MENT.—The table of sections for chapter 14 of title

1 35, United States Code, is amended by inserting
2 after the item relating to section 155A the following:

“155B. Patent term restoration review procedure for certain drug products.”.

3 (c) APPEAL OF DETERMINATIONS OF THE COMMIS-
4 SIONER.—Section 141 of title 35, United States Code, is
5 amended by adding at the end the following: “The appli-
6 cant under section 155B, or any aggrieved party that
7 made a submission commenting on an application under
8 section 155B, may appeal the determination of the Com-
9 missioner under such section to the United States Court
10 of Appeals for the Federal Circuit.”.

11 (d) COURT JURISDICTION.—

12 (1) COURT OF APPEALS FOR THE FEDERAL
13 CIRCUIT.—Section 1295(a)(4) of title 28, United
14 States Code, is amended—

15 (A) in subparagraph (B), by striking “or”
16 after the semicolon;

17 (B) in subparagraph (C), by adding “or”
18 after the semicolon; and

19 (C) by inserting after subparagraph (C)
20 the following:

21 “(D) the Commissioner of Patents and
22 Trademarks under section 155B of title 35;”.

23 (2) JURISDICTION BASED ON INFRINGEMENT
24 OF PATENT.—Section 271(e) of title 35, United

1 States Code, is amended by adding at the end the
2 following:

3 “(5) In any action brought under paragraph (2)
4 involving a patent, the term of which has been re-
5 stored under section 155B, the alleged infringer
6 shall have the right to seek compensation under sub-
7 section (e) of the Drug Patent Term Restoration Re-
8 view Procedure Act of 1999.”

9 (e) COMPENSATION.—

10 (1) IN GENERAL.—In the event a person has
11 submitted an application described in section
12 505(b)(2) or 505(j) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355(b)(2),(j)) for a drug
14 product covered by a patent for which a patent term
15 restoration was provided under section 155B of title
16 35, United States Code (as added by subsection
17 (a)(1)) and such application has been found by the
18 Food and Drug Administration on or before the date
19 of the enactment of this section to be sufficiently
20 complete to permit substantive review, such person
21 shall be entitled to compensation of \$2,000,000 by
22 the patent owner. Any holder of a Type II Drug
23 Master File that has permitted a reference to its
24 Type II Drug Master File to be made in such appli-

1 cation shall be entitled to compensation of
2 \$1,000,000 by the patent owner.

3 (2) LIMITS ON LIABILITY.—A patent owner
4 shall not be required to make under paragraph (1)
5 payments exceeding—

6 (A) \$10,000,000 to persons submitting ap-
7 plications described in such paragraph, or

8 (B) \$5,000,000 to holders of Type II Drug
9 Master Files.

10 If the aggregate limits are insufficient to pay the ap-
11 plicants or holders the full amounts specified in
12 paragraph (1), each such applicant or holder shall be
13 paid its per capita share of the aggregate liability
14 imposed by paragraph (1) upon the patent holder.

15 (f) EFFECT OF FILING OF ABBREVIATED APPLICA-
16 TIONS.—The fact that 1 or more abbreviated applications
17 have been filed under section 505 (b) or (j) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b) or (j))
19 for approval of a drug product, which is covered by a pat-
20 ent that is the subject of an application for term restora-
21 tion under this section, shall not preclude the grant of
22 such term restoration.

23 (g) REPORT TO CONGRESS.—Not later than 1 year
24 after the effective date of this section, the Commissioner
25 of Patents and Trademarks shall—

1 (1) submit to Congress a report evaluating the
2 patent term restoration review procedure established
3 under this section; and

4 (2) include in such report a recommendation
5 whether Congress should consider establishing such
6 a patent term restoration review procedure for other
7 patents.

8 (h) EFFECTIVE DATE.—This section shall take effect
9 on the date of enactment of this section and an owner
10 of record of a patent referred to under section 155B(b)(1)
11 of title 35, United States Code (as added by this section);
12 or an agent of the owner shall be immediately eligible on
13 such a date to submit an application to the Commissioner
14 for a determination in accordance with subsection (b)(3)
15 of such section.

16 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**
17 **COSMETIC ACT.**

18 (a) LIMITATION ON USE OF PATENTS TO PREVENT
19 ANDA APPROVAL.—

20 (1) APPLICATION.—Section 505(b)(2) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(b)(2)) is amended by adding at the end the fol-
23 lowing:

24 “For an approved product claimed in a patent, the term
25 of which has been restored pursuant to section 155B of

1 title 35, United States Code, the certification required by
2 subparagraph (A) is limited to any patent that claims an
3 active ingredient, including any salt or ester of the active
4 ingredient, of the approved product, alone or in combina-
5 tion with another active ingredient.”.

6 (2) ABBREVIATED APPLICATION.—Section
7 505(j)(2)(A) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355(j)(2)(A)) is amended by
9 adding at the end the following:

10 “For an approved product claimed in a patent, the term
11 of which has been restored pursuant to section 155B of
12 title 35, United States Code, the certification required by
13 clause (vii) is limited to any patent that claims an active
14 ingredient, including any salt or ester of the active ingre-
15 dient, of the approved product, alone or in combination
16 with another active ingredient.”.

17 (b) EXCLUSIVITY FOR GENERIC DRUG.—Section
18 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended by inserting
20 after “containing such certification” the following: “and
21 for which an action for infringement of a patent which
22 is the subject of such a certification has been brought be-
23 fore the expiration of 45 days from the date of the notice
24 provided under paragraph (2)(B)(i) is received”.

○

Mr. CHAIRMAN. In closing, I want to thank all of our witnesses for taking the time to join us today and I look forward to hearing their views on these critical questions.

With that, we will turn to our ranking member.

**STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR
FROM THE STATE OF VERMONT**

Senator LEAHY. Thank you, Mr. Chairman. I will be direct because we want to hear from the witnesses. I am concerned that Congress should not be in the business of approving individual patents for drugs, and I am also concerned that this bill could cost consumers \$5 billion. Every time I go home, I hear from one Vermonter after another about the prohibitive cost of medications; I know I will this week when I go back home. I am concerned that the bill goes in the wrong direction. Americans need better access to affordable prescription drugs, and they deserve it.

When I look at this legislation, it seeks to amend a bill that was crafted by the distinguished chairman, Senator Hatch, along with Congressman Henry Waxman. The Hatch-Waxman Act was intended to stop the practice of Congress legislating patent extensions one drug at a time. Now, when you have a bill sponsored by Senator Hatch and Congressman Waxman, it is either a darn good bill or one of them didn't read it. I suspect that it was a darn good piece of legislation.

Now, the matter before us is that Schering-Plough has enjoyed patent protection for its most popular product, the allergy medication Claritin, for many years, also a product that they spent a great deal of money in producing and one on which they can and should enjoy the benefits of what they have spent in preparing it.

When we passed the Hatch-Waxman Act, Claritin was granted a 2-year patent extension because it was being developed, or in the pipeline, when the new law was passed. In 1994, Claritin received a second 22-month patent extension under the terms of the GATT. With these two patent extensions, the patent on Claritin will expire in June 2002, after approximately 21 years of protection. Since I am told the original Claritin patent was granted in 1981, you can see why there has to be a lot of convincing to support a third extension.

I am also concerned the bill will increase the cost of medication to consumers and the Government. The PRIME Institute found that if we granted Claritin a 3-year extension, it would cost consumers \$5.3 billion from 2002 to 2007. Over the same period, the bill would cost the Government approximately \$2.5 billion. Medicaid bears the brunt of the costs at \$1.34 billion. A Medicare prescription medication benefit would cost about \$5 billion. So any true reform effort must preserve the balance that was so carefully created in the original 1984 Hatch-Waxman legislation. Each change we make now will have some effect on another provision of the original bill.

My final concern with S. 1172 is that it could create an unbalanced review process that would appear to undercut the responsibility of the FDA. It would create a new step in the patent review process by allowing the Patent and Trademark Office to have the

ability to undercut the scientific judgments made by the FDA and its advisory committees. It is hard to see how that might work.

Schering-Plough has expressed concerns that the patent approval process for Claritin was delayed at the FDA, and we should listen to these concerns. But because the patent review process at FDA is confidential, it has been difficult to determine the accuracy of this claim. So I asked, along with Representative Waxman, for the GAO to review the FDA process surrounding the Claritin patent to determine the cause of the delays.

I think, Mr. Chairman, it might be premature for this committee to act on any piece of legislation that would alter the review process until we hear the results of the GAO report, which I understand will be out soon. We may want to have that before us when we discuss the matter further, but I think these hearings are well worthwhile. There are a lot of questions.

As you know, I have a bill on the floor and I will be in and out. The CHAIRMAN. I understand.

Senator LEAHY. I would ask consent that after members of the committee enter statements or whatever they do that a statement by the distinguished Senator from Minnesota, Mr. Wellstone, be entered into the record.

The CHAIRMAN. Well, thank you. We will add that statement to the record.

[The prepared statement of Senator Wellstone follows:]

PREPARED STATEMENT OF HON. PAUL WELLSTONE, A U.S. SENATOR FROM THE STATE OF MINNESOTA

Today's hearing will consider possible patent extensions for a handful of brand-name prescription drugs under § 1172. These patent terms were originally established by the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), a landmark piece of legislation in 1984 that made drugs more affordable for American consumers. At the time of enactment of the Hatch-Waxman Act, Congress realized the importance of creating a more competitive marketplace in prescription drugs. That is why the Act provided for a process for the timely review of generic drugs. Hatch-Waxman Act offered something for everybody: the consumers, who benefitted from lower-priced generic drugs; the brand-name drug industry, who benefitted from patent protections; and, the generic drug industry, who benefitted from the establishment of a timely FDA process for generic drug approvals. At the hearing today, you will hear from individuals who wish to reverse course, and undo the progress that has been made.

Many of the generic prescription drugs approved since that time have provided affordable prevention and treatment for a large variety of diseases. Unfortunately, the battle has not yet been won. There are still occasions when peoples' access to prescription drugs is limited by their costs—especially for senior citizens who most need these products. Prior to approval of a generic version of a brand-name drug, the price of that drug is typically very high. The brand-name pharmaceutical companies are fighting to keep the price high by extending patent protection for so-called "pipeline drugs," which were under development during passage of the Hatch-Waxman Act. This issue was considered back in 1984, and appropriate provisions for patent extension were provided for in that law. Further extending the patents of pipeline drugs will only extend the length of time that patients may have difficulty paying the high price for their medications. This is completely unnecessary. The price of brand-name drugs is already too high!

Under the Hatch-Waxman Act, the brand-name drug companies currently receive patent extensions. They take full advantage of this situation. Further, patent protections were added for some products under the General Agreement on Trade and Tariffs. While the brand-name pharmaceutical companies already receive great patent protection, they want more. Should we want to fix something that is not broken? The Hatch-Waxman Act has worked well and no changes are necessary. The patent protection system in this country is designed to first reward an inventor for new ideas, then to share the invention to serve society's need for this technology after

the inventor has had a fair opportunity to make a profit. Any changes to the Hatch-Waxman Act should be made for the benefit of society, not for the benefit of a select few companies who desire greater profits. Passing this law would be a bad precedent. If this effort is successful, imagine every company lobbying to change the patent laws in a manner that suits their bottom line. Making changes to the length of patent protections for pharmaceutical products is a very serious matter.

Let me be clear about where I stand on this issue. Brandname pharmaceutical companies do not need further patent extensions, and I will fight efforts to unfairly extend their patents through revisions in the Hatch-Waxman Act. These companies have already made tremendous profits on prescription drugs due to existing patent extensions. Regardless, these same companies are now lobbying hard for an extension of their patents. Of course these companies should make a "fair" return on their investment, but they should not make an "excessive" return on their investment.

Schering-Plough Corporation produces Claritin, one of the products that is being considered for a patent extension. One of the arguments advanced is that Schering-Plough needs additional profits so that more money can be invested in new product development. In 1998, sales of Claritin were in the neighborhood of two billion dollars. Exactly what level of profits are needed for a company to invest in new product development? The reality is that much of the money generated from product sales is not devoted towards new product development, but rather is spent on television advertisements and lobbying or retained as profits by the companies. Without patent extensions, these companies will still have healthy research and development budgets. New products are necessary for companies to remain competitive, and patent extensions are unrelated to new product development.

Considering a number of indicators of profitability, the brand-name pharmaceutical industry is one of the most profitable industry groups in America. Should this industry be granted patent extensions that would only increase their profits to obscene levels at the expense of Americans? Of course not. It is not fair to extend the patents for pharmaceuticals when the industry is already making profits that other industry groups could only hope for.

It is ironic that we are considering legislation that will lead to an increase in the cost of drugs to consumers at a time when we are also considering a prescription drug benefit. We should be going in the opposite direction, decreasing the cost of prescription drugs. Drugs are very expensive right now. In fact, senior citizens in my district go all the way to Canada to purchase lower priced drugs because they cost too much in this country. Some senior citizens must decide between buying prescription drugs and buying food. Americans pay the highest prices for drugs in the world. The brand-name pharmaceutical companies are not doing any favors for Americans, but rather, these companies are taking Americans for a ride.

One of the provisions of S. 1172 requires the Patent and Trademark Office (PTO) to make a determination regarding patent extensions. This is especially troublesome because Waxman-Hatch specified that the Food and Drug Administration (FDA) is charged with making key decisions about the conditions of review and approval related to patent term restoration processes. The responsibility should not be transferred from FDA to PTO. The Senate Health, Education, Labor and Pensions (HELP) Committee is the appropriate Committee to consider the transfer of authority from FDA, and this issue should therefore be considered by the HELP Committee.

One purpose in enacting Hatch-Waxman was to stimulate investment into new products. Because this Act allowed generic competition after a period of patent and exclusivity protection, the brand-name manufacturers could not simply rely on the same products indefinitely. After the patent protection and exclusivity expired, the Act allowed for the approval of generic competition. The generic version of that product is less expensive and therefore cuts into the market share of the brand-name product. The brand-name pharmaceutical companies responded to that by spending more money on developing new products. The result of this effort was an increase in the number of new drugs that were brought to the market. Not only was this beneficial to the brand-name companies, it was also beneficial to the public who then had access to new drugs. Current efforts to extend patent protection, if successful, would lessen the need for brand-name companies to bring new drugs to the market. This erodes progress made after passage of Hatch-Waxman Act.

Extending patent protections for brand-name prescription drugs is the wrong medicine at the wrong time. Americans should pay less for their drugs, not more. We should not be considering legislation that would serve the special interests of a small number of pharmaceutical companies. Instead, we should be considering legislation that would make drugs more affordable. I urge my colleagues on the Committee to reject this bill.

The CHAIRMAN. Senator Kennedy and Senator Feingold also have submitted statements, and they will also be included in the record at this point.

[The prepared statements of Senators Kennedy and Feingold follow:]

PREPARED STATEMENT OF HON. EDWARD M. KENNEDY, A U.S. SENATOR FROM THE
STATE OF MASSACHUSETTS

Today, the Committee hears testimony about proposed changes to one of the most important health laws—the Drug Price Competition and Patent Term Restoration Act of 1984—the Hatch-Waxman Act, which has had an effective role in improving public health in America. The Act has enhanced research and development by pharmaceutical companies and encouraged the growth of the generic drug industry, which ensures affordable prescription drugs for patients at all income levels.

The law, which has now been on the books for 15 years, streamlined the approval process for generic drugs, and allowed generic drug firms to make plans to enter the market before a brand-name drug's patent expires. It also gave brand-name pharmaceutical firms an extension on their patents to accommodate the often lengthy regulatory delays, so that research and development costs can be fairly recouped. The law strikes a balance between major interests on both sides and has served the nation well for many years. Congress must carefully consider any proposed changes to ensure that the balance is preserved.

S. 1172, the Drug Patent Term Restoration Review Procedure Act of 1999 proposes to amend the Act to provide greater patent term extension for so-called “pipeline drugs”—drugs under consideration by the FDA when the Act became law. Proponents of the legislation believe it is necessary to ensure parity and fairness for such drugs—some of which currently reap millions of dollars—even billions of dollars—in revenue every year.

Opponents of this legislation argue that it is unnecessary and unwarranted. They believe the process proposed in S. 1172 will only create a larger bureaucracy and add to the cost of health care for millions of Americans. They also argue that it will do relatively little to remove Congress from the annual, end-of-the-year rush to provide patent term extensions for individual drugs, a process that many of us find particularly disturbing.

Before Congress takes action, we must ensure that patients are the beneficiaries. The careful balance that provides for research and development, and for affordable prescription drugs must be maintained. I look forward to today's testimony and to working with other members of the Committee on this important health issue.

PREPARED STATEMENT OF HON. RUSSELL D. FEINGOLD, A U.S. SENATOR FROM THE
STATE OF WISCONSIN

Mr. Chairman, I want to thank you for holding this hearing. It is important that the issues raised by this bill receive searching examination.

I have serious concerns about S. 1172, the Drug Patent Term Restoration Review Procedure Act of 1999. Our nation's patent system is designed to encourage creativity and ingenuity in the research and development of drugs, computer technology and so many other products that enhance our lives and keep our economy thriving. Giving exclusive market power to companies for a set period of time is a reward for the time and resources that the private sector puts into research and development. On the other hand, prolonged exclusive market power has an adverse impact on competition and consumers. Our patent laws strike a balance between these competing concerns. We should be very careful when we think about revisiting that balance.

The brand name drug companies signed off on an agreement reached when the Congress passed Hatch-Waxman Act in 1984. Hatch-Waxman provided for a two-year patent extension for pipeline drugs. The pipeline drug makers now complain that this two-year period was inadequate. The Senate should rewrite the 1984 agreement only upon the most compelling justification, and I am not convinced that high standard has been reached here.

I am concerned that rewriting Hatch-Waxman and providing for a patent extension for these drugs will result in an injustice to American consumers. Three more years of profits to the pipeline drug makers will come at the direct expense of consumers who rely on these drugs.

Let's take the example of Claritin, produced by Schering-Plough, which is the most popular of the drugs affected by this bill. Claritin is an antihistamine used to treat sinus problems and seasonal allergies. Schering-Plough received a patent for Claritin in 1981, so it was "in the pipeline" when the Hatch-Waxman Act was passed. Under current law, the patent will expire in June 2002—almost three years from now and twenty-one years after Schering-Plough first received this patent. The FDA approved Claritin in 1993. This means that by June 2002, Schering-Plough will have marketed and sold Claritin, competition-free, for nine years.

Americans who use Claritin take one pill a day for anywhere from one to two weeks for sinus problems, to months at a time for seasonal allergies. At the Walgreens Pharmacy in Milwaukee, Wisconsin, a month's supply of Claritin costs \$71.39. This cost comes straight from the pockets of Milwaukee residents and/or health insurers, depending on the consumers' health insurance status and whether their health plans pay for prescription medication.

Now, with generic drugs usually priced at a 25 percent to 60 percent discount, once the Claritin patent expires in June 2002 these same Milwaukee residents could buy a generic equivalent of Claritin at anywhere from roughly \$28 to \$53. It is probably fair to say that given the immense popularity of Claritin and the generic industry's intense interest in not extending the Claritin patent, there will be many Claritin competitors. The presence of numerous competitors, in turn, means the price of generic alternatives will be closer to the \$28 figure. In fact, Mr. Downey of Barr Laboratories, who is testifying today, suggested in recent testimony before the House Judiciary Committee that the price for generic Claritin could be a little over \$15 per month. \$71 versus \$15 a month. That's a huge difference, Mr. Chairman, to Americans who need this drug. Instead of lining the pockets of drug companies, hardworking Americans could use this money to put food on the table or buy school clothes for their children.

Schering-Plough and the other pipeline drug makers would like to delay the ability of Milwaukee residents and all Americans to buy generic Claritin at lower prices until June 2005. Thus, there is no other way to look at this bill than as a net loss for consumers. Consumers will pay roughly \$71 per month for Claritin for an additional three years under this bill. Private health insurers will pay higher prices for pipeline drugs for an additional three years. Consumers will pay for this bill either out of their own pockets or through higher premiums for health insurance.

Brand name drug companies like Schering-Plough have already benefitted quite handsomely from their exclusive sales periods. In just one of its patent years, 1998, Schering-Plough had \$1.8 billion in U.S. sales and \$2.2 billion in worldwide sales on Claritin. This is incredible. Claritin sales last year represented roughly one-third of Schering-Plough's total worldwide revenue. According to a study by Dr. Stephen Schondelmeyer of the University of Minnesota College of Pharmacy, Schering-Plough's R&D costs are generally only 12.5 percent of its revenue. Based on this data, I think it is fair to say that the enormous popularity of Claritin has more than amply compensated Schering-Plough for its R&D costs incurred in developing Claritin. It simply cannot be argued that Schering-Plough needs this extension to be repaid.

Dr. Schondelmeyer also finds that Claritin sales are expected to continue to climb to almost three and a half billion dollars in 2002. American consumers will save over \$7 billion during the first five years that generic alternatives to Claritin become available. But, if Schering-Plough gets its way and this legislation passes, American consumers can expect to pay—not save, but pay—anywhere from \$1.6 billion to over \$5 billion on Claritin alone. American consumers can expect to pay roughly \$11 billion for a three-year extension for all seven pipeline drugs. Mr. Chairman, each additional year of exclusive marketing for these pipeline drug companies means billions of dollars of additional profits for the companies, and billions of dollars of additional costs for consumers.

Mr. Chairman, I do appreciate the fact that allies of the pipeline drug manufacturers have chosen to seek redress through the standard legislative process, by fashioning a bill and submitting it for hearing and debate in this committee and possible consideration on the floor. That is not the way things often happen around here. Patent extensions are a favorite item to be slipped into big bills in the dead of night at the very end of the process. So I am pleased that we're having a chance to consider this bill rather than finding out about it at the last minute.

That having been said, this bill still has the scent of a special interest deal. It benefits a small number of drug companies at the expense of American consumers. And it comes as no surprise to this Senator, nor should it to anyone here, that the companies who are asking us to pass this bill have made major political contributions to the political parties and members of Congress. I will have more to say about this when I call the Bankroll on the floor if this bill gets that far, but let me give

just a few examples. According to the Center for Responsive Politics, Bristol-Myers Squibb made \$559,975 in soft money donations in the last election cycle. Schering-Plough contributed \$287,021 in soft money for the 1998 cycle. Both companies have reported millions of dollars in lobbying expenditures in 1997 and 1998.

This will be money well spent, of course, if the pipeline drugs succeed in convincing the Congress to pass this bill, which will result in not millions, but billions of dollars of additional profits for the manufacturers and costs for consumers. I believe we should think long and hard before we go along.

The CHAIRMAN. I will permit one other statement. The sponsor of the bill has asked for a few minutes to express himself on this bill and so we will turn to Senator Torricelli at this time.

**STATEMENT OF HON. ROBERT G. TORRICELLI, A U.S. SENATOR
FROM THE STATE OF NEW JERSEY**

Senator TORRICELLI. I wanted, among the other witnesses before the committee, particularly to welcome Richard Kogan, who is the CEO of Schering-Plough, one of the most respected corporations in New Jersey, and indeed one of the most respected business leaders in America. Mr. Kogan has provided extraordinary leadership to Schering-Plough and was invaluable in helping to draft this legislation in attempting to strike a balance between the understood and respected need of the pharmaceutical industry which is such a basis of the economy of New Jersey to be protected and provided with the incentives to continue in the multibillion-dollar investment in the production of new products, but also protecting the basic integrity of Hatch-Waxman and the redesign of the approval process which has proven so valuable to the industry.

I also want to note that Agnes Veras is here today. Agnes Veras is also one of the leaders in the generic industry in our country. She has personally created several of the most successful companies in the generic industry, and was also invaluable in working on this legislation to ensure that the generics themselves and their own incentives and their ability to hold down costs and provide alternatives to consumers were protected in this process.

As I am sure the testimony will reflect, this is not, as some would represent it, as the Congress has often done, simply a patent extension. This is not designed for any one product or any one company. It rather is an exception to the process to allow different companies and different companies that encounter difficulties in the approval process to have exceptions, those exceptions designed to provide the same incentives within the patent process, but nevertheless recognizing that sometimes delays and problems in the process involve unnecessary costs and therefore should be addressed specifically. That is what this legislation is designed to do.

We have taken one approach in our Senate legislation. I know the House of Representatives has taken a different approach. But I think, Mr. Chairman, by virtue of this hearing we will learn a great deal about the differences and the virtues of each. And I am very grateful that you gave us this opportunity and once again want to thank Agnes Veras, Richard Kogan, and the other participants in the hearing who have done so much.

I might also like to note on Senator Specter's behalf that Carole Ben-Maimon, of Teva Pharmaceuticals, has also been very important in this process, and for that I am also very grateful.

The CHAIRMAN. Well, thank you, Senator.

We have a distinguished panel of witnesses here today. First, we have our distinguished former colleague, Senator Howard Metzenbaum, who is testifying on behalf of the Consumer Federation of America.

Our next witness will be Dick Kogan, the CEO of Schering-Plough, a major research-based pharmaceutical company with an important stake in Senator Torricelli's legislation.

Next, we will be fortunate to have former FDA Associate Commissioner, Jerry Meyer, who will tell us about the intricacies of the FDA review process.

Joining us for the first time today is Carole Ben-Maimon, who is the Senior Vice President of Research and Development for Teva Pharmaceuticals. Dr. Ben-Maimon will testify on the Torricelli bill from the perspective of the generic drug manufacturer.

Next, a familiar face to this committee. We will hear from Peter Barton Hutt, a leading member of the food and drug bar, and a person for whom I think everyone has respect, as we do every witness here today.

Finally, we will hear from Mr. Bruce Downey, who is CEO of Barr Laboratories. Mr. Downey has testified before this committee previously and he represents the views of many in the generic industry. We are happy to have you here, Bruce, as well.

We are familiar with all of you and we appreciate having this distinguished panel here today.

Senator Kennedy.

Senator KENNEDY. Could I just add a word of welcome to an old friend, Howard Metzenbaum. He was, of course, a member of this Judiciary Committee for many, many years, and he has been a real watchdog for consumers over a long and distinguished career. I admire not only his service in the Senate and service on the committee, but his willingness after serving in the U.S. Senate to continue his interest in public affairs.

We thank you for joining us and we extend a very warm word of welcome.

The CHAIRMAN. Well, from the former chairman of this committee and from me, we are glad to have you here, Howard, and we look forward to hearing your testimony.

PANEL CONSISTING OF HOWARD M. METZENBAUM, CHAIRMAN, CONSUMER FEDERATION OF AMERICA, WASHINGTON, DC; RICHARD JAY KOGAN, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, SCHERING-PLOUGH CORPORATION, MADISON, NJ; GERALD F. MEYER, SENIOR CONSULTANT, AAC CONSULTING GROUP, INC., POTOMAC, MD; CAROLE S. GOLDFINE BEN-MAIMON, M.D., SENIOR VICE PRESIDENT FOR RESEARCH AND DEVELOPMENT AND SCIENTIFIC AFFAIRS, TEVA PHARMACEUTICALS, INC., SELLERSVILLE, PA; PETER BARTON HUTT, COVINGTON AND BURLING, WASHINGTON, DC; AND BRUCE L. DOWNEY, CHAIRMAN, BARR LABORATORIES, INC., WASHINGTON, DC

STATEMENT OF HOWARD M. METZENBAUM

Mr. METZENBAUM. Thank you. Good morning, Mr. Chairman, Senator Leahy, distinguished members of the committee. I appre-

ciate the opportunity to offer my comments regarding this legislation.

As you know, my name is Howard Metzenbaum and I now serve on a pro bono basis as Chairman of the Consumer Federation of America. The Consumer Federation of America is a nonprofit association of some 240 pro-consumer organizations with a combined membership of over 50 million Americans.

When I was in the Senate, I consistently opposed patent extensions as being a giveaway to the patentholder and a very costly and unwarranted invasion of the consumer's pocketbook. On more than one occasion, I went to the floor and held the floor in a one-man filibuster to keep such legislation from passing.

Now, at a time when Americans are calling on Congress to take decisive action to make prescription drugs more affordable, S. 1172 would place an additional financial burden on American consumers and the health system. The bill is essentially a tax on the uninsured, the poor, the sick, and the elderly. I strongly urge you to reject it.

Now, before I go on, let me make one important point. We will hear a lot of rhetoric today about intellectual property rights and FDA's delays in approving the so-called pipeline drugs. Don't be misled, don't be misled, don't be distracted by these red herrings. This bill is unjustified on its face because it would turn the intent of patent protection and of the Hatch-Waxman Act on its head.

Patent life is intended to encourage research and development, not after a drug is out on the market, but before a drug is granted approval, not to reward a drug manufacturer after the product has been on the market for a number of years. Moreover, the Hatch-Waxman Act deliberately made allowances for drugs already in the FDA review pipeline by granting two additional years of pipeline protection.

Ten years later, in 1994, a number of those same pipeline drugs received additional patent extension. Claritin got an additional 22.5 months. Claritin has received more than its fair share of extensions. Enough is enough. The bill is the latest attempt by the drug manufacturer Schering-Plough to protect its lucrative monopoly for its best-selling antihistamine Claritin.

Last year, CFA, the organization I represent, helped to defeat an attempt by Schering-Plough to get a back-door patent extension by attaching it to the omnibus appropriations bill. Schering-Plough has been well treated by the Congress and has made billions by having patent protection for Claritin for years. But I give Schering-Plough credit; they are very, very persistent and I respect them for that.

As a matter of fact, before this hearing commenced I walked up to three old friends who were at separate locations, not standing with each other, and when I said to each one of them, what are you here for, each one of them separately indicated to me "on behalf of Schering-Plough." Fortunately, I didn't talk to three other people because possibly they also would have been lobbyists on behalf of Schering-Plough. But they are certainly well, well represented, and maybe that is good for the economy, at least the lobbyist economy.

The CHAIRMAN. Are you suggesting there are no consumer members here?

Mr. METZENBAUM. Pardon?

The CHAIRMAN. I was just kidding.

Mr. METZENBAUM. It is time for Congress to call a halt. Let the free market prevail when the already extended patent expires.

Senator Hatch, you provided great and wise leadership in authoring the Hatch-Waxman Act, even though I am prepared to confess that I was the only member of the Senate who voted against it. [Laughter.]

The CHAIRMAN. And you have been repenting ever since, I know.

Mr. METZENBAUM. Maybe it was just a knee-jerk reaction.

The CHAIRMAN. It was just one of those days when you weren't thinking clearly, Howard. [Laughter.]

Mr. METZENBAUM. I do not have to tell you that the Hatch-Waxman Act was and is a balanced Act. It was designed to increase access to affordable generic drugs, while ensuring that drug manufacturers have adequate patent protection to justify substantial investment in research and development.

Unfortunately, S. 1172 would upset the careful balance by allowing the manufacturers of Claritin and six other so-called pipeline drugs to petition the Patent and Trademark Office for additional patent life. If the 3-year extensions are granted, a likely outcome under the terms of the bill, the cost will be an astonishing \$11.1 billion according to an analysis just released by the PRIME Institute. Earlier figures had indicated \$5 billion, but this new analysis by the PRIME Institute, which is a part of the College of Pharmacy at the University of Minnesota, says it will be over \$11 billion. It is unthinkable that Congress should consider a patent extension for Schering-Plough's blockbuster drug Claritin which had sales of \$1.8 billion in 1998. That is nearly \$5 million in sales each and every day.

Now, let me tell you about some of CFA's other concerns with S. 1172. Although Senator Torricelli deserves credit for making this legislation somewhat less problematic than its House counterpart, it is still fatally flawed. S. 1172 would cut the agency with the most expertise on drug review, the FDA, out of the decisionmaking process.

Right now, the Patent and Trademark Office performs a function regarding prescription drug patent disputes that can only be described and characterized as ministerial. Although the Patent and Trademark Office makes the final judgment on patent extension, the entire decision is based on key determinations made by the FDA.

The FDA's determination involves issues such as a drug's eligibility for patent extension, the appropriate length of extension based on a regulatory review period, and whether the manufacturer acted with due diligence during the FDA review process. S. 1172, on the other hand, would hand this decisionmaking authority over to an agency with no experience in drug review, the Patent and Trademark Office. It is sort of absurd on its face.

S. 1172 further mandates a review process based in favor of the drug manufacturer. Although the review process in S. 1172 is certainly less flawed than that outlined in H.R. 1598, the bill's short

decisionmaking timeliness and narrow criteria are likely to result in unwarranted approval of patent extension.

For example, while requiring the Commissioner of the Patent and Trademark Office to consider public interest and fairness, a job for which it is questionable as to its ability to evaluate, S. 1172 actually excludes the evaluation of the consumer's interest in lower prices or the negative impact of high prescription drug costs on taxpayers and their health. S. 1172 could subject Congress to an onslaught of copycat legislation. Passage of 1172 would serve as a great precedent for other drug manufacturers who might want Congress to pass similarly unjustifiable patent extension.

In closing, let me thank you, Senators Hatch and Leahy, and all the other members of this committee, for the opportunity to offer our comments on this misguided legislation. I urge the leadership of the committee, as well as each of the members of the committee, to continue your high-profile leadership on the issue of affordable prescription drugs by vigorously opposing this bill. It will promote high prescription drug prices and deny your constituents, our members, timely access to more affordable generic medicine.

I thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Metzenbaum.

[The prepared statement of Mr. Metzenbaum follows:]

PREPARED STATEMENT OF HOWARD M. METZENBAUM

Good morning, Mr. Chairman, Senator Leahy and members of the Committee. I appreciate your invitation to offer my comments regarding this legislation. My name is Howard M. Metzenbaum and I now serve as Chairman of the Consumer Federation of America (CFA). CFA is a non-profit association of some 240 pro-consumer organizations, with a combined membership of over 50 million Americans. CFA was founded in 1968 to advance the consumer interest through advocacy and education.

For 19 years in the U.S. Senate, I opposed patent extensions, even going so far as to use or threaten to use the Filibuster on many occasions. The organization for which I speak today, CFA, has worked very hard to improve access to affordable prescription drugs for all Americans. Unfortunately, the legislation before you today moves in the opposite direction. At a time when Americans are calling on Congress to take decisive action to make prescription drugs more affordable, S. 1172 will place an additional financial burden on American consumers and the health system. The bill is essentially a tax on the uninsured, the poor, the sick and the elderly. I strongly urge you to reject it.

The bill is also the latest attempt by the drug manufacturer Schering-Plough to protect its lucrative monopoly and achieve a patent extension for its best-selling antihistamine, Claritin. Last year, CFA helped defeat an attempt by Schering-Plough to get a backdoor patent extension by attaching it to the omnibus appropriations bill. Schering-Plough made similar efforts in 1997 and 1996.

THE HATCH-WAXMAN ACT

Senator Hatch, you provided great and wise leadership when you joined with Congressman Waxman in authoring the Drug Price Competition and Patent Restoration Act of 1984, also known as the Hatch-Waxman Act. It represents a careful balancing act. It was designed to increase access to affordable, generic drugs, while insuring that drug manufacturers have adequate patent protection to justify substantial investment in research and development.

In other words, the Act promotes innovation and affordability. And it has helped bring down drug prices. The Congressional Budget Office estimated in 1998 that buyers saved roughly \$8 billion to \$10 billion in 1994 alone in pharmacy purchases, by substituting generic for brand-name drugs. At the same time, the wider availability of generic drugs certainly has not affected the profitability of drug manufacturers. According to researchers at Boston University, the pharmaceutical industry was the most profitable in the U.S. in 1998 and has been so for the last thirty years.

Unfortunately, S. 1172 would upset the careful balance achieved by the Hatch-Waxman Act by allowing the manufacturers of Claritin and six other "pipeline

drugs” to petition the Patent and Trademark Office (PTO) for additional patent life. If the three-year extensions are granted—a likely outcome under the terms of the bill—the cost will be an additional \$2.2 to \$4.5 billion. It is unthinkable that Congress should consider a patent extension for Schering-Plough’s blockbuster drug Claritin, which had sales of \$1.8 billion in 1998. That’s nearly \$5 million in sales each and every day.

The Hatch-Waxman Act made allowances for drugs already in the FDA review “pipeline” at the time of enactment by deliberately granting two additional years of patent protection, instead of the five years granted to drugs approved after 1984. After all, the purpose of patent protection is to provide drug manufacturers with an incentive to pursue future research and development for new drugs, not to increase profits on existing drugs. At the time the Hatch-Waxman Act was enacted, drug manufacturers had already invested heavily in research and development for Claritin and the other pipeline drugs. Moreover, Claritin received an *additional* 22.5-month patent extension in 1994 under the General Agreement on Tariffs and Trade.

AMERICANS NEED ACCESS TO AFFORDABLE DRUGS

As I’ve said already, this bill couldn’t come at a worse time for Americans who desperately need access to affordable drugs. I’m sure that all of the members of this committee are aware of the scope of the problem, but let me provide you with a few “hot off the presses” statistics from the publication, “Affordable Medications for Americans: Problems, Causes and Solutions.” This report was released just last week by Alan Sager and Deborah Socolar, researchers at the Access and Affordability Monitoring Project (AAMP) of the Boston University School of Public Health.

- Roughly 70 million Americans of all ages—about one in four—have no prescription drug coverage, according to AAMP estimates. Under-insurance for medications is also rising.
- Retail prescription drugs will consume 8.4 percent of U.S. health spending in 1999, up from 7.2 percent in 1997.
- Prescription drug spending is rising about three times as fast as overall health costs. Prescription drug prices are rising 2.4 times as fast as the overall Consumer Price Index, from April 1998 to April 1999.
- In 1998, pharmaceuticals were the most profitable industry in the U.S. in return on equity, on revenue and on assets. In fact, drug manufacturing has been the most profitable U.S. industry over the past thirty years. The median return on equity was 1.5 times the all-industry in the 1970s and 1980s, increasing to 2.3 times the industry average in the 1990s.

These statistics provide compelling evidence of the need for more affordable prescription drugs, and of the fact that the drug manufacturing industry is in no need of the unjustifiable windfall that this bill would provide.

SPECIFIC CONCERNS WITH S. 1172

Although Senator Torricelli deserves credit for making this legislation somewhat less problematic than its House counterpart, H.R. 1598, it is still fatally flawed.

1. *S. 1172 would turn the intent of patent protection on its head.* Patent life is intended to encourage research and development before a drug is granted approval, not to reward a drug manufacturer with additional profits after the drug comes to market. Despite the elevated rhetoric about intellectual property rights and FDA review timelines and procedures that you will hear this morning, this bill is really about one thing: protecting Schering Plough’s lucrative monopoly on Claritin. The irony is that Claritin has undoubtedly earned back the investment made by its manufacturer in research and development many times over. Moreover, as mentioned above, Claritin has already received patent extensions of nearly four years.

2. *S. 1172 could cost consumers and the health system billions of dollars.* A 1996 Congressional Research Service report found that generic competition reduced the price of a drug between 30 and 60 percent. According to an analysis prepared by Public Citizen, this would mean savings on Claritin of between \$1.6 billion and \$3.2 billion over three years. Savings on all seven “pipeline” drugs would be between \$2.2 billion and \$4.5 billion over three years. Some consumers, especially older Americans, will pay hundreds of dollars a year more in out-of-pocket costs.

3. *S. 1172 would cut the agency with the most expertise on drug review, the FDA, out of the decision-making process.* The PTO is not equipped by experience or

training to make a judgment call in this area. Questions involving the drug review process are well beyond its area of expertise. Right now, the PTO performs a function regarding prescription drug patent disputes that can only be characterized as ministerial. Although the PTO makes a final judgment on patent extension, the entire decision is based on key determinations made by the FDA. The FDA's determinations involve issues such as a drug's eligibility for patent extension, the appropriate length of extension based on the regulatory review period, and whether the manufacturer acted with "due diligence" during the FDA review process. If a "due diligence" determination is challenged, the FDA will make a determination on the validity of the challenge and then convene a hearing to consider appeals. S. 1172, on the other hand, would hand this decision-making authority over to an agency with no experience in drug review, the PTO.

4. *S. 1172 mandates a review process that is biased in favor of the drug manufacturer.* Although the review process in S. 1172 is less flawed than that outlined in H.R. 1598, the bill's short decision-making timelines and narrow criteria are still biased toward approval of patent extension. For example, while ostensibly requiring the Commissioner of the PTO to consider "public interest and fairness", S. 1172 defines those terms to exclude consideration of the consumer's interest in lower prices, or the negative impact of high prescription drug costs on taxpayers and the health care system, when the Commissioner decides whether to grant patent extension approval. The bill also automatically grants an extension to drugs for which the patent expires during the bill's review process. Even if the application is denied, the applicant is authorized to apply to the Court of Appeals to continue the extension pending judicial review. All the dice are loaded to keep the patent extant while the appellate process drags on.

5. *S. 1172 could subject Congress to an onslaught of "copy cat" legislation.* Passage of S. 1172 will serve as a bad precedent for drug manufacturers who will want to push Congress to pass similarly unjustifiable patent extensions. If it is good for one, why not for all?

You probably know that the General Accounting Office is investigating allegations that Schering-Plough may have contributed to the delay in approval of Claritin at the FDA. This delay is obviously the basis for Schering Plough's claim that they deserve a patent extension. As you have heard from my testimony, CFA believes that using an FDA delay as justification for this legislation, no matter what the cause, represents a serious misreading of the Hatch-Waxman Act. This legislation should be rejected outright as unjustifiable and costly to consumers.

In closing, let me thank both Senators Hatch and Leahy again for the opportunity to offer our comments on this misguided legislation. I urge you both to continue your high-profile leadership on the issue of affordable prescription drugs by vigorously opposing this bill. It will promote high prescription drug prices and deny your constituents—our members—timely access to more affordable generic medicines.

Thank you.

Senator ASHCROFT. Mr. Chairman?

The CHAIRMAN. Yes, Senator Ashcroft.

Senator ASHCROFT. Due to pressing business on the floor, some of which is related to drugs, given the sanctions measure regarding medicine, I was late and didn't get a chance to make a statement and won't be able to stay. May I submit for the record my remarks which are in support of Senator Torricelli's bill?

The CHAIRMAN. Without objection, we will put those in the record. We appreciate that and we understand the pressures on everybody here today.

Senator ASHCROFT. Thank you.

[The prepared statement of Senator Ashcroft follows:]

PREPARED STATEMENT OF HON. JOHN ASHCROFT, A U.S. SENATOR FROM THE STATE OF MISSOURI

Good Morning. I would like to thank the Chairman for holding this hearing today on the important issue of the need for a system at the Patent and Trademark Office to consider applications for patent extensions for drugs that have been bogged down in regulatory bureaucracy at the FDA for an inordinate amount of time.

I can't say I'm surprised that this situation exists. As President Reagan used to say, 'the only example of eternal life on earth is a federal administrative agency.' President Reagan was right. Given this immortality, I guess it is only natural that to the bureaucrats, a delay of four, five, six or more years before approving the sale of a commercial product seems like a relatively short time.

But to a company that has invested fortunes in research and development to produce these drugs, every minute of regulatory delay is time ticking against their patent. It is time that the company can't be selling their innovation under the protection of a patent to recoup these research and development costs, and to make a fair profit. This is something that we cannot afford, if we create disincentives to research and development, if we diminish the financial incentives to innovation, we won't get any innovation. The Chairman rightly understood this when he introduced and passed the Hatch Waxman Act in 1984, setting the delicate balance between the intellectual property interests of pharmaceutical innovators and the public interest in a competition market for consumer drugs.

Recently I became aware of the so-called "pipeline" drugs—the small group of drugs that were already in the FDA review "pipeline" when Hatch-Waxman was enacted. These pipeline drugs may have been inadvertent victims of the legislative process.

Because they were already in the pipeline, these drugs were given a shorter patent extension (2 years) than drugs that had not started the review process yet (5 years). Unfortunately, the review process for the pipeline drugs took on average twice as long as expected.

Not surprisingly, the companies whose drugs were held up in the FDA review process don't think it is fair that they should suffer due to delay they claim was caused by the FDA. The companies want their patents extended to reflect this delay. There are others, however, who say that the delay at the FDA was warranted, or in some cases caused by the companies themselves. These others say that no patent extension is warranted.

Now, it seems to me that if the companies that made the pipeline drugs are right that they are the victims of bureaucratic delay, it is only fair that they get some relief in the form of a patent extension. However, if their opponents are right, and the delay was due to the companies' own actions, they do not deserve an extension.

One thing is clear, there needs to be a neutral and independent process to review these disputes, and it is not Congress that should make those determinations. That is why Senator Torricelli introduced S. 1172, a bill that reflects a lot of thought and hard work, and a bill of which I am proud to co-sponsor. S. 1172 sets up an independent review process at the Patent and Trademark Office to handle these disputes. Interested parties can make their case for or against a patent extension on any of these pipeline drugs. If the Commissioner of the PTO believes that the manufacturer of the pipeline drug has shown by clear and convincing evidence that it used due diligence in the review process, and the Commissioner determines that an extension would be in the public interest, the Commissioner can grant an extension of up to 3 years. If the Commissioner is not convinced, no extension is granted. Furthermore, this decision is reviewable by a federal circuit court, and may be appealed by either party.

Let me be clear, S. 1172 does not take sides. It does not express any opinion on the merits of granting an extension on any particular drug. What it does is simply set up a fair and independent process for these claims to be resolved, and that seems eminently reasonable to me. That is why I co-sponsored this bill. I again want to thank Senator Torricelli for his hard work and leadership on this issue and look forward to the testimony today and to hearing if there are ways that this process can be improved.

The CHAIRMAN. We will now turn to Richard Jay Kogan.

STATEMENT OF RICHARD JAY KOGAN

Mr. KOGAN. Thank you, Chairman. My name is Richard Jay Kogan and I am chairman and chief executive officer of Schering-Plough Corporation. I appreciate the opportunity to testify in favor of S. 1172, a proposal by Senator Torricelli that would strengthen intellectual property protection in the important area of pharmaceutical research.

The bill would establish an independent process within the Patent and Trademark Office to consider patent restoration for seven

pipeline drugs that lost years of patent life because of unanticipated regulatory delays. The bill would give the companies that discovered and developed these innovative drugs the chance to make their case for patent restoration. Let me repeat, the bill gives the companies a chance, not a guarantee, to make their case on the merits. That is all we are asking for, a fair hearing by the Patent and Trademark Office.

These seven drugs affected by S. 1172, because they were already in the regulatory pipeline and presumably close to approval for marketing, received 2 years of patent restoration under the terms of the Hatch-Waxman Act. By comparison, most other drugs that have come to market since the late 1980's received 5 years of patent restoration.

One of the pipeline drugs at issue here, as has already been mentioned, is Claritin, which is a successful product and has earned our company significant revenues. It is also important to point out that millions of allergy sufferers live safer, more comfortable, and more productive lives thanks to the dedication of the Schering-Plough scientists who discovered and developed this drug.

I was the company's Executive Vice President for Pharmaceutical Operations when Claritin was awaiting regulatory approval. An FDA advisory committee has recommended approval in October 1987, and it looked like the Hatch-Waxman 2-year patent restoration would be right on the mark. Unfortunately, though, it actually took another 5.5 years from the first advisory committee meeting before FDA allowed us to market the product.

During that time, the agency had a major reorganization that slowed drug approvals. And because of limited resources at the FDA during this same period, the agency was correctly giving priority to the approval of life-saving drugs, so products like Claritin were sort of sent to the back of the line.

We were also asked to respond to two new scientific questions that created further delays, and as a result, and despite Schering-Plough's diligence in responding quickly and fully to all FDA's requests, Claritin was stuck in the approval pipeline until 1983. Now, members of the committee, that is 9 years after the enactment—

The CHAIRMAN. You mean 1993?

Mr. KOGAN. I am sorry; 1993. Thank you, Chairman. So, that is 9 years; we were stuck for 9 years after the enactment of the Hatch-Waxman Act. In an industry where research is the key to success and where funds for research can only come from successful products, such a delay is highly detrimental.

Growth through research is a fundamental business strategy at Schering-Plough. This is clear when one looks at our business performance. We have increased our research spending by an average of 13 percent every year. In 1998, we raised it even more, by 19 percent, to just over \$1 billion, and this year we are going to spend 15 percent more than that. Pharmaceutical research involves both high risk and an enormous investment of resources, and without fair patent protection we simply could not generate the necessary capital that allows us to make these risky and large investments.

Schering-Plough has targeted many serious medical challenges. Today, our scientists are working on drugs that show promise

against several cancers, including ovarian, breast, lung, skin, pancreatic, and colon. We are also developing a drug that would treat brain tumors in children, and a new antibiotic that is highly effective against resistant bacteria.

In the area of biotechnology, our research team is conducting studies to better address devastating chronic inflammatory diseases such as rheumatoid arthritis and Crohn's disease. Also, Schering-Plough's gene therapy group in California is presently in clinical trials with P-53, a treatment that has shown encouraging results in certain solid cancer tumors.

Pharmaceutical research is one of America's great success stories. Generic drug companies provide a service by producing copies of our products, but they don't invest in innovation. Without research-based companies, generic companies would not have products. I hope the members of the committee will consider the strong connection between intellectual property rights and the research that produces breakthrough drugs. It is impossible to have one without the other.

The independent review process proposed in S. 1172 at the Patent and Trademark Office is an important part of the continuing fight against disease and illness, but it is also about something larger, a continuing commitment to encourage the spirit of invention and innovation that has helped make America a world leader in almost every discovery area. I urge you to embrace that commitment and support this bill.

Thank you.

The CHAIRMAN. Thank you, Mr. Kogan. We appreciate your comments.

[The prepared statement of Mr. Kogan follows:]

PREPARED STATEMENT OF RICHARD JAY KOGAN

My name is Richard Jay Kogan. I am Chairman and Chief Executive Officer of the Schering-Plough Corporation. I appreciate this opportunity to testify in support of S. 1172, the Drug Patent Term Restoration Review Procedure Act of 1999.

This Bill would establish an independent review process within the Patent and Trademark Office (PTO) to consider the possibility of patent term restoration for seven pipeline drugs.¹ These seven drugs lost significant patent life because of lengthy review in the new drug approval process. In each case, FDA's review of the new drug application (NDA) took over five years. Yet these drugs received only two years of patent term restoration under the 1984 Hatch-Waxman Act, compared to the five years of patent term restoration that other drugs received.

S. 1172 is a major departure from the private patent extension bills that Congress has considered in the past. The Bill does not extend any patent or guarantee that any patent will be extended. Rather it creates a nonpolitical process in which the PTO determines if it is fair and equitable to restore patent term on any of these seven drugs. In providing this process, Congress will reaffirm its commitment to strong intellectual property protection which drives new drug research and development (R&D).

SCHERING-PLOUGH'S COMMITMENT TO R&D

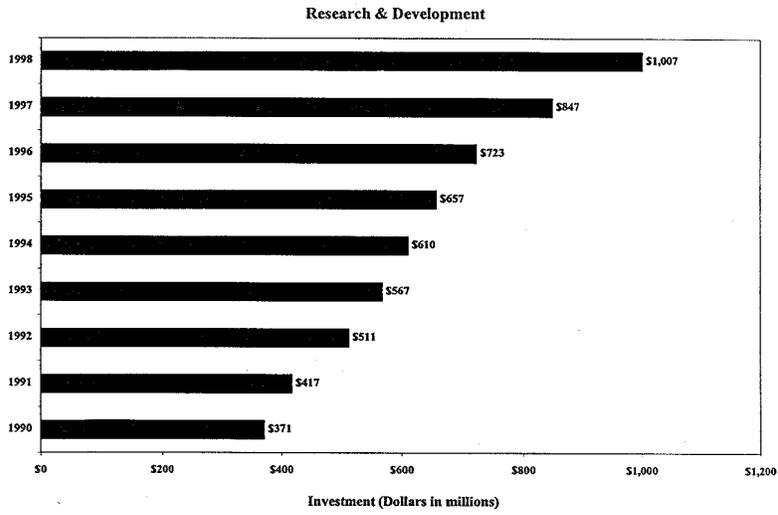
Schering-Plough has been successful because we know our future will be determined by research and by how well we identify discovery targets and conduct our development projects. We also understand that the development of new drug therapies is an extremely capital-intensive endeavor.

Schering-Plough's R&D expenditures in 1998 exceeded \$1 billion, which was an increase of 19 percent over the prior year. R&D expenditures for 1999 will increase

¹The seven drugs are Cardiogen-82®, Claritin®, Dermatop®, Eulexin®, Nimotop®, Penetrex®, and Relafen®.

by more than 15 percent. Within our peer group of large research-driven pharmaceutical companies, Schering-Plough ranks fourth in terms of research expenditures as a percentage of total sales. Our R&D expenditures have increased steadily and significantly in the 1990s, as shown in Table 1.

Table 1. Schering-Plough Corporation's Investment in Pharmaceutical Research and Development



R&D IS A HIGH-COST AND HIGH-RISK ENDEAVOR

Because of the cost and time it takes to bring a new drug to the market, it is essential that we maintain, if not increase, our high level of R&D investment. Schering-Plough continues to invest steadily in new research and technologies. Through new technologies we have increased the number of sample compounds tested from around 400,000 annually to an estimated 1.3 million this year.

Even with the research advances of today, only one in every 5,000 chemical compounds ever reaches the U.S. market. Bringing a drug to the market place takes 12 to 15 years and costs up to \$500 million.

R&D FUNDING IS DEPENDENT ON REVENUES FROM CURRENTLY MARKETED PRODUCTS

The market introduction of our product Claritin® in 1993, and its ongoing success since then, has fueled Schering-Plough's R&D efforts. Revenues generated in the current year from our marketed products are utilized to fund ongoing and future research initiatives. Strong sales support increases in R&D investment, which in turn delivers important new drug products to consumers. Especially critical are the revenues from a small number of very successful products.

PHARMACEUTICALS CRITICALLY IMPACT PUBLIC HEALTH

Schering-Plough's researchers are pursuing novel therapies that address important medical needs. Their efforts focus on cancer, infectious diseases (like hepatitis C), cardiovascular disease, central nervous system diseases (like Alzheimer's disease), and allergic and inflammatory disorders. Our scientists are developing drugs that can directly target the causes of disease, with the hope of offering significant improvements over existing treatments that only address disease symptoms.

But many of these promising drug candidates are years away from marketing. A potential new drug must be evaluated for many years—in laboratory testing, animal testing, and human clinical studies—in order to develop the necessary data for a new drug application (NDA). The speed with which we are able to pursue this innovative research is directly dependent on earnings from marketed products, and those earnings are directly dependent on strong and fair patent protection.

THE OUTLIER PIPELINE DRUG PROBLEM

Recognizing the importance of patent protection to pharmaceutical R&D, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.² Under that Act, the holder of a patent for a new drug can apply to the Patent and Trademark Office for restoration of part of the effective patent life lost due to regulatory review. For most drugs, the Hatch-Waxman Act limits the restoration period to five years. For drugs whose patent issued and whose regulatory review straddled the enactment date of the legislation—so-called "pipeline" drugs—the statute limits the restoration period to two years.

In 1984 when Hatch-Waxman was enacted, the average time for FDA approval of an NDA was 2.25 years.³ However, for the seven pipeline drugs that are covered by S. 1172, regulatory review took many years longer than Congress would have anticipated based on this 2.25 years average review time. FDA approval of the NDAs for these drugs took over 5 years, more than twice the amount of time that would have been expected.

The unfairness of applying the 2-year limitation on patent restoration to Claritin® and the other six pipeline drugs can be seen by comparing these drugs to drug products which began clinical trials just *after* the Hatch-Waxman enactment date and thus were not subject to the 2-year limit on patent term extension. Products with much *shorter* NDA review periods than Claritin® received much *longer* patent term extensions. For example, a blockbuster lipid lowering agent that just missed being classified as a pipeline drug spent 4.19 years in NDA review, received over 4.6 years of patent extension, and has an effective patent life of 14 years. Similarly, a well-known antibiotic that just missed being classified as a pipeline product spent only 1.56 years in NDA review, received 3.4 years of patent extension, and has an effective patent life of 14 years. In comparison to these successful drugs, Claritin® had an NDA review time of 6.45 years, received only 2 years of patent extension, and has an effective patent life of just over 9 years. These are but two examples. There are numerous others.

²Pub.L.No. 98-417, 98 Stat. 1585 (Sept. 24, 1984).

³FDA, "New Drug Evaluation Statistical Report" 53 (Oct. 1985) (FDA mean approval time of 26.9 months for new molecular entities in 1984).

Even drug products that were approved by FDA just prior to enactment of the Hatch-Waxman Act received better treatment than many of the outlier pipeline drugs covered under S. 1172. While these already approved drugs did not receive any patent extension, they did receive 10 years of market exclusivity under other provisions of that Act. Thus, they received ten years of protection against generic drug competition.

Pharmaceutical companies are under tremendous competitive pressure. Companies that do not discover and develop new products oftentimes do not survive. The number of pharmaceutical companies that have disappeared through mergers and acquisitions in recent years is evidence of this fact. Given this environment, and because so few compounds ever make it through the development process and to the market, it is critical that the rare successful product receive fair patent protection.

SOLUTION TO THE OUTLIER PIPELINE DRUG PROBLEM

Senator Torricelli has introduced legislation that would create a process by which the PTO could consider applications for patent term restoration for seven outlier pipeline drugs. The bill, S. 1172, would authorize the PTO to determine whether pipeline drugs that were subjected to more than five years of NDA review by FDA should be awarded patent term restoration of up to three years. The period of patent term restoration would be reduced for any period of time in which the applicant did not exercise due diligence in pursuing approval.

In past years, Congress has been asked to award patent term extension directly to a specified drug product. In fact, Congress has enacted product-specific patent extensions for pipeline drugs three times since enactment of Hatch-Waxman. But this private bill approach has been criticized for politicizing the patent term restoration process.

In contrast, S. 1172 creates a neutral administrative process. Under the Bill, the PTO—an informed decisionmaker with expertise on patent matters—conducts an administrative proceeding in which interested parties—including generic drug manufacturers—can participate. FDA is given a significant consultative role and PTO has access to all relevant documents and information. All seven outlier pipeline drugs would be eligible to participate in the process. No drug would automatically receive patent term restoration. We believe this process-oriented approach can effectively address the outlier pipeline drug problem.

Under the Bill, the applicant must show that it acted with “due diligence.” This is the same standard an applicant must meet to currently receive an extension under Hatch-Waxman. Due diligence is defined as “that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by,” an applicant during an NDA review period.⁴ Due diligence focuses on the applicant’s actions, not on FDA’s actions. As a result, the PTO is not put in the position of second-guessing FDA’s scientific judgments.

I was President and Chief Operating Officer of Schering-Plough Corporation and Executive Vice President—Pharmaceutical Operations during the time that Claritin® was awaiting FDA approval. Less than a year after the NDA for Claritin® was submitted to FDA, on October 23, 1987, an FDA advisory committee recommended that FDA approve the Claritin® NDA. FDA often promptly approves a drug that has received a favorable recommendation from an advisory committee. In the case of Claritin®, however, approval did not come until April of 1993. Schering-Plough had to wait more than six years after the NDA was submitted to market Claritin® in the United States. When the Claritin® approval finally came, the public received access to a once-a-day, nonsedating antihistamine that did not present the kinds of cardiac risks that existed with the other nonsedating antihistamine products on the market at the time.

Two unanticipated scientific issues arose after the FDA advisory committee recommended approval of Claritin® in 1987—one involved toxicology data and the other involved bioequivalence. FDA addressed both of these issues with caution. Schering-Plough acted with due diligence during the entire process.

The review of the Claritin® NDA was complicated by FDA’s reorganization of the Center for Drug Evaluation and Research (CDER) which began in 1987 and continued until 1989. Moreover, FDA reviewed Claritin® prior to enactment of the Prescription Drug User Fee Act (PDUFA) in 1992. Before enactment of PDUFA, FDA lacked the funding and resources to review NDAs expeditiously, particularly for drugs that were not designated for “priority” review. During the CDER reorganization Claritin® was assigned to the same division that reviewed cancer drugs, all of

⁴35 U.S.C. §156(d)(3).

which received "priority" designations. Claritin® received a "standard" review designation.

All of these factors certainly had an adverse impact on the time the Claritin NDA spent in the regulatory review. In contrast to the 6.5 years spent in regulatory review in the United States, Claritin® received approval in 2.5 years or less in many countries with sophisticated regulatory agencies, including Germany, France, Ireland, Italy and the United Kingdom.

Claritin® is a good example of why the manufacturers of the seven outlier pipeline drugs should be given an opportunity to present their case to the PTO for up to three years of patent term restoration. Claritin® received the worst of both worlds, extraordinarily lengthy regulatory review, and minimum patent restoration.

Congress recognized the importance of, and relationship between, fair and strong patent protection and pharmaceutical R&D when it enacted Hatch-Waxman. In order to properly fund R&D, successful products must have fair patent protection. S. 1172, in providing a nonpolitical forum and a fair process, furthers this goal. That is why Schering-Plough supports this Bill. That is why we urge you to do the same.

The CHAIRMAN. Next, we will turn to former FDA Associate Commissioner Jerry Meyer, and we will listen to your testimony, Mr. Meyer.

STATEMENT OF GERALD F. MEYER

Mr. MEYER. Thank you, Mr. Chairman. I appreciate very much this opportunity to appear and to speak in support of S. 1172, the Drug Patent Term Restoration Review Procedure Act of 1999.

As you may know, I previously testified in support of this kind of legislation before the House Subcommittee on Courts and Intellectual Property of their Judiciary Committee on both July 1, 1999, and on May 21, 1998. I also participated in a panel discussion on this subject with Surgeon General Koop and others sponsored by the Intellectual Property Institute that was held on the Senate side of this Capitol on June 10 of this year.

Mr. Chairman, I remain convinced of the merits of this legislation, and I am personally pleased that this committee is pursuing it, as well as appreciative that I have been given this opportunity to appear in support of it. I say that from the perspective of having served on the front lines of FDA's drug review and approval processes as Deputy Director of FDA's Center for Drug Evaluation and Research some 8 years ago. I remember with both some pride and with some pain appearing before both you and the distinguished Senator from Massachusetts on a number of occasions.

I also want to make clear that I am not here on behalf of anyone, and I am not being paid in any way by anyone in any manner for my appearance in connection with this legislation or any other activity in connection with this legislation. I am here as a former official of the Food and Drug Administration. I do now work as an independent consultant and I work for several other organizations, but I am here strictly on my own.

Prior to enactment of the Prescription Drug User Fee Act of 1992, as you and Mr. Kennedy will remember, FDA faced enormous difficulties in reviewing new drugs within the statutory timeframe because of a chronic lack of adequate funding and resources. And I believe that despite the very substantial efforts of a talented and dedicated review staff to carry out our responsibilities, our agency simply could not keep up with the number of new drug applications that were being submitted and are continuing to be submitted by the pharmaceutical industry. There are almost 150 NDA's that come in every year.

Review and approval times increased, and it was not until enactment of the user fee legislation that the drug review activities of the agency began to receive the funds and manpower that were needed to make a significant impact on this extended review time. The fact is that the lack of sufficient staff before enactment of this legislation meant that when someone was ill or resigned or retired or had a child or was otherwise unavailable to work on an application, there was no one else available to step in.

And when the number of applications in a particular drug class increased substantially, as they did for certain types of drugs at different times, they could simply overwhelm the available staff in a review division. You will remember this occurred, for example, over time with antihypertensive, with nonsteroidal antiinflammatory drugs, and with certain classes of antiinfective drugs. It also occurred when an application presented a difficult and complex scientific issue that required extended time to address, such as occurred with conjugated estrogens not very long ago.

In such cases, a division would simply have to defer review until they could work through this backlog or this scientific question. In some cases, these kinds of delay could and did add years to review times. Mr. Chairman, I could cite examples, and I remember Dr. John Harter telling me that it would be 2 years before he could even pick up an application for a nonsteroidal antiinflammatory drug to begin review because there were that many applications in front of it.

In all candor, Mr. Chairman, I also don't believe these kinds of problems will ever be completely eliminated. There will always be applications that come in in a rush in a particular class of drugs that overwhelm the reviewers who are trained in that class of drugs. There will always be some complicated scientific issue presented by a particular product, where making the risk/benefit decision will be difficult and require extended time. And there will also be situations where we have trouble in recruiting people.

At the moment, the current number of applications for products to treat asthma is an example of a division that is almost overwhelmed with those applications. Learning how to measure how much of a drug gets into the lungs by a novel delivery system is a difficult and complicated task. Working through the scientific issues that are involved is tough, and the difficulty in recruiting pulmonologists for a government salary is also a worthy, worthy challenge.

That is why a process like that proposed in this legislation is so important, and not just for those few problems that occurred in the past, but also for those problems that I believe will occur in the future. And I hope the legislation provides for that. I think there will always be those kinds of issues.

It is true that the FDA did, and continues to assign priorities to applications for products that represent drugs for life-threatening diseases for which there is only limited or no adequate authority. I agree with that priority. You and others in our Congress agree with that priority. But I acknowledge that it only adds years to the review time and delays for other applications that may later on prove important. I say that because as you know, Mr. Chairman,

all patients do not respond equally, in the same way, to all products.

The additional resources provided to the drug process through user fee legislation and appropriations that have been made available are invaluable, but they have not eliminated all of the inequities that existed before this legislation and may somehow exist in the future. That is what I hope this new legislation will correct. And as a matter of public policy, I believe an open administrative process will almost always be preferable to other alternatives.

Thank you, Mr. Chairman, for this opportunity and I will be pleased to respond to any questions.

The CHAIRMAN. Well, thank you, Mr. Meyer. We are glad to have you before the committee again. We have always respected you and enjoy your point of view, or at least have enjoyed listening to it.

Ms. Ben-Maimon, we look forward to hearing your testimony. I think this is the first time you have appeared before our committee, so we are happy to welcome you here and we look forward to hearing what you have to say.

STATEMENT OF CAROLE S. GOLDFINE BEN-MAIMON, M.D.

Dr. BEN-MAIMON. Thank you. Good morning, and thank you for inviting me to testify before the Senate Judiciary Committee. My name is Carole Goldfine Ben-Maimon and I am a physician board-certified in internal medicine who has worked in research and development in the pharmaceutical industry since 1991.

Currently, I am Senior Vice President for Research and Development at Teva Pharmaceuticals. Teva is a manufacturer of both pharmaceutical products and raw materials, with facilities in New Jersey, Pennsylvania, and Missouri. Teva is a member of the Generic Pharmaceutical Industry Association and the National Pharmaceutical Alliance, and my testimony today is on behalf of both of those trade organizations. In my current position, I have been responsible for obtaining the approval of a multitude of generic drug products, as well as working with the FDA to obtain approval for several novel and new orphan drug products.

I would like now to focus on the legislation at hand. Hatch-Waxman is a law that was carefully and thoughtfully drafted to strike a balance between the brand industry and the generic industry, and to serve the public interest. The generic industry is dependent on the brand industry for its lifeblood. It is only through the brand industry's continued research and development that new products ultimately become available for the generic industry to develop and market.

It would be naive to believe that the risks involved in drug development would be incurred without the anticipation of significant financial reward. Thus, we understand the need to protect intellectual property rights and the importance of incentives to stimulate the costly research and development for new drugs. We emphatically support the protection of these rights. The question now is only when does the patient deserve access to lower-cost generics.

S. 1172 is a bill that proposes extending the patents on several branded pharmaceutical products, the most notable of which is Claritin, Schering-Plough's multibillion-dollar drug for allergy sufferers. I would ask that today we take a different look at this and

look at the alternative. In our view, allowing Schering's Claritin patent to expire would accomplish exactly what Congress intended when they passed the Hatch-Waxman Act.

First, Hatch-Waxman has already provided the incentive to continue the development of Claritin and ultimately bring the product to market. Second, American consumers will finally have access to more affordable generic versions of the drug. And, third, and most importantly, letting patents expire stimulates and encourages the development of new, improved and novel approaches to disease. Allowing the brand industry to rely on profits from an aging product line is not only inconsistent with the intent of Hatch-Waxman, but undermines the incentives to seek needed advancements in the treatment of disease.

S. 1172 accurately, although inadequately, acknowledges some of the widely debated issues surrounding the 180-day generic exclusivity. One of the mechanisms by which the brand industry has delayed marketing of generic drug products is by abusing the listing of patents in the Orange Book. FDA has taken the position that they do not have the expertise to oversee the listing of these patents and has accepted for listing in the Orange Book any patent. This has resulted in a situation where inappropriate patent listings have become a major obstacle to the lawful market entry of competitive generic drug products. It is clear to us that as a matter of both law and policy, only patents on drug-active ingredients should be listed. FDA initially agreed with that approach and documented it in a letter to industry in 1984. Today, however, FDA lists any patent.

S. 1172 in its current form creates additional inequities. Generic drug applications for these seven products, already at FDA, were forced to certify to all listed patents. If S. 1172 is passed in its current form, applications being submitted in the future will not be required to certify to all the same patents. In order to create a level playing field, filing requirements for products which generic applications containing paragraph IV certifications are already on file at FDA should remain unchanged, while innovators should be required to remove irrelevant patents from the Orange Book for all other products.

Finally, the extension of patents for pharmaceutical products must be considered in light of the impact on patients who will now be required to pay more for prescription drugs and, as importantly, who may now have to wait longer for new and improved drugs as the lack of incentive for their development may delay their market entry. Requests for patent extensions must be considered in an open forum in which knowledgeable parties can adequately and fairly debate the issue.

In summary, as a physician and a representative of the generic industry, I implore you to consider the implications of approving S. 1172. This bill does not achieve anything other than an extension of several long-running monopolies at the expense of the patients who suffer from the diseases these products treat. I hope that if, prior to my testimony, Congress believes that a balance had been struck, I have convinced you to the contrary.

The CHAIRMAN. Thank you, Ms. Ben-Maimon.

[The prepared statement of Dr. Ben-Maimon follows:]

PREPARED STATEMENT OF CAROLE S. GOLDFINE BEN-MAIMON

Good morning. Thank you for inviting me to appear before the Senate Judiciary Committee today and for giving me the opportunity to share with you the generic pharmaceutical perspective on S. 1172. Before I begin to address the specific legislation at hand, I would like to take a moment to tell you a little about my background. My name is Carole Goldfine Ben-Maimon and I am a physician, board certified in Internal Medicine, who has worked in research and development in the pharmaceutical industry since 1991. Currently, I am Senior Vice President for Research and Development and Scientific Affairs at Teva Pharmaceuticals, Inc. Teva is a manufacturer of both pharmaceutical products and raw materials with facilities in Pennsylvania, New Jersey and Missouri. Teva is a member of the Generic Pharmaceutical Industry Association and the National Pharmaceutical Alliance and my testimony today is on behalf of both trade organizations.

My responsibilities at Teva have included the development of both brand name drug products and generic drug products. As Senior Vice President of Research and Development, I manage the entire development process for our pharmaceutical products. This has included obtaining the approval of a multitude of generic products as well as working with the FDA to obtain approval for several new and novel orphan drug products, specifically a product called Copaxone for the treatment of Multiple Sclerosis and a product called Galzin for the treatment of a very rare and terminal disease, Wilson's Disease. I make this point because it is important and relevant to understand that many generic manufacturers, such as Teva, are engaged in the development and innovation of new medicines in addition to the development of more affordable generic medicines.

My work in research and development for the pharmaceutical industry has allowed me to participate in some of the most exciting research occurring today. As a physician committed to advancing the health care profession's ability to significantly impact disease, there is nothing more rewarding than providing quality pharmaceutical products to the patients who need them. With this as my background and interest, I hope my testimony will provide the committee with a somewhat unique view on the issues presented in S. 1172.

When one talks about the pharmaceutical industry, one must keep in mind that decisions made relating to drug development have a direct impact on a very large and vulnerable subset of consumers; those who are ill, those who are looking to pharmaceuticals sometimes to save their lives and almost always to improve the way they feel and thus their quality of life. As we all know, these necessary pharmaceuticals can be very costly, all too often forcing a patient to choose between spending their limited income on the drug or some other essential or desired commodity. We all also know that senior citizens are often the ones forced to make these unfortunate choices.

With this in mind, in 1984 Congress tackled the task of balancing the public need for cost-competitive generic drug products while providing incentives to encourage innovation and creativity by the brand industry. The result was passage of the landmark Hatch-Waxman Act. The Act was carefully and thoughtfully drafted to strike a balance between the brand industry and the generic industry and to serve the public interest. The generic industry relies on the brand industry for its lifeblood. It is only through the brand industries' continued research and development that new products ultimately become available for the generic industry to develop and market. Thus, we understand the need for strong intellectual property rights and the importance of incentives to stimulate the costly research and development that is required to bring new, safe and effective drugs to market. Therefore, we emphatically support the protection of these rights. As I stated earlier, many generic companies actually have patents of their own and many also market branded products themselves. Thus, there is no controversy over the importance of adequate and appropriate patent protection, the question is only when does the patient deserve access to more affordable medicines.

One can easily see the success of Hatch-Waxman worked when financial data is reviewed. Since 1984 brand sales have increased steadily, exceeding \$80 billion in 1998. Last summer, the Congressional Budget Office concluded that, "Between 1983 and 1995, investment in R&D as a percentage of pharmaceutical sales by brand name drug companies rose from \$17 billion to \$57 billion, thus demonstrating that the brand industry is not only continuing to invest in the development of novel pharmaceutical properties but it is increasing its commitment." During this time of escalating R&D, generic market share increased from 13 percent to 41 percent. This is proof that generic competition is the motivation for innovation.

Let's be realistic the brand industry is not developing new products out the goodness of their hearts. They are doing this because of the profits that are realized when a novel product is introduced to the market place.

In light of what I have just said, let's consider the specific issue at hand, whether or not so called "pipeline drugs" are entitled to seek additional patent life. Let me be clear. Teva and other members of the generic industry oppose patent extensions. There is a cost associated to patent extensions and it is the American consumer who ultimately pays the price. While the generic industry opposed patent extensions back in 1984, it was provisions like the Bolar safe harbor and the abbreviated new drug application process that rallied the generic industry behind passage of the Hatch-Waxman Act. The cost of the patent extension provisions were balanced out with the tremendous savings consumers would reap from having access to more affordable generic medicines the day after a patent expired.

A pipeline drug is a drug for which a patent had been issued and an investigational new drug application (IND) or a new drug application (NDA) was pending at FDA before the enactment date of the Hatch-Waxman Act. While there were over 100 drugs in the FDA pipeline back in 1984, S. 1172 applies to only seven. The most notable of which is Claritin, Schering-Plough's multi-billion dollar drug for allergy sufferers.

Congress specifically addressed the brand industry's concerns that their expected returns on their investment in these pipeline drugs would be diminished by the accelerated generic competition stemming from changes in the law. This would have led them to abandon the development of these products. Thus, they were awarded a two year extension as an incentive to bring the products to market.

Let me reiterate that the intent of the Hatch-Waxman Act was to encourage future investment in research and development, not to reward past investment. This is why the Act provides new chemical entities with the opportunity to seek up to five years of additional patent life when drugs like Claritin were limited to the two-year patent extension. It is also important to note that that in addition to the two-year extension, Claritin enjoys a 22.5-month extension under the General Agreement on Trade and Tariffs (GATT). As a result of past extensions, in June 2002, Claritin will have enjoyed patent life of approximately 21 years— four years beyond the original patent term.

I would ask that today you consider the alternative. What if Schering's patents were permitted to expire? In our view it would accomplish exactly what Congress intended when they passed the Hatch-Waxman Act.

First, Hatch-Waxman provided the initial incentive to continue to development Claritin and ultimately bring it to market. Second, American consumers will finally have access to more affordable generic versions of the drug without additional costly delay. Third, and most importantly, allowing patents to expire stimulates and encourages the development of new, improved, and novel approaches to disease. Allowing the brand industry to rely on profits from an aging product line is not only inconsistent with the intent of Hatch-Waxman, it undermines the incentive to seek needed advancements in the treatment of disease. The knowledge that the Claritin patent will expire sooner rather than later has encouraged Schering to invest in new products like the metabolite of Claritin, desloratadine or better known as "Super Claritin", whose patent will not expire until 2014. This product according to Richard J. Kogan, Chief Executive of Schering-Plough is in late stage human testing. Hopefully this product will provide some advantages over Claritin, thus advancing medical therapy. At the end of the day Schering has rightfully profited from Claritin sales of approximately \$30 billion.

I'd like to address some of the other issues in S. 1172. The bill accurately acknowledges some of the widely debated issues surrounding the 180-day "generic exclusivity" provided for in the Hatch-Waxman Act. As you may know, this exclusivity was created to encourage generic companies to challenge or circumvent weak patents and thus bring lower cost pharmaceuticals to the market earlier. This provision has been surrounded by controversy. One of the mechanisms by which the brand industry manipulates the 180-day exclusivity clause is by abusing the listing of patents in the Orange Book. Although the generic industry whole-heartedly supports "cleaning up" the Orange Book, unfortunately the proposal contained in S. 1172 as written is completely inadequate to achieve that goal and may even exacerbate the problem.

FDA has taken the position that they do not have the expertise to oversee the listing of drug patents, and has accepted for listing in the Orange Book any patent that the sponsor of a reference listed drug has submitted. This has resulted in a situation where inappropriate patent listings have become a major obstacle to the lawful market entry of competitive generic drug medicines. For example:

A patent covering "multifractionable tablets with bisectable/trisectable structures" has been listed for the drug trazadone, even though the patent does not refer to trazadone or any other specific drug product. Because of this listing, a generic applicant was forced to file a paragraph IV certification to the patent, precipitating litigation that triggered the statutory 30-month stay on final ANDA approval, and causing substantial delay and expense.

A listed patent covering Terazosin drug products was held to be expired in a 1996 federal district court case. Notwithstanding that decision, the patentholder insisted on maintaining the listing for the expired patent until specifically ordered by the court to request FDA to delist it, an order that was upheld by the Federal Circuit on appeal. Meanwhile, generic applicants were forced to incur additional expense and delay contesting a patent that had been held expired and ordered to be delisted. The reference drug sponsor ended up enjoying a de facto extension of patent protection for well over a year after the actual expiration date of the patent.

Several method-of-use patents that cover unapproved uses of bupropion were listed, without use codes. Although ANDA applicants for bupropion are not seeking approval of such uses, those applicants were being forced to file paragraph IV certifications to these patents because, in the absence of use codes, FDA does not recognize them as use patents that may be omitted from an ANDA that does not seek approval of the corresponding indications. Subsequent to the innovator being notified and bringing suit these patents were delisted from the Orange Book.

A patent is listed for the drug gabapentin that covers only a monohydrate form of the compound not found in the approved, marketed formulation. Yet because of this listing, generic applicants will be forced to file paragraph IV certifications to the patent, giving the patentholder the opportunity to trigger a 30-month stay, and invoking the 180-day exclusivity mechanism, over a patent that does not even claim a compound in the reference drug itself.

It is clear to us that as a matter of both law and policy only patents on drug active ingredients (and on methods of using them) should be listed, and that patents that claim final formulations incorporating such active ingredients (i.e. drug product patents) should not be listed in the Orange Book, FDA initially agreed with that approach, and documented it in 1984 in a Letter to Industry from Harry M. Meyer, Jr., MD, Director, Center for Drugs and Biologics, dated November 16, 1984.

The patents that FDA regards as covered by the statutory provisions for submission of patent information are those on the active ingredient or ingredients, or use patents for a particular indication or method of using the product. The agency will not publish patents relating to chemical intermediates, methods of manufacturing, excipients or formulations.

Today, however, FDA lists any patent, and refuses to even consider ways to remedy the abuse potential its current approach has engendered.

S. 1172 in its current form, creates additional inequities. You may not know there are generic drug applications (ANDAs) for these seven products already pending at FDA. Each of these applicants was forced to certify to *all listed* patents, whether or not these patents were appropriately listed. If S. 1172 is passed in its current form, generic applications submitted in the future will not be required to certify to *all listed* patents, but only to the compound patent. By reducing the burden of certification for these later-filed applicants, they could potentially avoid the 30-month approval stay and enter the market before the other ANDA applicants who filed first. Thus the current proposal is essentially backwards and creates an unlevel playing field within the generic market. Products for which generic applications containing paragraph IV certifications that are already filed at the FDA should remain untouched, while innovators should be required to remove irrelevant patents from the Orange Book for all other products. Resolution of this problem requires a more far-reaching and all-inclusive approach than that contained in S. 1172.

Finally, we in the generic industry oppose any new process for obtaining patent extensions. The extension of patents for pharmaceutical products must be considered in light of the impact on patients who will now be required to pay more for prescription drugs and who may now have to wait longer for new and improved drugs as the lack of incentive for their development may delay their market entry. The Patent Office is not and has never been charged with this responsibility. They do not possess sufficient knowledge of the FDA and its processes nor do they possess sufficient knowledge of the impact on the public good or pharmaceutical policy to

justify this delegation of authority. A truly fair and transparent process would insure that those making the decision would have complete information available, the expertise to evaluate this information, and would be capable of fully understanding the impact of the extension on patients, third party payors and the pharmaceutical industry. It is of the utmost importance to those of us who use drug products, prescribe them for others, and rely on generic products to help make ends meet, that requests for patent extensions be considered in a forum in which knowledgeable parties can adequately and fairly debate the issue. Given this type of process, we are of the opinion that there would be no patent extensions except in the most extreme of situations.

11 Using Claritin as an example, one can clearly see the intensity with which a company will lobby for these extensions. This is the fourth effort to extend these patents. In May 1997, Schering attempted to add a patent extension amendment to the Omnibus Patent Act of 1997. In the closing moments of the 1997 congressional session, there was another attempt to extend the patent through the appropriation process, and last year there was an attempt to add this proposal to the 1998 Omnibus Appropriations Bill. Schering is not the only company that has made these submarine attempts to extend patents. Debating this process in Congress has allowed the interests of the public to be kept at the forefront of the debate and thus has assured an open debate based on the merits. In contrast, such openness and fairness will be lost under the extension process proposed in S. 1172.

In summary, as a physician and a representative of the generic industry, I implore you to consider all the implications of granting a patent extension for these products. S. 1172 is clearing focused on the extension of several long-running monopolies at the expense of the patients who suffer from the diseases these products treat. The improper listing of patents in the Orange Book definitely needs to be addressed, as must the problems surrounding the 180-day exclusivity provision. Other important patient oriented issues such as providing low cost generic biologics must also be confronted. However, this bill does not remedy any of the above controversial issues while it focuses on a self-serving strategy that only benefits a few select innovator companies. I hope that if prior to my testimony, Congress believed that S. 1172 struck a balance, I have convinced you to the contrary. S. 1172 provides no such balance in its current form; it is merely a patent extension for a multi-billion dollar allergy drug. Thank you for your time.

The CHAIRMAN. We will turn to you, Mr. Hutt.

STATEMENT OF PETER BARTON HUTT

Mr. HUTT. Thank you, Mr. Chairman. When the Hatch-Waxman was being considered during 1983 and 1984, I served as counsel to the pharmaceutical industry on that particular legislation. I was deeply involved in the development, negotiation, and drafting of the provisions in the ultimate statute. As a result, you have invited me to present testimony today on the origin of the pipeline drug provision in that legislation.

The general rule under the 1984 Act was that the pioneer drug received up to 5 years of patent term restoration. There was, however, one general exception to this rule and it is the exception that brings us here today. A pipeline drug was limited to 2 years of patent term restoration. Pipeline drugs are defined as any drug for which a patent has been issued and an investigational new drug application submitted to FDA prior to the date of enactment of the 1984 Act, which was September 24, 1984.

Accordingly, there was 3 years of disparity, a full 3 years of difference in patent year restoration between two new drugs that were being developed at the identical time simply by reason of the fact either, first, that the IND was submitted shortly before the enactment date for one and the other was submitted shortly after the enactment date. Or, second, the patent for one went through the patent process quickly and was issued before the enactment date

and the other went through the patent process slowly and was issued after the effective date.

Now, 2 years ago, the chief counsel for the Senate Committee on Governmental Affairs asked me about the origin of this 3-year disparity. I provided a letter describing the two reasons for the 2-year limitation on pipeline drugs. Let me summarize those two reasons.

First, it was felt the pipeline drugs would be approved by FDA shortly after enactment of the 1984 statute, and 2 years of patent restoration was therefore fair and equitable under those circumstances. Second, it was felt that because of anticipated short time to approval of only 2 years that less of an economic incentive was needed to assure continued pursuit of the drug to final FDA approval.

Now, to make sure that my understanding was completely correct on this, in October 1997 I discussed the matter with John McLaughlin, who had been Representative Waxman's counsel to the Subcommittee on Health and the Environment and was involved in the legislation on a daily basis throughout 1983 and 1984. Mr. McLaughlin wrote me to confirm my recollection that these two reasons were, in fact, the two reasons for the pipeline drug limitation. I have attached to my testimony, Mr. Hatch, all of that correspondence for the record.

Now, for most of the pipeline drugs, the assumption that FDA approval would come shortly after enactment turned out to be quite accurate. At that time, the average time for FDA approval was approximately 2.25 years. For a few outliers, however, this assumption turned out to be quite inaccurate. For these outlier pipeline drugs, the time for FDA review and approval of an NDA was well over twice the average.

It is important to understand that a number of post-1984 new drugs that received a full 5 years of patent term restoration were, in fact, approved by FDA before the agency approved the pre-1984 outlier pipeline drugs, and they received only 2 years. This produced the anomalous result that the outlier pipeline drugs whose NDA approval time was more than twice the average received less than half the normal patent term restoration. I can assure you that none of us who participated in the drafting of the 1984 Act anticipated or intended this inequitable result. And I am sure, Mr. Hatch, that you as one of the leaders in that fight for legislation never thought this would happen either.

Now, I want to make clear one part of this because there is a great deal of misunderstanding about it. FDA approval of the outlier drugs was not completed, as we have heard, until April 1993, which was more than 8 years after enactment of the 1984 statute. Within that 8-year period, many other drugs received FDA approval, together with a 5-year patent term extension.

Now, like the pipeline drugs, these other drugs that got 5 years of patent extension had begun development, testing and research prior to 1984, prior to the enactment date. Let me emphasize that point because the opposite has been stated twice so far in this hearing. Drugs that were approved by FDA prior to the outlier pipeline drugs, yet received a full 5 years of patent term extension, were undergoing active research, development and testing for more than 5 years before the enactment date of the 1984 legislation.

Now, in conclusion, let me say that, without doubt, outlier pipeline drugs have not been treated fairly. These drugs received only 2 years of patent term restoration, whereas competitors who submitted their INDA applications later, but received their NDA approvals earlier, received a full 5 years of patent term restoration. This result cannot be justified on any principled basis.

The assumptions on which the 2-year pipeline drug limitation was based have turned out to be erroneous for this very limited category of seven drugs. Under similar circumstances, Congress on seven prior occasions in the past has enacted specific legislation to redress the resulting inequity. In the case of these outlier pipeline drugs, this kind of redress of inequity could be accomplished either by drug-specific legislation, or I believe far more efficiently by establishing the type of new administrative procedure that is contained in S. 1172.

Thank you very much.

[The prepared statement of Mr. Hutt follows:]

PREPARED STATEMENT OF PETER BARTON HUTT

Mr. Chairman and Members of the Committee, I am Peter Barton Hutt. I am a partner in the Washington, D.C. law firm of Covington & Burling.

I have been asked by the Committee to present testimony on patent term restoration and S. 1172. For almost forty years, I have been engaged in the practice of food and drug law. During 1971–1975, I served as Chief Counsel for the Food and Drug Administration (FDA). I am the co-author of the casebook used to teach food and drug law in law schools throughout the country.¹ I teach a full course on food and drug law during Winter Term at Harvard Law School and I have taught the same course during Spring Term at Stanford Law School. When the Drug Price Competition and Patent Term Restoration Act of 1984 was being considered during 1983–1984, I served as counsel to the Pharmaceutical Manufacturers Association (now the Pharmaceutical Research and Manufacturers of America) and was deeply involved in the development, negotiation, and drafting of the provisions in that statute.² I have published articles on the subject of patent term restoration both before³ and after⁴ enactment of the 1984 Act. Finally, I have twice before testified on legislation intended, and ultimately enacted, to provide patent term restoration for specific products as a matter of fairness and equity.⁵

THE ORIGIN AND PURPOSE OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

In 1962, Congress enacted new legislation to increase the regulatory requirements for new drugs. The Drug Amendments of 1962⁶ replaced the 1938 requirement of premarket notification with a more stringent requirement of premarket approval, and added a requirement of proof of effectiveness to the 1938 requirement of proof of safety. In the years that followed, the time required to obtain the necessary evidence of safety and effectiveness increased, and the time required for FDA review and approval of a new drug application (NDA) also increased. As a result, instead

¹Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law: Cases and Materials* (1st ed. 1980 & 2d ed. 1991).

²See, e.g., my testimony on behalf of PMA in “Patent Term Extension and Pharmaceutical Innovation,” *Hearing before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives*, 97th Cong., 2d Sess. 123 (1982).

³Peter Barton Hutt, *The Importance of Patent Term Restoration to Pharmaceutical Innovation*, 1 *Health Affairs*, No. 2, at 6 (Spring 1982).

⁴Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 *Food Drug Cosmetic Law Journal*, No. 3, at 269 (July 1985).

⁵“Lopid Patent Term Restoration and Fairness Act of 1987,” *Hearing before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the Committee on the Judiciary, House of Representatives*, 100 Cong. 1st Sess. 41, 72 (1987), 101 Stat. 1107, 1569 (August 23, 1988); “Patent Extension Hearing,” *Hearing before the Subcommittee on Patents, Copyrights and Trademarks of the Committee on the Judiciary, United States Senate*, 102d Cong., 1st Sess. 44 (1991), 107 Stat. 2040 (December 3, 1993).

⁶76 Stat. 780 (1962).

of receiving the full statutory patent term of seventeen years, the effective patent life for a new drug gradually was reduced to less than ten years and at times to zero. The longer it took a company to prove safety and effectiveness and the longer it took FDA to review and approve the NDA, the shorter the effective patent life became.

By 1980, the average effective patent life of new drugs had deteriorated to such an extent that many concluded it required remedial legislation. During 1981 and 1982, Congress considered legislation relating solely to patent term restoration. This legislation narrowly missed enactment in September 1982.

Following enactment of the Drug Amendments of 1962, FDA approved the marketing of generic versions of pioneer drugs under abbreviated NDAs for those pioneer new drugs first marketed before the 1962 Amendments, but not for new drugs with NDAs approved after the 1962 Amendments. For two decades, generic versions of post-1962 new drugs were virtually precluded from the market. Both administrative and legislative approaches were considered during this time to permit FDA approval of generic drugs, but none was successful.

In 1983 and 1984, the pending patent term restoration legislation was combined with legislation authorizing FDA approval of generic versions of post-1962 new drugs through an abbreviated NDA. That legislation was ultimately enacted in September 1984 as the Drug Price Competition and Patent Term Restoration Act of 1984 (which is shortened in this testimony to the "Patent Term Restoration Act" or the "1984 Act").⁷

The 1984 Act was an attempt to balance two competing interests. The research-based drug industry obtained up to five years of patent term restoration for pioneer new drugs, to compensate for part of the diminished effective patent life resulting from the FDA requirements for the investigation and approval of a new drug. The generic drug industry received the assurance that generic versions of a pioneer drug would be approved by FDA following expiration of applicable patents and market exclusivity through an abbreviated NDA that did not require duplicative testing for safety and effectiveness.

THE PIPELINE DRUG EXCEPTION

As noted above, the general rule under the Patent Term Restoration Act of 1984 was that the pioneer drug received up to five years of patent term restoration. There was, however, one important exception to this general rule. A pipeline drug was limited to two years of patent term restoration. Pipeline drugs are defined in what is now 35 U.S.C. 156(g)(6)(C) as any drug for which a patent had been issued and an investigational new drug (IND) application had been submitted to FDA prior to the date of enactment of the 1984 Act, which was September 24, 1984. Accordingly, there was a full three years difference in patent term restoration between two new drugs that were being developed at the same time, simply by reason of the fact that either:

- (1) The IND for one was submitted shortly before the enactment date and the other was submitted shortly after the enactment date or
- (2) The patent for one went through the patent process quickly and was issued before the enactment date and the other went through the patent process slowly and was issued after the effective date.

THE CONGRESSIONAL RATIONALE FOR THE REDUCED PATENT TERM RESTORATION FOR PIPELINE DRUGS

The three-year disparity between the two years of patent term restoration provided where an IND had been submitted before the date of enactment and the five years provided for all other new drugs has provoked substantial interest and concern. Two years ago, the Chief Counsel for the Senate Committee on Government Affairs asked about the origin of this disparity. I provided a letter in May 1997 describing the two reasons for the two-year limitation on pipeline drugs. A copy of that letter is attached to this testimony.

As already noted, I participated in the development, negotiation, and drafting of the 1984 Act on behalf of the industry trade association. My clear recollection of the reasons for the two-year limitation for pipeline drugs, as set forth in that May 1997 letter, are as follows:

There were two fundamental reasons why the two-year limitation was included for pipeline drugs in what is now 35 U.S.C. 156(g)(6)(C). These rea-

⁷98 Stat. 1585 (1984).

sons were frequently discussed among those of us who were involved in the daily negotiations.

First, it was felt that the pipeline drugs would be approved by FDA shortly after enactment of the 1984 legislation. Accordingly, it was thought that the five year period of patent term restoration granted to all post-enactment drugs would be unjustified for pipeline drugs, and that a two-year period of patent term restoration would more appropriately reflect the anticipated short period of time between the date of enactment and the date of FDA approval for pipeline drugs. (While this assumption has in large part proved to be true, I understand that for a handful of pipeline drugs the time between date of enactment and FDA approval has extended beyond the time needed for approval of post-enactment drugs and has in fact exceeded ten years—something clearly not contemplated by any of us when we were drafting the legislation in 1984.)

Second, it was felt that, for any drug for which an IND had been submitted to FDA prior to the date of enactment, the manufacturer had already made the decision to invest resources in the drug and therefore less of an economic incentive was needed to assure continued pursuit of the drug to final FDA approval—particularly when it was anticipated that approval would come not long after enactment of the legislation. Accordingly it was concluded that two years, rather than five, would provide sufficient economic incentive to assure that a pipeline drug would not be abandoned.

These were the two considerations that led to the two-year limitation on patent term restoration for pipeline drugs, as contrasted with the five-year grant of patent term restoration for post-enactment drugs, in the 1984 Act. To the best of my recollection, they were the only two considerations that were discussed at that time.

In October 1997, I discussed this matter with John P. McLaughlin when I saw him at a meeting and then sent him my May 1997 letter to ask his recollection. Mr. McLaughlin had served as Counsel to the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, and was involved in the legislation on a daily basis, throughout 1983 and 1984. At the time I wrote him, Mr. McLaughlin was Executive Vice President of Genentech, a highly successful biotechnology company. Genentech has no interest of any kind in any pipeline drug. Mr. McLaughlin wrote back to confirm my recollection of the above reasons for the pipeline drug limitation. Copies of my letter to Mr. McLaughlin and his reply are also attached to this testimony.

THE OUTLIER PIPELINE DRUGS

For most of the pipeline drugs, the assumption that FDA approval would come shortly after enactment of the 1984 Act turned out to be accurate. At that time, the average time for FDA approval of an NDA was approximately 2.25 years.⁸

For a few outliers, however, this assumption turned out to be quite inaccurate. For these outlier pipeline drugs, the time for FDA review and approval of an NDA was more than twice the average, and they therefore suffered an even greater reduction in effective patent life. A number of post-1984 new drugs that received a full five years of patent term restoration were in fact approved by FDA before the agency approved these pre-1984 outlier pipeline drugs that received only two years of patent term restoration. This produced the anomalous result that the outlier pipeline drugs, whose NDA approval time was more than twice the average, received less than half the normal patent term restoration. None of us who participated in the drafting of the 1984 Act anticipated or intended this result.

FDA approval of the outlier pipeline drugs was not completed until April 1993 which was more than eight years after enactment of the 1984 Act. Within that eight year period, many other drugs received FDA approval together with a full five years of patent term extension. Like the pipeline drugs, these other drugs that received five years of patent term extension also began development prior to the enactment date. The average time from first pharmacological testing to the filing of an IND in the 1980s was 5.2 years.⁹ Thus, drugs that were approved by FDA prior to the outlier pipeline drugs, yet received a full five years of patent term extension, were

⁸FDA, *New Drug Evaluation Statistical Report 53* (October 1985) (FDA mean approval time of 26.9 months for new molecular entities approved in 1984).

⁹Tufts Center for the Study of Drug Development, *Time From First Pharmacological Testing to New Drug Approval, 1963–1997* (1998).

undergoing active research for more than five years before the enactment date of the 1984 Act.

In testimony before the House Judiciary Subcommittee on Courts and Intellectual Property on July 1, 1999, on legislation (H.R. 1598) that is similarly designed to address the inequity suffered by outlier pipeline drugs, Representative Henry Waxman presented the following rationale for the pipeline drug provision in the 1984 Act:

The pipeline drugs were not made eligible for five years of patent extension precisely because the point of the patent extensions was to encourage the research and development of future products. All products which had not yet undergone testing or review by the FDA were judged to be appropriately eligible for the full five years of patent extension.

This statement is demonstrably inaccurate. Dozens of drugs that had already undergone testing prior to the date of enactment received the full five years of patent extension.¹⁰ It was no more necessary to provide five years of patent extension to these drugs, in order to encourage the research and development of future products, than it was for the pipeline drugs that received only two years of patent extension. If Mr. Waxman were correct, none of the drugs that were being tested and were under development before the enactment date would have received the five years of patent term extension that they in fact received. Thus, contrary to Mr. Waxman's contention, the criteria in the 1984 Act that define a pipeline drug—the filing of an IND and the issuance of a patent prior to the enactment date—were completely arbitrary. As Mr. Waxman's counsel at that time has verified, the rationale for these arbitrary criteria was the assumption that the pipeline drugs would be approved by FDA shortly after enactment. For the outlier pipeline drugs, however, that has proved to be an erroneous assumption.

These outlier situations, with approval times more than double the average, reflect the large new drug review workload imposed on FDA in the late 1980s and early 1990s, the increasingly restricted resources available to the agency to do this work, and thus the growing shortfall in the personnel assigned to these tasks. FDA was doing everything it could to meet its new drug review obligations throughout this time. But the resources simply were not there to satisfy the workload needs.

Congress squarely faced this issue in the early 1990s and found a solution in the Prescription Drug User Fee Act of 1992.¹¹ Using the additional funds made available under the 1992 Act, FDA hired approximately 650 new employees to handle NDAs in a more expeditious manner. As a result, the time for NDA approval was cut in half. If this approach had been adopted earlier, there would have been no outlier pipeline drugs and no need for legislation to redress the inequity in patent term restoration that has in fact occurred for these drugs.

LEGISLATIVE ATTEMPTS TO REDRESS THE INEQUITY FOR OUTLIER PIPELINE DRUGS

The two-year limitation for pipeline drug patent term restoration in the 1984 Act was intended to deal with the expected FDA average approval time of about 2.25 years. It made no attempt to address unusual or unique situations of lengthy regulatory review for which accepted principles of fairness and equity would justify exceptions.

As a result, Congress has on seven specific occasions enacted legislation to address particular FDA-regulated products where application of the general rules in the 1984 Act would have been unfair and inequitable. Two of those occurred in the middle of the congressional consideration of the 1984 Act, two occurred at the end of the congressional consideration of the 1984 Act and were enacted a month later, and the remaining three occurred in 1988, 1993, and 1996. In all seven instances, Congress concluded that the general rules applicable under the 1984 Act were insufficient to address the particular situations involved, and thus that legislation was necessary and appropriate. The following table lists those seven statutes:

¹⁰Mr. Alfred B. Engelberg makes an even more inaccurate statement in his letter to Senator Hatch dated June 11, 1999, where he states that five years of patent term extension was reserved for “drugs which were first developed after the new law was enacted.” Initial “development” of a drug occurs prior to pharmacological testing, and thus even more drugs that received a full five years of patent term extension were under development prior to enactment of the 1984 Act.

¹¹106 Stat. 4491 (1992). The 1992 Act, which was limited to five years, was reauthorized for an additional five years in the Food and Drug Administration Modernization Act of 1997, 111 Stat. 2296, 2298 (1997).

Statutory Patent Term Restorations Since 1980

Product	Statute
Aspartame (food additive)	95 Stat. 2049, 2065 (January 4, 1982)
Forane (new drug)	97 Stat. 831, 832 (October 13, 1983)
Impro (new animal drug)	98 Stat. 3430 (October 19, 1984)
Glyburide (new drug)	98 Stat. 3434 (October 19, 1984)
Lopid (new drug)	102 Stat. 1107, 1569 (August 23, 1988)
Olestra (food additive)	107 Stat. 2040 (December 3, 1993)
Daypro (new drug)	110 Stat. 1321, 1321-320 (April 26, 1996)

In a number of other instances, similar legislation has been considered by Congress for other FDA-related products but has not been enacted.

I have in the past supported this type of legislation, because I believe it is entirely appropriate for Congress to enact legislation addressing the inequities that inevitably arise in the application of general rules to unique situations. It is, however, time-consuming and inefficient for Congress to examine and take action on each specific product where a general problem has been identified, such as outlier pipeline drugs. During a Senate hearing held in August 1991 to consider patent term restoration bills for three specific products, Bruce Lehman, who later served as Commissioner of Patents and Trademarks, offered the thoughtful suggestion that Congress establish some type of new administrative procedure to consider identified problems of fairness and equity rather than to handle each individual product on an ad hoc legislative basis.¹² As Mr. Lehman pointed out at that time, this alternative way of approaching the matter offers substantial advantages. This approach for outlier pipeline drugs has been discussed since 1991, and legislation incorporating it has recently been introduced as S. 1172.

CONCLUSION

Without doubt, outlier pipeline drugs have not been treated fairly. These drugs received only two years of patent term restoration, whereas competitors who submitted their IND applications later but received their NDA approvals earlier received a full five years of patent term restoration. This result cannot be justified on any principled basis. The assumptions on which the two-year pipeline drug limitation was based have turned out to be erroneous for this limited category of drugs. Under these circumstances, Congress has in the past enacted legislation to redress the resulting inequity. In the case of outlier pipeline drugs, this could be accomplished either by drug-specific legislation or, more efficiently, by establishing a new administrative procedure to evaluate the few remaining outlier pipeline drugs involved as set forth in S. 1172.

COVINGTON & BURLING,
Washington, DC, May 12, 1997.

FREDRICK S. ANSELL,
Esquire, Chief Counsel, Senate Committee on Governmental Affairs, Dirksen Building, Washington, DC.

DEAR MR. ANSELL: This is in response to your request for information on the origin of the two-year limitation on patent term restoration for pipeline drugs under the Drug Price Competition and Patent Term Restoration Act of 1984. As counsel to the Pharmaceutical Manufacturers Association (now the Pharmaceutical Research and Manufacturers of America) with respect to that legislation, I participated in the development, negotiation, and drafting of the 1984 Act.

The 1984 Act established patent term restoration of up to five years for new drugs approved by the Food and Drug Administration (FDA) after the date of enactment, except that a two-year limitation was placed on pipeline drugs. Pipeline drugs were defined as those drugs for which an IND was submitted prior to the date of enactment.

There were two fundamental reasons why the two-year limitation was included for pipeline drugs in what is now 35 U.S.C. 156(g)(6)(C). These reasons were frequently discussed among those of us who were involved in the daily negotiations.

First, it was felt that the pipeline drugs would be approved by FDA shortly after enactment of the 1984 legislation. Accordingly, it was thought that the five year period of patent term restoration granted to all post-enactment drugs would be un-

¹²"Patent Extension Hearing," note 5 supra, at 218.

justified for pipeline drugs, and that a two-year period of patent term restoration would more appropriately reflect the anticipated short period of time between the date of enactment and the date of FDA approval for pipeline drugs. (While this assumption has in large part proved to be true, I understand that for a handful of pipeline drugs the time between date of enactment and FDA approval has extended beyond the time needed for approval of post-enactment drugs and has in fact exceeded ten years—something clearly not contemplated by any of us when we were drafting the legislation in 1984.)

Second, it was felt that, for any drug for which an IND had been submitted to FDA prior to the date of enactment, the manufacturer had already made the decision to invest resources in the drug and therefore less of an economic incentive was needed to assure continued pursuit of the drug to final FDA approval—particularly when it was anticipated that approval would come not long after enactment of the legislation. Accordingly, it was concluded that two years, rather than five, would provide sufficient economic incentive to assure that a pipeline drug would not be abandoned.

These were the two considerations that led to the two-year limitation on patent term restoration for pipeline drugs, as contrasted with the five-year grant of patent term restoration for post-enactment drugs, in the 1984 Act. To the best of my recollection, they were the only two considerations that were discussed at that time.

Sincerely yours,

PETER BARTON HUTT.

COVINGTON & BURLING,
Washington, DC, October 16, 1997.

JOHN P. McLAUGHLIN,
Esquire, Executive Vice President, Genentech, Inc., South San Francisco, CA.

DEAR JOHN: For the past several years, manufacturers of “pipeline” prescription drugs—those drugs that received only two years of patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 because a clinical trial had begun before the date of enactment—have pursued legislation to expand their term of patent term restoration to a full five years. They argue that the 1984 Act unjustifiably discriminated against the pipeline drugs and that the premises on which the reduction from five to two years of patent term restoration was based have turned out to be incorrect.

Recently I was asked to provide a letter to the Senate Committee on Governmental Affairs to relate my views on why the pipeline drugs were provided a shorter term of patent term restoration. A copy is enclosed.

I would be very interested in knowing your recollection of this matter. When you have a moment, please give me a call.

With best regards,
Sincerely yours,

PETER BARTON HUTT.

GENENTECH, INC.,
South San Francisco, CA, October 31, 1997.

PETER BARTON HUTT,
Covington & Burling, Washington, DC.

DEAR PETER: Thank you for your letter of October 16, 1997. You ask whether I have a recollection as to the rationale for affording two years of patent restoration for “pipeline drugs” (as compared to five years for certain other categories of drugs) in the Drug price Competition and Patent Term Restoration Act of 1984. Based on my service as Counsel to the House Subcommittee on Health and the Environment, I have a very clear recollection of the rationale. It is accurately summarized in your letter of May 12, 1997 to the Senate Committee on Governmental Affairs.

If you would like to discuss this matter further, please feel free to give me a call.
Sincerely,

JOHN P. McLAUGHLIN,
Executive Vice President.

The CHAIRMAN. Mr. Downey, I have to go vote. That is why everybody has left here. I think what we had better do so we don't disrupt your testimony is wait until I can get back so we can re-

sume the hearing. And I presume most of my colleagues will come back, as well. It is an important testimony.

So, with that, I will recess until I can get back and I will try to hurry as fast as I can.

[The committee stood in recess from 11:22 a.m. to 11:39 a.m.]

The CHAIRMAN. We will turn to you, Mr. Downey. I apologize for the delay, but I couldn't have taken your testimony before the vote and so we will take it now after the vote.

STATEMENT OF BRUCE L. DOWNEY

Mr. DOWNEY. Thank you very much, Mr. Chairman. It is good to be back before the committee. I am Bruce Downey. I am chairman and president of Barr Laboratories, a generic and proprietary drug firm located in New York, as a constituent of Mr. Schumer; in New Jersey, as a constituent of Mr. Torricelli; and in the State of Virginia.

The CHAIRMAN. You know how to put the pressure on these people.

Mr. DOWNEY. I would remind them that, in fact, there are also generic companies in those districts. We are also a member of the National Pharmaceutical Alliance and the Generic Industry Association, two of the leading trade associations for our industry.

I have prepared a written statement I would like to have submitted for the record. To go through that statement would take longer than the amount of time allotted and I would like to confine my remarks to some of the things that were said today.

The CHAIRMAN. We will put the full statement in the record as though fully delivered.

Mr. DOWNEY. Thank you, Mr. Hatch.

The first thing I would like to do really is address the questions that you asked at the beginning of the hearing because I think that really gets to the heart of what we are about today.

Your first question was is this bill in the interests of the American public. I think the answer to that is decidedly no. The Hatch-Waxman Act that you helped craft in the 1980's was really built on two twin pillars. The first pillar was to provide incentives to stimulate innovation, and that is a value that we all share, something we all think is an important public policy interest.

The other pillar of the Act was to guarantee competition and to make sure that a date certain generic pharmaceuticals were available to reduce the cost to the consumer. And by embracing those two concepts and writing them into the law, you were able to achieve remarkable success for consumers and for the branded and generic industry. I would submit that this legislation serves neither of those purposes.

In the first instance, the reward or the extension of the patents that would be contemplated by this Act would reward work that was done years ago. It wouldn't stimulate anything. It might provide some funds for the Schering-Plough company or any other company that gains a patent extension, but it is certainly not directly designed to stimulate innovation. It is only rewards that are offered for the work that actually stimulates innovation in the way that I think your legislation contemplates.

And, second, it certainly would not guarantee competition or serve the consumer interest of those allergy sufferers who take Claritin and the other products that are part of the pipeline bill. Clearly, they have an interest in early access to low-cost, high-quality generic products that will save them literally billions of dollars on Claritin alone. So in answer to your question, will this serve the public interest, I think the answer is clearly no.

The second question you asked is, under the circumstances presented here, does the delay warrant legislative action. Again, I think the answer is clearly no. In the first instance, the approval time for Claritin, the principal drug product that precipitated this legislative proposal—that approval time was consistent with the time of other products being approved at the time. And that is all laid out in our written testimony, and I think when you review that you will see quite clearly there was no disparate treatment or no unfair treatment of Claritin at the time.

In the second instance, I think you will see that the Claritin approval process, to the extent it was delayed, was delayed in substantial part because of the decision of the company to switch from a capsule to a tablet product. The original FDA advisory panel recommendation to approve the product that Mr. Kogan mentioned was one at a time when Claritin was in a capsule form. In 46 countries around the world, Claritin moved directly to the market in capsule form.

In the United States, the company for their own reasons decided to change that product from a capsule to a tablet. As part of the approval process when you make that change you have to submit scientific data to show that the tablet performs in the same way as the capsule in bioequivalent studies. On two occasions, they submitted those studies with failing results. So it was the inability to promptly move from a capsule to a tablet that accounted for a good part of the delay in the approval of this product.

So we think the answer to: Should there be some delay here or some extent for the pipeline drugs? We think the answer is no. And when you look at Claritin particularly, it is a product that is already enjoying 21 years of patent life, the original 17 in the patent that was granted, 2 years' extension through the Hatch-Waxman Act, and 2 additional years through the GATT treaty implementation legislation. So at the time of expiry, there will be 21 years of patent life for this product and we think that is enough.

The third question you posed is, is a new process required to allow for patent extensions to avoid this ad hoc consideration in the Congress. Again, I think the answer to that is clearly no. The Congress and the laws of our country establish a 20-year term for patents from date of application. And, second, they have a Hatch-Waxman provision to grant an extension under situations of regulatory delay.

To a third really exception to the exception and provide for a second extension, I think is a political decision. It is a decision where the Congress needs to balance those twin pillars of stimulating innovation and guaranteeing competition, and look at the particular subject matter of that particular patent and decide how those interests are best served, whether they are served through a patent extension or allowing it to expire as the law contemplates.

I would like to close by debunking two points that we have learned maybe some members of the staff and some members of Congress have come to believe because of the lobbying efforts that have been put forward on this bill.

The first of those is do we think the Senate bill is somehow better than the House bill, we in the generic industry, so that the passage of Senate 1172 or some tinkering with that bill would solve our basic objections? And the answer to that is clearly no. I would describe the House bill as a wolf in wolf's clothing, and no one is fooled by what it is. I think the Senate bill is really a wolf in sheep's clothing, and so there is a little packaging around the sides. I don't think it is really clear.

What we object to is the wolf, and the wolf in this case is the ability to extend patents beyond their natural period of expiration in a way that does not serve the interests of promoting competition or innovation. And for that reason, we would urge the Senate to oppose this legislation, to vote it down, because I think when you get down to the bottom line what you really have here is a piece of legislation, carried to its logical extension in granting the patent extension, that is really a multibillion-dollar tax on allergy sufferers. And from a consumer point of view, there is absolutely no difference between extending the patent life on Claritin, and on the other side imposing a tax on allergy sufferers, collecting the money, and wire-transferring those funds to Schering-Plough. I think when you look at it in that light, it is clear that this is a piece of legislation that should be defeated.

Thank you, sir.

[The prepared statement of Mr. Downey follows:]

PREPARED STATEMENT OF BRUCE L. DOWNEY

Mr. Chairman, members of the Committee, thank you for the opportunity to testify. My name is Bruce L. Downey, and I am Chairman of Barr Laboratories, Inc., which has facilities in New York, New Jersey and Virginia and manufactures and distributes a wide range of prescription medicines for the treatment of diseases ranging from cancer to heart disease to depression. Barr Laboratories is a member of the National Pharmaceutical Alliance and the Generic Pharmaceutical Industry Association, two of the three largest generic pharmaceutical industry associations.

The future of the generic pharmaceutical industry is directly linked to a vibrant brand industry that has appropriate incentives to develop new and innovative pharmaceutical products. The flow of such products provides patients with improved alternatives to currently available therapies, and also generates the opportunities for our industry to develop more cost-effective versions of existing products. The best way for Congress to preserve the balance among competition, innovation and intellectual property rights is to preserve and expand the Hatch-Waxman Act. S. 1172 fails to meet this objective.

The members of the generic pharmaceutical industry stand together in strong opposition to the approval of S. 1172. We believe it will upset federal drug policy that has served patients for nearly two decades for the sole purpose of extending patents protecting a specific product and thereby delaying generic competition.

Our industry opposes S. 1172 because it:

- Imposes an unwarranted multi-billion dollar burden on patients through years of lost access to cost-saving generics;
- Establishes a process that substantially reduces brand company incentives to innovate new therapies by delaying competition;
- Imposes piecemeal changes to Hatch-Waxman that disrupts the delicate public policy balance that has generated a decade of increased innovation and patient savings;
- Invites imitation by other special interests for countless other products; and

- Diverts the attention of Congress from concentrating on ways to dramatically increase patient access to pharmaceutical products at reasonable costs.

HISTORY OF CLARITIN PATENT EXTENSIONS

Although this legislation is proposed in part as a mechanism to address suggested deficiencies within the Hatch-Waxman compromise, the driving force behind this initiative is Schering-Plough and its efforts to extend the patents that protect Claritin, a multi-billion dollar international allergy drug.

This is the sixth effort by Schering-Plough to use the Congress to obtain a third extension of the patents protecting Claritin. Last month, the House Subcommittee on Court and Intellectual Property considered a similar legislative proposal for the second time in two years. While S. 1172 purports to improve upon the House version addressing procedural deficiencies, in fact the inevitable result—if not the purpose—of this bill and the House version are identical—a patent extension for Claritin.

Previous efforts to extend these patents have been more direct, and not disguised as public health policy initiatives. In May 1997, Schering-Plough attempted to add a patent extension amendment to the Omnibus Patent Act of 1997, an effort that was blocked in this very Committee. In the closing moments of the 1997 congressional session, there was a second attempt to extend the patent through the appropriation process, while a bill was in conference. That effort was also rejected. Last year, there was an attempt to add this proposal to the 1998 Omnibus Appropriations Bill. That initiative failed as well. I am confident that when you have considered all of the evidence you will reach the same conclusions that the Congress has previously reached and reject S. 1172.

A fundamental reason for the previous rejections of an extension to the Claritin patents is that the government has already granted two such extensions. If you look at the record, the patents protecting Claritin have already been extended far beyond what Schering-Plough could have expected at the time it was developing this product. The original patents for Claritin were filed on June 19, 1980 and granted on August 4, 1981. The product was launched in 1993 and without any extensions the patents would have expired on August 4, 1998, after 17 years of protection.⁰⁰

According to a *Federal Register* Notice of August 31, 1993, Schering-Plough sought a two-year patent extension pursuant to Hatch-Waxman and was successful in extending the patent until August 4, 2000. As part of the GATT implementation legislation, the patent was further extended by another 22 months to June 19, 2002. As a result of these extensions, in June 2002 Claritin will have enjoyed patent life of approximately 21 years—four years beyond the original patent term.

POTENTIAL LOST SAVINGS TO PATIENTS

The two-year Hatch-Waxman extension protected approximately \$5 billion in Claritin sales from generic competition. The two-year GATT extension is estimated to protect approximately \$7 billion in sales, based on projections by ABN AMRO Associates of Boston. From the patient's point of view, anywhere from 30–80 percent of this \$12 billion cost could have been saved if generic competitive market forces were in play. While analysts' projections for Claritin's growth end with the patent expiry, if one were to assume the same growth levels through 2005, S. 1172 would protect more than \$20 billion from competition.

Extending the patents will delay generic competition and force Claritin patients to continue to pay more than \$80 per month for a typical prescription for three more years. For those patients covered by insurance these costs will be borne by the insurance firm subscribers and employers who pay for medical coverage. For those who must cover prescription costs themselves, the monthly cost will come directly out of their pockets. And taxpayers will be forced to pay the additional federal costs that these patent extensions will create.

INHIBITING INNOVATION AND INVESTMENT IN NEW PRODUCT DEVELOPMENT

Clearly, if Claritin were not protected from competition, the pressure on Schering-Plough to innovate new, equally effective and profitable therapies would increase significantly. In fact, it is this very pressure to innovate, while simultaneously providing an economic benefit to patients upon patent expiry, that was the heart of the Hatch-Waxman compromise.

Mr. Chairman, any senior corporate executive can appreciate Schering-Plough's corporate motives in working to preserve its Claritin profit stream from competition. But there are few instances in our nation's history where corporate monopoly interests have made sound public policy. We don't need to tell you that competition in the pharmaceutical industry is good for the consumer, and our most needy citizens.

When a product patent expires, it is not unusual for multiple generic pharmaceutical companies to launch versions of the product. As a result, prices fall rapidly and dramatically, as competition increases. One need only look at Zantac, an ulcer medication, for a good example. Following introduction, generics rapidly climbed to 80 percent of the units sold in the market in less than three months. The cost savings were equally as dramatic for patients, falling from more than \$80 a month to less than \$12 per month.

But perhaps as important, working with a finite period of protection promotes investment in new product innovation, encourages creativity and results in new and improved therapies. Last summer, the Congressional Budget Office considered the very issue of innovation when it examined the value and impact of generic competition. The CBO study concluded that, "Between 1983 and 1995, investment in R&D as a percentage of pharmaceutical sales by brand name drug companies increased 14.7 percent (\$2.7 billion) to 19.4 percent (\$14.4 billion). Over the same period, U.S. pharmaceutical sales by those companies rose from \$17 billion to \$57 billion. Overall, then, the changes that have occurred since 1984 (the Hatch-Waxman Act) appear to be favoring investment in drug development."

Since the Hatch-Waxman Act, brand sales have increased steadily, exceeding \$80 billion in 1998. Generic companies and consumers also have benefited. Since 1984, the generic industry has grown steadily and today has total annual revenues of approximately \$11 billion. In fact, 42 percent of all prescriptions filled today are for generics. Because of generic competition, consumers have saved literally billions of dollars by having access to generic pharmaceuticals that are priced as much as 70 percent-80 percent below their brand counterparts.

There is compelling evidence today that the underlying premise of the Hatch-Waxman Act works—the entire pharmaceutical industry and all consumers will benefit if there is a proper balance between rewarding innovation and guaranteeing competition. A study recently commissioned by Warner Lambert and prepared by the Boston Consulting Group explored issues related to access to brand pharmaceuticals as related to market interventions outside the U.S. marketplace.

The study considered market interventions, including government price controls, and concluded that, "the net effect of reducing the degree of market intervention would be to encourage competition later in the product life cycle, and reward and encourage innovation in the early years * * * It is ultimately the patient who suffers from a poorly designed and ineffective intervention regime." S. 1172 contradicts this conclusion.

PIECEMEAL AMENDMENTS TO HATCH-WAXMAN

The Hatch-Waxman Act was a delicate compromise that sought to encourage competition from generic pharmaceuticals while maintaining the brand industry incentives to invest in the development of innovative drugs. It has also provided American consumers and taxpayers with more than 15 years of multi-billion dollar savings in health care costs. The generic industry strongly encourages Congress to maintain the fundamental provisions of the Act while simultaneously expanding the benefits of this landmark consumer legislation through appropriate legislation. S. 1172 is not the vehicle for the consideration or approval of mechanisms to extend the benefits of Hatch-Waxman.

However, two of the arguments made in support of S. 1172 would significantly recast the effect of this legislation. One of the arguments for extending the patents on Claritin is related to the product's status at the time of Hatch-Waxman, and the other argument is that the Claritin product was unnecessarily delayed by the FDA.

At the time the compromise for extending patents under Hatch-Waxman was forged, all of the parties recognized that one of the key objectives of the Act was to promote innovation. The formula for these incentives was straightforward. The Act recognized the need to provide incentives for drug products in the early stages of development, and research projects initiated after the implementation of the Act. Hatch-Waxman also recognized that there was no need to provide incentives for those products that were already on the market, and therefore they received no patent extension. The parties recognized that there was no obligation to offer an incentive for investing in products that had already reached the marketplace because the investment in innovation had already been made. For those products that were in the middle stages of development, including Claritin, it was agreed that the Act should provide some incentive for the work remaining to be completed, so a partial extension of patents was granted for these products. The amount of time granted was based on the point in development when the Act was implemented. S. 1172 would repudiate this deal.

In addition, Schering-Plough argues that Claritin deserves additional patent protection because FDA approval was unusually delayed. The facts, however, do not support this argument. The IND for the product was filed with the FDA in January 1983, and the NDA was filed in October 1986. An FDA advisory committee recommended approval for Claritin one year after the NDA was filed. Normally, prompt FDA approval would have followed. Schering-Plough, however, amended the application to change Claritin from a capsule product to a tablet product. This decision ultimately delayed the approval process by several years.

In the pharmaceutical industry, changes in the dosage form require bioequivalence tests to ensure—as in the case of Claritin—that the capsule and tablet will work the same way. That is, Schering-Plough was required to prove that the active ingredient in the tablet would be absorbed into the patient's blood stream at the same rate and to the same extent as the capsule version. Schering-Plough twice provided failing bioequivalence data, which further delayed Claritin's approval.

Had Schering-Plough proceeded with approval to market the capsules as originally intended, and as it did in 46 other countries, the product could have been launched years earlier and we would not be here today. Had it submitted appropriate bioequivalence data, the approval could have proceeded normally. Clearly the delay in entering the U.S. market rests solely with Schering-Plough's management and scientists and cannot be blamed on an FDA delay.

Another defect in S. 1172 is the requirement that the patent holder exercise due diligence during the NDA review process. In the context of this bill, "due diligence" is a meaningless standard. The most minimal efforts to communicate with FDA during the review process, for example, would likely satisfy "due diligence." This standard does not permit a proper determination of whether the patent holder was responsible for any delay or to apportion accountability.

Proponents of S. 1172 suggest that they have corrected a deficiency in the House version (H.R. 1598) by placing the burden of proof for gaining an extension on the patent holder. (H.R. 1598 placed the burden of proof on those opposing the extension.) The problem with this argument is that engaging in the discussion of where the burden of proof belongs legitimizes the consideration of the validity of the patent extension process proposed under S. 1172. Congress has already established the appropriate period of patent life and the appropriate process for extending patents within the Hatch-Waxman Act. Only an act of Congress should extend the life of patents beyond the original and already generous extensions already existing. S. 1172 would substitute an administrative procedure that upsets the balance of Hatch-Waxman and replaces congressional scrutiny with an inappropriate bureaucratic decision-making process.

As was true with H.R. 1598, S. 1172 would place the technical decisions of the FDA under scrutiny of a separate agency ill-qualified to address them. The bill requires the Commissioner of the United States Patent and Trademark Office to make a legal determination about whether a separate agency, the Food and Drug Administration, performed its responsibilities in accordance with its statutory mandate. At no time during the entire consideration of this legislation has there been a credible demonstration that the Commissioner of Patents has sufficient knowledge and understanding of the FDA and its processes or pharmaceutical policy to justify this delegation of authority. In addition, if Congress wanted to give PTO this type of authority, it would have specified it in the Hatch-Waxman Act. Instead, Congress made a conscious decision to give FDA the responsibility for reviewing and calculating agency delay to support an extension.

Finally, the argument is made that S. 1172 provides a benefit to the generic industry by resolving issues related to the listing of product patents. In essence, this legislation is designed to offer something to the generic industry in exchange for their support for granting extensions to brand product patents. This proposal, however, offers the generic industry no real benefits. The generic industry believes that there are a number of more substantive, critical problems, that if corrected, would strengthen the Hatch-Waxman Act and directly benefit consumers. Unfortunately, the proposals put forth in S. 1172 are extremely limited and would generate additional inequities by benefiting some manufacturers at the expense of others.

The bill is further evidence that the development of effective drug policy or the improvement of Hatch-Waxman can not be achieved by periodic, limited legislation designed to award a specific benefit to one or two companies. These issues are far too complex to be addressed in a procedural bill whose primary purpose is to protect one drug from the very competition envisioned by the Hatch-Waxman Act.

For example, Section 2(a) of S. 1172 does attempt to limit the breadth of required Paragraph IV certifications to only the patents that claim, in one form or another, the active ingredient. In this way, the bill tries to exclude Paragraph IV certifications for extraneous patents.

However, the bill's Paragraph IV limitation only applies to patents for the eight or so "pipeline" drugs affected by the bill itself and would apply only after the pipeline drugs had received the additional three years of patent protection proposed by S. 1172. Generic companies have already filed Paragraph IV certifications for some of these pipeline drugs, and have relied on the existing law in making investment decisions about the development of generic versions of these drugs. S. 1172 does not address that investment or the resulting inequity to the generic companies pursuing these products.

The limitation also does not apply to the hundreds of patents that are presently listed erroneously in the Orange Book (*FDA's Approved Drug Products With Therapeutic Equivalence Evaluations*), or in any way limit future improper patent listings attempted by the brand industry.

The generic industry has been concerned for some time about the brand industry's abuse of patent listings in the Orange Book. The Hatch-Waxman Act requires that FDA compile—the Orange Book, and that NDA applicants submit patent information to FDA for inclusion in the Orange Book. FDA may not approve a generic drug application until the listed patent terms have expired. For generic applicants, the listing of patents in the Orange Book triggers the Paragraph IV certification requirement discussed above.

Thus, whenever an NDA holder has a patent listed in the Orange Book, the NDA holder is eligible to exercise the statutory 30-month stay against generic competition, thereby extending its product monopoly. With such a lengthy monopoly period at stake, it is no surprise that NDA applicants submit patent information to FDA that is voluminous or only tangentially related to the drug at issue. For example, some products, such as the osteoporosis drug Evista, have more than 100 patents listed in the Orange Book.

The generic industry believes that only compound patents should be listed in the Orange Book and entitled to Paragraph IV certification and the 30-month stay. A separate "Grey" Book could then be created to provide industry notification of other patents. To accomplish this, the industry proposes three statutory changes to prevent the Orange Book listing of irrelevant patents.

- *Limit patents eligible for listing in the Orange Book.* Congress should amend the Act's patent listing and protection provisions to limit listings to patents that claim a new active molecule(s) of a pharmaceutical product. Only those new molecule patents would require a Paragraph IV or other patent certification. Furthermore, if eligible patents are submitted to FDA later than 30 days after the date the patents are issued, as required by Section 505(c)(2) of the Act, generic drug applicants would be excused from making the patent certification.
- *Develop a "Grey Book" for patents that are merely related to the drug product.* In addition, Congress should require that all NDA holders list all other patents related to a new drug product, including the use of the drug product or the method of manufacturing the drug product, in a new book to be compiled by FDA called the "Grey Book." Patents listed in the Grey Book would not require patent certification by generic drug applicants.
- *Provide administrative relief for improperly listed patents.* Congress should authorize FDA, with assistance from the Patent and Trademark Office, to identify and remove improperly listed patents from the Orange Book. As a penalty for submitting improper patents to FDA, the patent holder and NDA applicant should lose the right to enforce the patent against a generic drug applicant.

S. 1172 also purports to address the complex issue of market exclusivity. While clearly an area where there has been a great deal of controversy and litigation, this bill is not the appropriate vehicle for that debate. According to the Hatch-Waxman Act, FDA is to award 180 days of market exclusivity to the first company that seeks to market a generic drug product and, in so doing, challenges the scope or validity of an existing patent covering the brand drug product.

Numerous administrative challenges and court cases have ensued over the statutory provision itself and over how FDA has interpreted it. While the generic industry agrees that Congress should address the confusion by clarifying the meaning of the 180-day exclusivity provisions, the limited provision proffered in Section 2(b) is inadequate. The proposed amendment would not begin to address the numerous and complicated fact patterns that have arisen to make this section of the Hatch-Waxman Act such a controversial matter. It also does not provide relief for companies that have invested based on the current reading of the law. Only prospective application of solutions to these questions would be equitable for the generic industry and a benefit for consumers. Without prospective application, the delay in introduction and cost savings to consumers could be very significant.

The generic industry believes that these are only a few of the areas where the Hatch-Waxman Act could be clarified, strengthened and expanded. However, these complex issues require measured consideration and complete, knowledgeable debate. Amending significant provisions of Hatch-Waxman, which is what is proposed in S. 1172, would occur without the benefit of such a comprehensive debate. It is bound to produce further inequities, disrupt innovation, and harm patient access to new and more affordable medicines, all in the name of extending the patent protecting Claritin from competition.

Even though S. 1172 attempts to resolve procedural flaws contained in earlier proposals and tries to provide some a very limited benefit to some generic companies, it still fails what should be the fundamental test of any legislation affecting federal drug policy—namely, will this proposal benefit consumers by encouraging innovation while ensuring affordability or will it simply protect a product from competition? Schering-Plough has not demonstrated a true injustice that would support such an upset of the Hatch-Waxman balance.

THE PROBLEM WITH IMITATION

Success in moving S. 1172 will breed imitation. There is no reason to believe that the proposed legislation will not be amended to provide other companies with additional patent relief. In fact, some brand pharmaceutical firms have made it clear that they will attempt to amend this legislation to provide patent relief to other products should it be considered seriously by Congress. Thus, one of the real dangers of S. 1172 is its inexorable and inevitable disruption of the Hatch-Waxman Act, opening the door for the ultimate reversal of the most significant consumer health care access and savings act in history.

SUMMARY

In closing, I would like to pose a question, and then answer it. What will happen to Schering-Plough if they are unsuccessful in getting Congress to extend their Claritin patents? The answer comes directly from Schering-Plough's Chief Executive, Richard Jay Kogan. In a story published in the Wall Street Journal on June 28, Mr. Kogan is quoted as saying that his company had several add-on patents on Claritin that may protect the drug for years beyond 2002, when the first patent expires on the chemical compound. The story went on to note that the "company was in late-stage human testing of desloratadine, a metabolite of the chemical in Claritin, whose patents expire in 2004 and 2014," and as such Schering-Plough is in a "good position to compete on its own and isn't interested in a merger at this time."

It is our hope that when Congress considers the issues of federal pharmaceutical policy, the debate will not focus on how to construct a process designed to achieve only one outcome—the endless preservation of one company's product monopoly. Instead, we urge that the focus should be on how to protect the public health policy issue of balancing brand pharmaceutical research and development with the introduction of new generic medicines, and the economic balance of rewarding innovation while promoting competition.

The American people would be better served by a debate on ways to extend access to affordable medicines, such as looking for ways to expand the benefits of the Hatch-Waxman Act. Some examples might include closing loopholes, speeding approvals, and expanding coverage to new classes of drugs such as biotechnology products.

Today, the biotechnology industry is unique in the pharmaceutical industry in that it does not have generic competition. There is no explicit regulatory pathway for generic biotech approval, despite the fact that a number of blockbuster biotech products are already off patent or will be by the turn of the century. Not only would consumers and government purchasers benefit greatly from the cost savings attributed to generic biotech products, but allowing new competition from generic manufacturers would serve as an incentive for the biotech industry to innovate the next generation of biotech drugs. In this way, we could save money for all consumers, rather than tax consumers to the benefit of select companies.

When you look at the headlines from the past several months, the cost of pharmaceutical products is of paramount concern to a broad, bipartisan group of legislators deeply concerned about the ability of Americans to afford their medicine. The generic industry encourages Congress to turn its back on this debate over special interest legislation and focus instead on the more important discussion over how to give every citizen access to the medicines they need.

The brand and generic industries agree that affordable medicines are the key to longer, healthier and more productive lives. Let us work together with you to re-

solve the problems of dispensing medicines to all Americans, including the underinsured and uninsured, and not waste time debating the dispensation of special corporate favors that drive up the cost of medicines. We urge the Committee to reject S. 1172. I am happy to answer any questions.

The CHAIRMAN. Well, thank you. We certainly have differences of opinion on this matter, but that is what makes this place interesting as far as I am concerned. And as the author of the Hatch-Waxman bill, I am very concerned about these areas. I am always concerned about equity and fairness both ways.

Frankly, as I heard the testimony today, especially the way that Jerry Meyer and Peter Hutt tell the story, I am not clear in my own mind whether Senator Torricelli's bill should be thought of as a Hatch-Waxman reform measure. Perhaps the question here is should the Congress enact a process to provide relief for certain pipeline products. It seems to me that is the question. This process would be governed by standards that are applied by experts.

So let me ask each of you, do you believe that pipeline drug issue and the way this bill attempts to address it is actually a legitimate exercise by Congress of the law of equity or should it be considered as part of a more general discussion of the Hatch-Waxman reform?

Why don't we start with you, Mr. Hutt, and then why don't we go to Ms. Ben-Maimon, Mr. Meyer, Senator Metzenbaum, then Bruce Downey and then Dick Kogan?

Mr. HUTT. Senator, let me state unequivocally this is not an attempt to reform the 1984 Hatch-Waxman law, nor have any of the seven prior statutes enacted to provide specific, equitable relief to one, or in one case a class of five patents, been attempts to reform the basic 1984 statute.

This is a pure equitable relief bill targeted to solve a problem because a statute was enacted with very broad objectives and very broad terms, the original Hatch-Waxman Act. And no one back in 1984 could have anticipated this kind of inequitable result. And so what Congress has had to do—this is not the first time, as you pointed out—is to enact specific legislation each time one of those inequities surfaces.

Here, this is a process rather than a product-specific bill, and I believe very strongly, as I stated in my prepared statement, that a process is much better. We will find out, in response to Mr. Downey, whether, in fact, there was a lack of due diligence on the part of the seven companies involved or whether they were engaging in due diligence.

The CHAIRMAN. So you are saying they would have to prove their case within this process?

Mr. HUTT. They must prove their case.

The CHAIRMAN. Within this process?

Mr. HUTT. Yes.

The CHAIRMAN. Ms. Ben-Maimon?

Dr. BEN-MAIMON. I would like to answer the question on three specific points. First of all, I think it is very clear that the generic industry clearly does not endorse patent extension. We believe that the expiration of those patents is actually what stimulates research and development.

The CHAIRMAN. But you do agree that patents are important in order to stimulate investment to begin with?

Dr. BEN-MAIMON. No question about it.

The CHAIRMAN. OK.

Dr. BEN-MAIMON. But this is not a request necessarily for a guarantee of patent life, which they already have at 21 years. It is a request to guarantee market life; that because of what is occurring during the regulatory process, there should be a guaranteed market life for products. And that is very different than the extension of patent and the protection of intellectual property rights, which we clearly believe are exceptionally important.

The intent of Hatch-Waxman clearly included in its concept the encouragement of research and development, and allowing patents to expire actually stimulates some of that research and development. So it is important that patents, in a timely manner—and clearly when is the question—are permitted to expire so that research and development is encouraged and aging products don't just remain on the market forever.

From the standpoint of the process itself, the issue here is that in order for a process to be fair, it needs to understand the technical nature of the review process. It needs to understand and take into account what are the motivators of the innovator, why are things being changed. And the PTO clearly doesn't have the expertise to be able to evaluate the processes at FDA.

Should we be granting extensions for products that there is a choice made during the regulatory review process to switch a formulation that actually delays the entry of market willingly by the innovator? I am not sure about that. Or should we be encouraging them to bring the product to market, especially if it truly is an advantage for patients over what is currently on the market? I don't know that we should be allowing them to make switches in formulations and things like that for drugs that we clearly want to have on the market.

And, last, I think 1172 also does try to address some of the issues that we do consider important, such as the Orange Book issues which clearly get at the heart of Hatch-Waxman. And I think in other hearings this has been likened to the unraveling of a button, and I think we have to be very cautious when we start to unravel that button. We start to change things that were clearly discussed and negotiated and we can unravel the button to the point where it falls off.

And I would hope that we take these issues in the context of what is good for patients and what is good for the public health, and look at them separately from a patent extension which is clearly what the intent of the bill was originally.

The CHAIRMAN. Thank you.

Jerry.

Mr. MEYER. Thank you, Senator. I certainly did not intend, Mr. Chairman, to suggest that this bill or whatever form it finally takes would be viewed as a Hatch-Waxman reform bill. That is not my intent at all. I think that legislation was extraordinarily helpful and I think it continues to be so today.

But I also believe there have been and there will always be a few outlier products that will have faced very extenuating circumstances. And there ought to be a process, and that is what I saw was a process being created that at least permits open public

consideration of that issue. That is how I see that legislation, and I don't think it is limited to a few products in the past. I think it will probably include a few products in the future.

There was one just recently. A constituent of yours, Senator, that was involved in obtaining approval faced circumstances that were certainly not anticipated—that is probably the kindest thing I could say—at the time the application was reviewed, and then extended by well over a year after an advisory committee has recommended approval, 19–0. So I believe there will always be a few of these products around and they will surface, and unfortunately no one could ever write legislation that would cover every conceivable circumstance. So I am hopeful that a process will be created that will provide at least public consideration of those kinds of issues.

The CHAIRMAN. Thank you.

Senator Metzenbaum.

Mr. METZENBAUM. I think, Mr. Chairman, the question before the committee is what is equitable and fair to the consumers of this country. The focus should be on public policy and how to contain high drug prices.

Now, let's face it. This company has been incredibly successful and able in its effort to extend its patent. Part of the reason for its delay originally was that it had switched from a capsule form to a tablet form during the process of going through the approval. And had they not done that, the process would have moved much more rapidly. But Schering-Plough, I give them double-A for being persistent and being determined because even coming in the middle of the night with an amendment to an appropriations bill, they attempted to get an extension.

The real question is what is the right thing to do for the American consumer. This company has been treated fairly, very fairly by the Congress and by FDA, and now I think they are just being a bit hoggish in wanting to extend their patent which, as I previously stated, cost the American people an additional \$11 billion, according to an impartial source.

So, Mr. Chairman, I say to you as the author of a piece of legislation that was major legislation—the Hatch-Waxman Act was not just a piddling bill; it was a major piece of legislation. This is an effort to hang onto that, move forward and say, well, yes, but now we want an exception, we want to make another \$11 billion, or whatever the actual number is, by getting an exception.

And I just say to you, Mr. Chairman, and I urge upon you, you and I have differed at times on various issues, but on the matter of fairness we have never differed. And in this instance, the Congress and the FDA have been very fair to this company and I think they are just being rather hoggish in now asking the Congress to see to it that they can exploit the American public for an additional sum of about \$11 billion.

The CHAIRMAN. Thank you, Senator.

Mr. Downey.

Mr. DOWNEY. I think it is clear that this bill as written is not a Hatch-Waxman reform or an expansion piece of legislation. I do think from our perspective in the generic industry, there are a number of issues that we would like to see taken up. Principal

among those would be the expansion of Hatch-Waxman to biotech products, to biologics. There is no clear regulatory pathway to get a generic biotech product approved. We think that is a logical expansion. That is the kind of subject we think should be taken up rather than an ad hoc bill that benefits one or two companies.

The balance was struck between innovation and competition, 40, 50 issues resolved. There was compromise on both sides. To reach out and move one item from the pro-competitive side and move it over to the innovation side as an ad hoc approach, we think that is wrong. If we are going to approach it, we should do it on a comprehensive basis.

The CHAIRMAN. Thank you.

Mr. Kogan, we would like to hear your viewpoint.

Mr. KOGAN. Thank you, Mr. Chairman. The issue under consideration is to provide a fair and open process at the Patent Office to determine whether certain pipeline drugs—and here we are just limiting it to seven drugs—lose valuable patent time due to unanticipated regulatory delays. So I think this is clearly an issue of equity.

But let me comment on some facts I think that have not been correctly presented to the committee, Mr. Chairman. I want to talk about the 17 years of patent protection, the 20 years of patent protection, and I think somebody mentioned the 23 years of patent protection that Claritin has received. That is really misleading.

We have received, if Claritin runs to its normal patent life—we will receive 9.2 years of effective patent protection; that is, from the date we introduced the product, we will have 9.2 years of patent protection, not 17, not 20, not 23.

Furthermore, if we are successful in our attempt here, if S. 1172 is passed by the Congress, if we prevail at the Patent Office, if we then prevail on appeal in the Federal judiciary, we will gain 3 more years of patent extension which will give us an effective patent life for Claritin of 12.2 years. That is less, Mr. Chairman, than the average patent life drugs received in the 1980's. That was 12.6 years.

So even if we go through the hurdles that are being set up here, even if we are successful in passing legislation, even if we are successful in the Patent Office and successful in the Federal judiciary, we still will receive a total effective patent life that is lower or less than the average of those products approved in the 1980's.

The CHAIRMAN. But you are saying that you have to prove your way all the way up that tree?

Mr. KOGAN. That is right, sir.

The CHAIRMAN. And you could lose at any time on the way up?

Mr. KOGAN. Well, that is correct.

The CHAIRMAN. Even under this bill?

Mr. KOGAN. Yes, and even if we win all the way, we will have less effective patent protection for Claritin than the average product approved in the 1980's. So it is clearly an issue of equity.

Just one other comment. It has been referenced here that there was an effort on Schering-Plough's part to delay approval of Claritin by, well, different vehicles. I mean, that is nonsense. We worked absolutely diligently and hard to get this product approved. We were in a competitive race to get it approved and we worked hard.

The issue of bioavailability—I can explain that, but just let me say that we don't market this product in 46 countries in capsules. We market it pretty much the same way we market it in the United States, in tablet form, because that is the presentation that consumers like and that is the presentation that is safer in terms of product tampering, which was an issue, as you all will recall, back in the late 1970's and the 1980's.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, this whole area has always interested me. It is a very, very interesting area, and there are the two competing sides, plus the generic industry competing. Anything that is done has to be fair. But as I understand it, Claritin was approved in 1993. Let me just make sure I am right on these issues. It was approved in 1993 and its primary patent will expire in 2002. Am I right on that?

Mr. KOGAN. That is correct, sir.

The CHAIRMAN. OK, so that gives you a marketing exclusivity period of 9 years?

Mr. KOGAN. Yes, sir.

The CHAIRMAN. Now, under today's patent law the patent term is 20 years. Let me just ask you, Mr. Meyer, this. What is the effect of a legal and regulatory system that renders important pharmaceutical patents with a market exclusivity period of 9 years as opposed to a widget that has 20 years? Does that affect a company's ability to raise capital and invest in research and plan their future business strategies?

Mr. MEYER. Well, I certainly think it would. You know, I was here as a representative—

The CHAIRMAN. It seems to me that is one of the issues here.

Mr. MEYER. I mean, you know, it has to. You know, I work, Mr. Chairman, for both generic and innovative firms now.

The CHAIRMAN. Right. Well, that is why your testimony is very important here.

Mr. MEYER. This is a delicate balance that people try to do, and that is why I see the process as such an important process so they can at least have their views considered. But, you know, the current patent system is difficult from a pharmaceutical point of view because you file for a patent without ever knowing when you will be able to begin to achieve the protection of that patent, and that happens when the product is finally launched.

Another firm that I worked with, as a matter of fact, faced an issue where they had built a manufacturing facility for millions and millions of dollars for a product whose review time was extended and extended and extended—it was an antibiotic—to the point where the firm had to make a decision as to whether it was worth to pursue because by the time they got approval, they wouldn't even be able to get back the money for the building they built that would never be used.

So you can be very squeezed in the way our patent process is set up, and somehow I hope that the right committee will take a look at some point at some combination of marketing exclusivity and patent protection to establish it for when the product is approved and to start there so it will be equal for everyone. That is the position I argued. I am not an attorney, so I don't know how to craft

that. When I was at FDA—and I still believe that is the only ultimate fair way to resolve that.

The CHAIRMAN. Well, thank you. My time is up, but I would like to ask you and Peter Hutt and Dick Kogan this because you are for this bill, as I see it. Former Patent Commissioner Lehman and Judge Randy Rader of the Federal Circuit have proposed that Congress consider assigning the role of fact-finder with respect to pipeline drugs to the Federal Court of Claims.

Do you have any opinions on the advisability of this recommendation? If you could answer it really quickly, I will go to you.

Mr. MEYER. I don't have opinions on that issue, Mr. Chairman. I heard those arguments. I don't have a personal opinion on that.

The CHAIRMAN. Mr. Hutt.

Mr. HUTT. Senator, I believe that would be an unproductive approach. First, we need something that can be resolved very quickly because for these seven—

The CHAIRMAN. That is why you want the Patent Office to do it?

Mr. HUTT. That is exactly right.

The CHAIRMAN. Then there would be an appeal to the Federal circuit court?

Mr. HUTT. Exactly, but if this were given to the judiciary, particularly to a court that has thousands of cases in backlog, it is highly unlikely the court would ever even hear the case before the patent is expired. So we need an administrative process.

Second, I don't believe that litigating this in court is the best way to resolve the issue. We need an independent, neutral administrative tribunal that can look at the entire record; can ask questions of FDA, of the company, of the generic industry; put it together quickly and resolve this in a matter of months. This is, I think, easily the best way to do it.

The CHAIRMAN. Mr. Kogan.

Mr. KOGAN. I have nothing to add to that, Senator.

Mr. METZENBAUM. Mr. Chairman.

The CHAIRMAN. Yes.

Mr. METZENBAUM. Let me just add one word in view of these comments.

The CHAIRMAN. Sure.

Mr. METZENBAUM. If there were to be some procedure, certainly under no circumstances should the determinative body be the Patent and Trademark Office. It ought to be FDA, where the original jurisdiction lay. At least they have some cognizance of what is right or wrong. I am not advocating that that be the solution, but I am saying that if the chairman and others should conclude to go forward, then I certainly think that the idea of giving the Patent and Trademark Office the authority with respect to this determination is absolutely the wrong place to put it. They don't have the background for it.

The CHAIRMAN. What do you think of that, Mr. Meyer?

Mr. MEYER. Well, I think the FDA should certainly be a party to the proceedings and provide information. But you must understand that when some of these applications are delayed, it is in part because of things the FDA has done. And I suppose I would

worry about the FDA being so defensive of their actions that they would be less than partial.

The CHAIRMAN. One of the actual parties then, if you took Senator Metzenbaum's view, would be making the determination.

I have taken too long, but I have got to ask this. Why, Howard, do you have such a lack of confidence in the PTO? I mean, I have a lot of confidence.

Mr. METZENBAUM. Not for matters within their normal jurisdiction, but I don't think they know anything at all about this subject.

The CHAIRMAN. But they would have to deal with FDA as one of the interested parties, as well as in this case Schering-Plough and the genetic industry.

Dr. BEN-MAIMON. But, Senator Hatch, confidentiality is a major issue here.

The CHAIRMAN. I see.

Dr. BEN-MAIMON. The genetic industry doesn't have access to any of the documentation at FDA.

The CHAIRMAN. I see.

Dr. BEN-MAIMON. So unless FDA is able to play a major role, you will have no equity.

The CHAIRMAN. I would presume they would play a major role.

Mr. MEYER. I envision they would.

Mr. KOGAN. I think the issue is one that should be described as due diligence. I mean, that is the original basis of the Hatch-Waxman Act is that a company pursued its approval with due diligence. You need an independent party.

The CHAIRMAN. And if the FDA is not doing its job—

Mr. KOGAN. Yes, sir, you need an independent party. The FDA may be embarrassed, may be concerned about the role they played. And we don't want to point the finger at anyone. We don't want anybody—we are not pointing blame.

The CHAIRMAN. So it is more a question of equity, what should be done?

Mr. KOGAN. Yes, it is an issue of equity. The Patent Office has been looking at patent extension since 1984. It is not new to them.

The CHAIRMAN. Yes.

Mr. KOGAN. They have been doing this as part of their role under the Hatch-Waxman Act. It is an independent body. It can react quickly. The patent commissioner said it is an appropriate thing for the Patent Office to look at, and so it seems like a fair and equitable place.

The CHAIRMAN. Let me go to Senator Schumer.

Senator SCHUMER. Thank you, Mr. Chairman.

Senator SESSIONS. Well, Mr. Chairman, I will have to leave. Could I have 1 minute?

The CHAIRMAN. Could I let him ask a couple of questions and then I will turn to you, because I know he has to go?

Senator SCHUMER. Sure.

Senator SESSIONS. I will just share the thought that Randy Owens, the lead singer and writer from the group Alabama, asked me recently—he said, do you believe in private property? And I said yes. He said, protect my songs. I know you share that view. [Laughter.]

The CHAIRMAN. Yes, but not enough of you are buying those songs. [Laughter.]

Senator SESSIONS. I think Senator Torricelli's bill has really, Senator Metzenbaum, emphasized public interest a lot more than the House bill has, and I feel pretty good about it. I do not suggest for one moment I am capable of deciding this matter, and I wouldn't begin to.

The CHAIRMAN. Well, that is what has been happening. Congress has been deciding these matters, and you have the two very at-odds sides and we get into a fight every time and I feel like I am right in the middle all the time. You know, I would like to be fair to everybody.

I am sorry to interrupt you.

Senator SESSIONS. Well, I would just like to introduce for the record former Surgeon General, Dr. Koop's support for this, and a letter from Mr. Lehman, Assistant Secretary of Commerce for Patents and Trademarks. They may be part of the House record, but may not be part of this.

The CHAIRMAN. That is fine.

[The information referred to was not submitted.]

Senator SESSIONS. I am sorry I will have to leave, Mr. Chairman. Thank you for your leadership.

The CHAIRMAN. We understand. Thank you.

Senator Schumer.

Senator SCHUMER. Thank you, Mr. Chairman, and I appreciate the testimony and I appreciate everything that you are doing here, Mr. Chairman. Let me give you my thoughts on this and then ask people to comment.

First, it is my view, Mr. Chairman, that if you had to choose a law during the last 20 years that has probably had the most impact on average people with the least amount of people knowing about it, it is Hatch-Waxman. The law has allowed for the creation of a vibrant generic drug industry. It has saved the consumer billions of dollars. At the same time, it has maintained the balance between brand and generic pharmaceutical firms so that brand name companies are still profitable—in fact, more profitable than ever—and they have ample incentives to conduct research and development into new drugs.

Since the passage of Hatch-Waxman, pharmaceutical R&D has increased from \$3 billion to \$21 billion. So, obviously, these folks are doing it because they think they can make money under that regime, and that is fine. God bless America. Schering-Plough, the company that is testifying today, was recently mentioned in a news article, for instance, as being close to a vaccine for AIDS, and we all pray you are successful in that. So Hatch-Waxman has worked extraordinarily well.

And one thing I would just add, Mr. Chairman, is even though 20 years was the full time in Hatch-Waxman, the average drug was supposed to get, and does get about 12 years. There is a difference, but it is not that great a disparity as 9 to 20 would be; it would be 9 to 12.

But in my view, the balancing act which Hatch-Waxman achieved has become more precarious over time, and that is because those with a vested interest in this complicated law have

used, shall we say, innovative means. With the same innovation they use to produce drugs, they have been very innovative at trying to get around Hatch-Waxman and delay the entry of cost-saving generic drugs onto the market. They have been very good at finding new ways at market exclusivity.

So if you look at the Claritin case in a vacuum, I can understand why Schering-Plough feels they deserve a patent extension. They were in the pipeline during Hatch-Waxman. It put them in a hazy category, a little less than everybody else gets. And rightly or wrongly, the FDA took a long time to approve Claritin, so they have had less time with an exclusive product than the typical drug. So I believe that saying that Schering-Plough is simply being greedy, as some opponents have argued, is an oversimplification. That is not what I would say.

But we are not in a vacuum. Branded drug companies routinely list additional and sometimes inappropriate patents in the FDA's Orange Book to complicate and frustrate the generic drug industry's ability to develop a competing product and get it to market. The citizen's petition, originally intended to ensure that generic drugs are safe, has been abused, in my judgment, to delay the approval of a generic drug firm's application with the FDA. And there have been numerous attempts to pass rifle-shot amendments in the dark of night without hearings to extend a patent for a drug.

So I am concerned that simply allowing, Mr. Chairman, Claritin and these six drugs to have a few more years is more of the sort of ad hoc-racy which has threatened Hatch-Waxman. So I have a suggestion. I believe that after 15 wonderful and highly effective years of Hatch-Waxman, it is time to modernize the law. It is time to restore the certainty for both sides, branded and generic, so that there is a definite period of market exclusivity after FDA approval, not different than what some have suggested. Maybe it is 10, maybe it is 12. I don't know. We could pick an amount of years that we thought was fair, with a balance, but it is a different period with a definite end date where generics can enter the market with no delays; no more of this Orange Book, no more of the citizen petitions, no more ways to extend the period beyond the other way.

I would support an extension for a handful of drugs like Claritin which got less, provided there were limits to prevent other drugs from getting more. And when Mr. Kogan came to my office, he gave a very good presentation and then I asked him would he support a change on the other end. And to his credit to the fidelity he has to his fellow manufacturers, he said I couldn't say that. So I am a little frustrated here.

Are we going to come and do this because there is a good reason on one side? But when there is a good reason to let the generic go ahead on the other side, we all know—you know it well, Mr. Chairman; you are the champion of this. The generic industry doesn't have the clout to do the cut-off for individual drugs. They are not going to come here and say, OK, drug "x" has more than the 12 years; they would have 16 by what they have done with the Orange Book or the citizen's petition.

So let's put it all together. Let's reexamine Hatch-Waxman. Let's come up with a set period of years that might give some relief to these drugs which have too short a period, but prevent other drugs

from getting too long a period. I think that would make the most sense.

I am reluctant to vote for this bill if it doesn't include broader reform. I am reluctant to say that this one case should get an exception when we are going to find other instances everyday where maybe even Schering-Plough itself, but certainly other companies, are going before the FDA, are going before other things, and trying to get more than the 12 years through what I would consider, to be charitable, things that were never intended by Hatch-Waxman, such as use of these citizen petitions to actually extend the life of drugs.

So, in conclusion, Mr. Chairman, I have sympathy for the makers of Claritin. I will keep an open mind should this bill move forward, but I hope that we also take this opportunity to realize that after 15 years of great success, it is a tribute to you, Mr. Chairman. I think that is one of the 10 laws that has been passed in the last 15 or 20 years that really has made this country a better place and done just what we wanted—new breakthroughs, lots of money going into R&D by a great industry, the pharmaceutical industry, but at the same time making those drugs, after the reward for all the research, available to people.

I guess to sum up my position, to deal with the unfairness on one side of the equation without dealing with the unfairness on the other side of the equation might well be unfair. And so I have said my little piece here, but I would like the views particularly of those who advocate this particular piece of legislation, Mr. Meyer, Mr. Hutt and Mr. Kogan, about what I said about putting this in a bigger package to prevent the abuses on the other side.

The CHAIRMAN. I think I am going to invite Senator Schumer to come with me to Iowa this next weekend and tell people about Hatch-Waxman—

Senator SCHUMER. You deserve it, Mr. Chairman.

The CHAIRMAN [continuing]. And how much we have benefited consumers all these years.

Senator SCHUMER. You deserve it.

The CHAIRMAN. I appreciate your kind remarks. I think it is really a very important bill, but it hasn't solved all the problems. No bill solves all the problems, but at least it comes close, but I wish we could get everybody together some way or other.

Senator SCHUMER. Well, that is just what I would say. So in the remaining period, I would like Mr. Meyer, Hutt and Kogan to comment on what I had to say about doing it all in one package and being a little fair on the other side, too.

Mr. MEYER. I would be very supportive, Mr. Chairman, of a fixed period of exclusivity, or whatever you want to call it, that begins at the date of approval. I would be very supportive of that, sir. I was when I was at FDA, and was ineffective in the position I was in to be able to see that through.

Senator SCHUMER. Well, I hope I won't be able to say the same about myself a few years from now.

Mr. HUTT. Senator Schumer, we are obviously dealing with two quite different issues here this morning. On the one hand, you and many others have raised the concept of structural reform of both the patent law and the generic drug approval system. That is a

very complex matter that I assure you is not going to be resolved in a short period of time. It is not on the table today.

What we are dealing with today is the last seven drugs. There are no others for people to come in and talk about. So when people say, well, this is just the beginning, no. This is the end.

Senator SCHUMER. No, no. I disagree with you strongly, Mr. Hutt, and that is not a way to win me over because you can say that this particular inequity should be dealt with by itself. I want to know how we are going to deal with some of the other inequities, such as citizen petitions. To me, since I am, and we are on this side of the table elected officials, politicians, trying to balance interests, I would tell you if I let this horse go out of the barn, you may never get a chance to rope in the others.

Now, do you believe that there are abuses on the other side? Just answer that, if you would, yes or no.

Mr. HUTT. I do not.

Senator SCHUMER. OK, then we are not on the same wave length.

Mr. HUTT. And I will tell you why I do not, and let me explain very clearly. It happens I invented the citizen petition process when I was chief counsel for FDA, and that process depends upon FDA handling those citizen petitions in a forthright, effective way. What is the problem isn't the citizen petition process. What is the problem is FDA's lack of resources to provide responses.

Now, just because there is delay at FDA doesn't mean it is the agency's fault. It isn't the fault of the person who submitted the petition. It isn't the fault of anyone there. It is the fault of our system of not having adequate resources at FDA. I will stand here and defend the citizen petition process as a process, as being the height of American democracy. If you can't petition your Government to take action, then there is something wrong in America.

So, yes, the process works. It is the implementation because of resources that is the problem, and you are not going to solve that by another statute. That is not the problem. If this were an appropriation committee, then we could begin to address that problem.

But let me turn back to where we were because there were some important points, I think, that have to be addressed. You are raising structural reform of the entire system. You can't just take one little thing like the citizen petition or another little thing—it is not little, it is large, as Jerry Meyer was talking about, the date when a patent begins to run. This is all part of a continuum. It is going to require several years of hearings, debate, intellectual thought about the best way to approach this.

To hold these seven last drugs hostage to that process, I think, is the height of inequity. We ought to decide for these seven drugs are we going to be fair or not. Are we going to have a process that will decide whether there was due diligence or not? And we ought to get this off the table and then we can approach structural issues of the entire statute.

Now, people have said this is a tax on the sick and the elderly. I look at this totally differently. What this does is provide funds so we can develop drugs for the sick and the elderly. If we don't have pharmaceutical process, if we don't have an industry willing to invest in the future research for our dread diseases in this country,

then we are going to be stuck forever where we are today with the same diseases claiming the same number of lives every year. We are dependent on research and we are dependent on profits. We are dependent on the profits of these seven drugs.

Senator SCHUMER. No one is disputing that. The dispute is where you find the equilibrium.

Mr. HUTT. That is correct.

Senator SCHUMER. And I would say this to you, in all due respect, sometimes it is better to look at the forest than the trees. You are looking at the trees, these seven little trees. I would argue to you that the forest here is the same exact argument—you can't separate the two—which is how long, how many years should a drug have once it is on the market—let's even define it that way, which is the way you would want to define it—and be protected from competition. That is the issue, at least the way I look at it.

Again, I haven't had the years of looking at it in detail that you have, but I think it is a pretty sound way to look at it. I could re-term what you are saying as, well, to say that we should deal with it when the period is too short separately from dealing with it when the period is too long, I don't buy it.

Mr. HUTT. Well, I am not suggesting that we should.

Senator SCHUMER. Well, in effect, you are, sir.

Mr. HUTT. No, I am not because the period—we are not arguing here for these seven drugs for a period that even remotely approaches either 17 or 20 years. We are arguing for a period that would bring these drugs—

Senator SCHUMER. Mr. Hutt, in all due respect, there are pharmaceutical companies right now filing all sorts of extended petitions before the FDA to get 17 to 20 effective years. That is what is happening right now, not on these drugs but on others, as we speak.

Mr. HUTT. But what you are suggesting then is we treat these drugs inequitably because other people are doing something that Congress may not agree with. That doesn't seem right.

Senator SCHUMER. No; I am saying for the greater good—and my concern is not one company; my concern is having, as you say, a balance between consumer prices and the ability of somebody to recapture years of hard work, which I agree with. I believe in intellectual property very strongly. It is at the core of my beliefs. And to find that balance, you ought to find it in macro, not just looking at this little piece.

The CHAIRMAN. Well, it is true that there is a cap of 14 years under Hatch-Waxman, as I recall.

Mr. HUTT. Yes, Senator.

The CHAIRMAN. And so we do have—

Mr. HUTT. There is a cap.

Senator SCHUMER. But it can go beyond that when people file petitions.

The CHAIRMAN. Only if they can make an equitable case, as I understand it.

Mr. HUTT. That is true, and there is no question that Senator Schumer is right that some citizen petitions are not handled as quickly as they should be, just as some NDA's are not handled as quickly as they should be. But that isn't resolved by a statute.

The CHAIRMAN. You are saying that would be resolved if we would give FDA the—

Mr. HUTT. The adequate resources.

The CHAIRMAN. I have always felt strongly about that, but we have failed to do that up here. It is our fault more than anybody else's.

This has been a very interesting exchange, but I want to give Mr. Downey a chance to respond.

Mr. DOWNEY. I would like to respond to Senator Schumer's points because I think they are really at the core of our objection to this legislation. This legislation, given its best reading, is an ad hoc address of a problem that some people perceive in the Act. We disagree with whether that is a problem or not on the merits, but clearly we think there are problems in the Hatch—Waxman Act, things like the unavailability of a regulatory pathway for biologics; the unavailability of a regulatory pathway for nonabsorbed drugs; the Orange Book listings that Senator Schumer mentioned where, in fact, we are improperly, we think, delayed from market entry.

So we see great inequities in particular provisions of the statute, while we see overall equity in the statute as a whole. So I think it is clearly wrong to take an ad hoc approach to pipeline drugs and move it around and do something there without addressing all of the problems that we see in the Act. So I support Senator Schumer's approach to this.

The CHAIRMAN. This has been a good discussion.

Senator Torricelli, we will turn to you. I have to leave for a minute, but if you will—

Senator TORRICELLI. We will proceed immediately to a vote, then, Mr. Chairman. [Laughter.]

Senator SCHUMER. It might be tied.

The CHAIRMAN. Listen, any time we talk to the Senator from New Jersey, we have to be very, very careful is all I can say.

If you would allow me time to get back in, I would appreciate it.

Senator TORRICELLI. Thank you, Mr. Chairman. I have clearly succeeded in providing an unprecedented amount of unity on this subject, since everyone has had criticism of my bill. It didn't actually concern me until Senator Sessions spoke at length in endorsement of the Torricelli bill and I noted—perhaps I was the only one who did—it is actually the Torricelli-Sessions bill.

Senator SCHUMER. It was noted, it was noted. [Laughter.]

Senator TORRICELLI. First, let me just suggest to Senator Schumer's point, I not only agree with some of his thesis, but I attempt to accomplish some of his points in writing this legislation as someone who is both sympathetic and supportive of the generic drug industry. It was noted that in addition to the process that has been established, Orange Book certification and the *Mauve* decision have been addressed in this legislation because indeed there is some need for systemic reform.

Hatch-Waxman, I agree with Chuck Schumer, is remarkable legislation that has impacted the health and the finances of almost every American family. But 15 years is a long time. No one, even the distinguished chairman of this committee, could have the kind of foresight to anticipate all problems and every way in which this industry would be impacted by the legislation.

So if in some small measure by this legislation, or whatever vehicle ultimately is approved by this committee, we can address assorted other problems, I believe we should take the opportunity to do so. I believe in some small measure I have done so. Nevertheless, it is always a problem in legislating to make the perfect the enemy of the good. I would like a broader vehicle, I would like to deal with these problems, but I would like to not do so much in one vehicle that in the end we accomplish nothing, including dealing with the potential injustice of these seven specific products, which is before this committee with a deadline that is approaching. That is a problem that is before us.

Now, I know that I have been in enough of these hearings that no matter what is said or no matter how much testimony we give, there are several inaccuracies that will come through the reporting of the hearing. And in a vain attempt to deal with those, though I know nothing will come of my efforts, I would like, Mr. Kogan, to ask several specific questions to you.

What guarantees are provided to Schering-Plough as a result of this legislation on patent extension?

Mr. KOGAN. Senator Torricelli, there are clearly no guarantees. Senator TORRICELLI. None?

Mr. KOGAN. None whatsoever.

Senator TORRICELLI. If this bill is passed, your assurance that Claritin gets a single day of patent extension amounts to nothing?

Mr. KOGAN. That is correct, sir.

Senator TORRICELLI. And whom is the burden of proving that there is a need, a just end for patent extension? Where does that burden lie?

Mr. KOGAN. As I understand it—and, of course, you know, Senator Torricelli, I am not a lawyer.

Senator TORRICELLI. We make allowances in this committee.

Mr. KOGAN. Thank you. The burden in the Senate bill rests on us, and I think that is quite unfair, sir. I would much prefer, if I might—I know you didn't ask this question, but the House bill—

Senator TORRICELLI. I didn't, and you are breaking my whole rhythm here, but that is all right. [Laughter.]

Senator SCHUMER. Did the dress rehearsal go like this? [Laughter.]

Senator TORRICELLI. It really didn't. We need new consultants here.

Can I get back to the House bill? It is in my sequence here. One, there is no guarantee. Second, the burden is entirely on you to prove the justice of your application, and the standard of proof that is before you is "clear and convincing."

Mr. KOGAN. I understand that that is the highest standard of proof.

Senator TORRICELLI. Now, if indeed the FDA disagrees with your application or believes that you have not met a clear and convincing standard, the legislation has provided for the commissioner to be able to enter the process and be heard, is that not correct?

Mr. KOGAN. That is correct, sir.

Senator TORRICELLI. Now, the commissioner then can make his or her own case as to whether or not they believe you have met the burden of proof. Now, even if they do so, and then even if the

Patent Office is in agreement with your case, there is then a third hurdle you face, is that not correct, in an application to the Federal court?

Mr. KOGAN. That is correct.

Senator TORRICELLI. So indeed not only does the legislation not give you a guarantee, but you have no guarantee because you may not meet the burden of proof. You have no guarantee because the FDA Commissioner may not agree with you and may meet their own burden. And then you have no guarantee because there may be an application to Federal court which finds a contrary judgment.

Mr. KOGAN. That is correct. Now, not to break your rhythm, but even if we make it through the Congress and even if we make it through the Patent Office and even if we prevail on judicial review, we will still get less effective patent life for Claritin than the average drug approved in the 1980's.

Senator TORRICELLI. Mr. Kogan, I am getting to this now. [Laughter.]

Mr. KOGAN. Sorry, Senator.

Senator TORRICELLI. Therefore, you have four of these independent hurdles over which you must pass. So clearly there is not only no guarantee, but indeed an arduous process through which you have to go. And indeed for those who will write this about Claritin, and indeed as we now have for the record, there are seven potential drugs that have dealt with this.

Now, even if you pass these four hurdles and meet this burden and you succeed, the total amount of time, then, under this patent would compare how with other pharmaceutical products under Hatch-Waxman?

Mr. KOGAN. The effective patent life for Claritin, if we succeed, would be 12.2 years.

Senator TORRICELLI. And how would that compare with other products?

Mr. KOGAN. The average, I am told, is 12.6 years, so it is less.

Senator TORRICELLI. So if we pass this legislation and everything goes in your favor and every burden is met, the net result is you still have less patent life than otherwise is provided under the legislation?

Mr. KOGAN. Correct, sir.

Senator TORRICELLI. Now, in spite of this extraordinarily thoughtful legislation which I believe gives you a very fair opportunity, it is my information that you actually still prefer the House equivalent, is that correct?

Mr. KOGAN. Yes, sir.

Senator TORRICELLI. Could you explain why?

Mr. KOGAN. Well, I think the number of hurdles we have to go through here are sufficient. They ought not to be added on by higher standards than I understand were required in the original Hatch-Waxman bill.

All we are saying is we believe we acted with due diligence. We believe we acted with appropriate resources and in an appropriate period of time to solve the scientific issues with Claritin. We were held up unduly for a long period of time at FDA. We are not pointing a finger there. That was an issue of priorities and resources. So all we think we have to prove to make this issue a very clear

issue, rather than get a lot of lawyers involved and a lot of terminology, is did we do what we were supposed to do. Did we diligently pursue the approval of this drug at the FDA? That ought to be the hurdle we have to get over.

Senator TORRICELLI. Mr. Kogan, thank you very much. I just want to conclude again by making an offer both to the chairman and to Mr. Schumer that I am very concerned that the continuing potential in the generic industry for the availability of products and the price competition be as available as possible. And if, in drafting this legislation to deal with this significant but individual problem, there are other ways to improve this process, I certainly want to be available to do so.

Finally, Mr. Chairman, I neglected when I actually began and introduced Mr. Kogan at the beginning of this hearing to welcome Senator Metzenbaum, for which I apologize. While he may not be here to endorse my legislation, I endorsed most of the legislation that he has brought before this committee in his career, which has been a remarkable achievement for the people of our country.

Mr. METZENBAUM. Thank you.

Senator TORRICELLI. Also, Senator Metzenbaum, if, in the process of passing this legislation, there are other ways for consumers, for generics, or for other interests that we can make this more responsive and deal with other related problems, I am only too glad to work with you.

Mr. METZENBAUM. Thank you.

Senator TORRICELLI. Mr. Chairman, thank you very much.

The CHAIRMAN. Well, thank you very much. Frankly, this has been a good hearing today. I hope that we can all agree on at least one thing, that the Judiciary Committee presented a balanced view of this issue. Without objection, I will hold the record open for an additional week so that any interested party may provide written comments on this important issue.

Now, I wish to thank each of the panelists. I think you all did a tremendous job, and I hope that we can all continue to work together and exchange views as the legislative process continues. It is critical that we agree on one thing. We must be guided by what is in the best interest of the American public, and I am convinced that everybody on this panel shares that exact goal.

Frankly, I think that the proponents of this legislation, including our colleagues, Senators Torricelli, Sessions and Ashcroft, have done a good job. They have made a good-faith effort in putting this bill together. I also believe that the critics of this legislation, some of whom are with us here today, have made some valid points. I plan to stay involved as this legislation continues to be reviewed by Congress. And who knows? Maybe this Congress and the affected parties will give consideration to Senator Schumer's proposal. Frankly, he is coming at it from a view that a lot of us have shared for a long time, and I am concerned about every one of these issues.

We should not be against Schering-Plough's rights here just because they are a very successful company. They are, and I commend you for the leadership you have provided. If they haven't been treated fairly in this process, Howard, we ought to look at that. To be honest with you, if we don't have correct patent term

extensions, we are not going to have the innovation and the products that we want.

On the other hand, it seems to me what you are saying here is you want a chance to present your case. You may not win it, but you at least want a chance to present it. Howard is concerned about having the PTO handle it, but to be honest with you, I have a lot more confidence in the PTO, Howard, than you do. And I don't think it is particularly an organization that is going to go one way or the other on this issue. I would think that they would take this pretty seriously.

I would have to believe, as Jerry Meyer says, that the FDA would play a significant and very important role in this process in every case, probably making it pretty tough for companies like Schering-Plough to present their case. So if I haven't misconstrued this, of course, Ms. Ben-Maimon and Mr. Downey are concerned about getting these matters out to the public in a less expensive form so that the public—and Howard feels this way, too—can save money. We have to balance these interests. They are all good interests. And, Mr. Hutt, there is hardly anybody in the industry who knows more about this subject than you. So this has been a great panel.

I am very concerned about these issues because year after year we have had people coming to the Congress wanting to resolve these issues. I know, Senator Metzenbaum, there were a couple of times when you went along with a couple of extensions. All of us have, because it seemed equitably right. Now, a 9-year patent process versus the average of a 12 on its face looks like something is wrong here, even though you have been successful, and you have a right to be successful.

So I am going to look at this as clearly as I can. I am going to ask each of you to give us any additional remarks or suggestions that you have for us. I am going to look at what Senator Schumer has to say because there may be some way of buttoning this down so it works better for everybody. But I have to say I agree with Senator Schumer that when we did the drug price competition and patent term restoration bill, the Hatch-Waxman Act, it was one of the toughest things I ever did. I mean, it was a solid 2 weeks, 18 hours a day, and I had a root canal right in the middle of it and I threatened to kill every one of the people who did not cooperate in getting that thing done. Finally, we did.

And nothing is perfect, but that bill has saved consumers a considerable number of billions of dollars since 1984, but there are some inequities that still exist. And on its face, Mr. Kogan, it appears that there is an inequity in your case. Now, Mr. Downey feels that there is not. Well, you ought to both have a chance at presenting your case, it seems to me.

Now, I am going to look at it. It is awfully hard for me because every one of you at this table is a close friend. I don't know you, Ms. Ben-Maimon, very well, but I am very impressed with your testimony, and it is clear that you are a very effective person for Teva Pharmaceuticals. But all the rest of you have been friends for a long time and I just want to do what is right. So, just help us to do it. We will keep this record open, and if we need further hearings, I think this is significant enough that we can do it. But,

frankly, this hearing kind of covered it all, all of the respective points of view.

The question is can we find some way of putting this together so that everybody at least is somewhat satisfied, like we did with the Hatch-Waxman bill. Everybody was somewhat satisfied, everybody was somewhat disappointed, but in the end the bill has worked. I am hoping that we can solve these problems, and I wish you all great luck. As someone who has wanted to see the generic industry be very successful and works hard to try and do that, I wish you luck, certainly, as well. But as somebody who has watched what Schering-Plough has gone through, I have got a lot of empathy for you, no question about it, and you ought to have a chance to present your case. The question is how can we provide that best opportunity and a fair opportunity, with both sides being able to present their cases—or all sides would be a better way of saying it because it is more than just generics versus mainline pharmaceuticals. It is the FDA, it is the consumers, it is a lot of different people.

So it has been a great hearing. I want to thank each of you. I appreciate the comments that you have made and we will certainly think these things through even more. Last but not least, I would like to make sure that those out there who have comments on this or who believe that they can add to what has been said here today that you will submit—we will keep the record open until Friday for any additional comments or any additional written remarks.

With that, we will adjourn until further notice.

[Whereupon, at 12:44 p.m., the committee was adjourned.]

A P P E N D I X

ADDITIONAL SUBMISSIONS FOR THE RECORD

PREPARED STATEMENT OF HON. EDWARD BRYANT, A U.S. REPRESENTATIVE IN
CONGRESS FROM THE STATE OF TENNESSEE

Thank you, Mr. Chairman, for providing me with the opportunity to journey to the other side of the Capitol in order to present my views on the important issue before you. It is, indeed, a pleasure to have the opportunity to visit again with a number of my former colleagues from the House who have exchanged one view of Washington for another.

I would like to commend one of those former House members, Senator Torricelli, for his commitment to fair patent treatment for pharmaceutical products and for his support of an independent process to review possible inequities in the patent treatment of pipeline drugs.

But before I do so, Mr. Chairman, I also would like to acknowledge your leadership on this issue over the years. I want to emphasize that, despite my belief that we need a process to review the patents of some pipeline drugs, I consider the 1984 Hatch-Waxman Act a monumental achievement. It has helped spur pharmaceutical research and also enabled consumers to experience the benefits of this research in a more timely fashion.

We are here to discuss S. 1172, Senator Torricelli's proposal to establish an independent process within the Patent and Trademark Office to review the status of seven pipeline drugs that faced significant delays in the regulatory approval process. While the bill differs in some respects from the Bryant-McDermott measure, we are in accord on the core proposal.

This effort is about three principles—fair play, equity, and removing politics from the patent process. We believe in fair and equitable treatment of all involved in this issue—both in the regulatory process and in the independent review process that we and Senator Torricelli propose. Importantly, the review process would be a public process open to all interested parties and—by taking it out of Congress—we would provide for a decision on the legal merits.

Hatch-Waxman, as you know, limited patent restoration for pipeline drugs to two years, which was intended to deal with a Food and Drug Administration approval time that averaged slightly more than 2.25 years. But it later turned out that several drugs were caught in the regulatory approval pipeline much longer.

Since 1984, Congress has occasionally enacted specific legislation to deal with inequities discovered in the implementation of Hatch-Waxman. In each case, Congress concluded that the general rules adopted in 1984 were insufficient when applied to a particular situation. But Representative Jim McDermott and I, and more than [50] cosponsors from both sides of the aisle, have concluded that Congress needs a better way of addressing regulatory delays that have diminished the useful life of a pharmaceutical patent. We believe that Congress needs to enact a *process* to handle these issues rather than tackling each situation on an *ad hoc* basis.

Our approach—and I believe this is true of Senator Torricelli's proposal as well—is based on two worthwhile principles. One principle is that patents are an important incentive for research and inventions. The second principle is that Congress should not make patent extension decisions on a case-by-case basis.

First, there is no question that our prosperity in America is built, to a great extent, on research and development. Patents foster that research. In fact, the relationship of R&D and patent integrity is one of mutual dependence in which each fosters the other for the benefit of us all. We know that those who conduct pharmaceutical research help provide one of the best patient protection policies that we can

buy as Americans. Just ask anyone who has benefited from the healing powers of a new breakthrough pharmaceutical. At the same time, we also know that R&D can be expensive. This is particularly the case when it comes to pharmaceutical innovations. Without strong and fair patent protection, research-based pharmaceutical companies would not have the incentive or the wherewithal to continue research that would lead to tomorrow's breakthrough drugs.

The second principle involves the necessity of establishing a fair, consistent process to protect the integrity of patents. In this context, it is vitally important to say what H.R. 1598 and S. 1172 would *not* do. They do *not* automatically extend a patent. Rather, they would establish a fair and open process that is conducted in a public forum. This would be an independent, non-political review. These bills would apply to seven pipeline drugs than spent over 60 months in the FDA's New Drug Approval process. All affected parties would be able to make their case before the appropriate body—the PTO, an independent agency whose experts deal with the legalities of patent issues day in and day out.

I believe strongly that these bills fulfill the intent of Congress. The record since 1984 is clear. When Congress passed Hatch-Waxman, it believed that there would be relatively quick FDA approval for drugs that were in the approval "pipeline" at the time. In fact, that did not occur. Because of lengthy regulatory reviews, many pipeline drugs received substantially less patent coverage than Congress intended. Often in Washington we talk of "unintended consequences." Hatch-Waxman truly involves a case of unintended consequences. But they are consequences that, nevertheless, should be dealt with.

Mr. Chairman, I am gratified that H.R. 1598 has attracted so many co-sponsors—Democrat and Republican alike. I also am gratified that Senator Torricelli has introduced parallel legislation. I think this support demonstrates that there is widespread and growing support to enact a fair, independent process that protects patent integrity.

In sum, Mr. Chairman, I believe these bills have identified the right solution. It is a solution that provides patent integrity and, in so doing, ensures the continuation of research that leads to breakthrough drugs and other innovations that truly help people live longer and better lives. Thank you.

PREPARED STATEMENT OF HON. JIM McDERMOTT, A U.S. REPRESENTATIVE IN
CONGRESS FROM THE STATE OF WASHINGTON

I am pleased that the Senate Judiciary Committee is taking the time to review the facts behind the Drug Patent Term Restoration Review Procedure Act of 1999. I have sponsored similar legislation in the U.S. House of Representatives, H.R.—1598—the Patent Fairness Act, and I appreciate the opportunity to share with you the reasoning behind the proposal.

The Patent Fairness Act encompasses three principles—fair play, equity and taking politics out of the process.

Maintaining the integrity of our system of patents is central to whether or not our society continues to receive the desired public benefits from pharmaceutical research—or any other type of cost-intensive research for that matter.

Creating a fair and impartial process where an independent body can determine whether or not to restore lost patent life is a matter of fairness. And it is the right thing to do. It also is a matter of ensuring adequate incentives for research and development in the future.

This bill takes the first step in attempting to find a long-term solution to the patent integrity issue that is impacting several drugs that were caught in a review process that took significantly longer than Congress anticipated.

As a result of this lengthy delay, the patent life of these "pipeline" drugs—drugs that were at FDA for more than 60 months—was reduced by an unintended consequence that had nothing to do with their medical safety. I believe that the developers of these pharmaceuticals deserve to have their grievances evaluated in a fair and impartial manner.

There are two important questions: What type of process can we put in place to guarantee a fair and reasonable evaluation of the issues? And, what types of assurances should be embedded in this process to make sure it is equitable and removed from politics?

H.R. 1598 answers these questions. Our bill establishes a process that is fair, equitable, independent, separated from politics, fully open to the public, and subject to judicial review. Let me expand on these features.

The bill establishes an independent and public review process within the U.S. Patent and Trademark Office. This would be a new administrative procedure—one that is fair and impartial.

The Patent and Trademark Office is the right place to hold a hearing about these issues, because these issues involve questions not of medical research, but go to the core of the definition of patent life.

Within the office, a procedure would be established to review claims for patent term restoration to compensate for unanticipated lengthy regulatory review of five years or more in the FDA's New Drug Approval proceeding.

The process established by this legislation would be akin to a court hearing.

Any company that believed its product was unintentionally deprived of patent protection would have the opportunity to present its case. Any other interested party would also be free to make its case. Both sides would be treated equally.

Everything would occur in the open. The review board would be bound by objective criteria. And, after an opinion has been rendered, each side would be allowed *an additional opportunity* for judicial review.

Now contrast the process H.R. 1598 would establish with the way things usually work around here. Patent extensions—regardless of their merits—are snuck into a bill in the middle of the night, by some Congressman or Senator, regardless of the consequences. I disagree with that tactic and I think it's a lousy way to legislate.

By turning over the issues of patent integrity to an independent panel of experts, as H.R. 1598 would do, the process would be driven by public policy objectives—not politics.

This is an important point. Our bill is driven by the principle that it is best to take politics out of the equation, to de-politicize the process, to take Congress out of the job of deciding individual patent issues.

And finally, our legislation would require the Commissioner of Patents and Trademarks to evaluate the review procedure established by the bill and report to Congress.

Another way to describe the legislation is to outline what it does not involve.

There is no preferential treatment for any affected pipeline drug. There are no arbitrary decisions. There are no guarantees. Our bill is about process, not about a predetermined outcome.

There is one more point that I would like to make that strikes at the heart of the argument being made by the generic drug industry against the Patent Fairness Act. They argue against a fair and open process to resolve patent disputes because they feel that if a party wins its case before the PTO and then its case survives judicial review, the American consumer will then be harmed. Well, I hope that you keep an open mind about this claim. The idea that generic drug makers—copiers of prescription drugs developed by pharmaceutical companies—offer lower prices to consumers should NOT be assumed as fact.

For example, last December the Federal Trade Commission filed an unprecedented \$120 million suit against Mylan laboratories for its conspiracy to hoard pharmaceutical ingredients. The hoarding, according to the FTC, led to more than a 3,000 percent increase in the cost of a hypertension generic drug and more than a 2,000 percent increase in the cost of an anxiety drug.

Due to Mylan's actions, the cost of a bottle of pills rose from \$11 to \$377 a bottle, for a drug which the company did not spend one research dime to develop but copied from one of its competitor's. So to say that the generic industry is somehow a victim of any attempt to look at the fairness of our current patent system in protecting the rights of companies that spend billions of dollars to develop life saving drugs is dearly a stretch of the truth.

I am convinced that the Patent Fairness Act—or similar legislation that also initiates an equitable process to resolve patent disputes—is the right solution. As a medical doctor and psychiatrist, I have seen the benefits of breakthrough drugs and innovations. They truly can make people's lives better, and there is more to do.

Thank you.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF PHARMACEUTICAL
MANUFACTURERS

The National Association of Pharmaceutical Manufacturers (NAPM) is a national, not-for-profit trade association representing manufacturers and distributors of finished, multi-source generic pharmaceuticals, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic drug industry. NAPM appreciates the opportunity to submit this testimony

to the Senate Committee on Judiciary regarding S. 1172, the “Drug Patent Term Restoration Review Procedure Act of 1999.”

We believe it is ironic that as this Congress debates ways to reduce the high cost of prescription medications to the elderly and Medicare Reform, we are here today to discuss S. 1172, which would grant special-interest patent extensions of up to three years to eight brand name drug products.¹ S. 1172 denies the American consumer the choice of selecting a more affordable generic version of these brand products. According to a recent study by the PRIME Institute of the College of Pharmacy at the University of Minnesota, a three-year delay in generic competition for Claritin, the drug that would most benefit from S. 1172, would cost consumers \$7.36 billion from 2002 to 2012. (See attached report.) There would also be a tremendous fiscal impact on government programs offering a drug benefit, such as Medicaid and programs offered by the Veterans Administration and the Department of Defense.

This being said, by this testimony, NAPM will demonstrate that S. 1172 would, in fact:

- Increase the cost of prescription medicines by foreclosing generic competition;
- Undo the delicate, agreed-to compromise and policy decision essential for the passage and success of the Hatch-Waxman Act of 1984;
- Establish a procedure for extending patent terms, despite the fact that the need for a procedure outside of Congress, much less the need for the bill itself, has not been satisfactorily demonstrated; and,
- Offer a gesture at Orange Book reform that would have a minimal benefit because the reform would be limited to the eight pipeline drugs.

In short, NAPM strongly opposes S. 1172. The bill would not be a constructive way to reopen a successful law that put public health concerns, and not company pocket-books, first.

In 1984, the U.S. Congress fairly balanced all the interests of the pharmaceutical industry and consumers by passing the Drug Price Competition and Patent Term Restoration, Act of 1984 (Hatch-Waxman Act). This law created a framework for patent term extensions and non-patent exclusivity periods for brand name drug products and a system for speeding the Food and Drug Administration (FDA) approval of generic drug products. As a result of the Hatch-Waxman Act, generic competition entered the marketplace, which in turn served to motivate the brand name industry to innovate the next generation of life-saving drugs. Since 1984 brand name drug companies’ profits and research and development expenditures have grown exponentially. The generic drug industry has enabled American consumers and taxpayers to save billions of dollars in the purchase of medicines, while creating new jobs and investment opportunities in every region of the country.

During the negotiations that led to the Hatch-Waxman Act, it was agreed by all parties, including the brand name industry, that brand name drug companies would receive up to a two-year patent term restoration for so-called “pipeline drugs”² instead of up to a five-year patent term restoration granted for later developed products. Patent term extensions were more generous for future development rather than for pipeline drugs because a purpose of the Hatch-Waxman Act was to encourage future investment.

Representative Henry Waxman, the co-author of the Hatch-Waxman Act, recently stated on the House floor that the difference in the maximum times of patent term restoration was far from arbitrary. He stated “the pipeline drugs were not made eligible for five years of patent extension precisely because the point of the patent extensions was to encourage the research and development of future products.”³ This explicitly demonstrates that the decision to grant a two-year extension to the pipeline drugs was a carefully considered policy decision to create a process which has proven successful in assuring high-quality research and development in conjunction with providing access to affordable pharmaceuticals in a competitive marketplace. With S. 1172, certain brand name companies, led by the Schering-Plough Corporation, are selectively attempting to undo the policy decision struck in 1984—the policy that all sides agreed to—in order to extend their monopoly periods at the ex-

¹The eight drugs are Claritin®, Eulexin®, Nimtop®, Relafen®, Dermatop®, Penetrex®, Cardiogen-82®, and Daypro®.

²A drug for which a patent had been issued and an investigational new drug application (IND) or a new drug application (NDA) was pending at FDA before the enactment date of the Hatch-Waxman Act (September 24, 1984).

³Congressional Record, H4220, June 14, 1999.

pense of competition, consumer savings, and healthcare costs without a corresponding benefit to the consumer.

S. 1172 purports to put eight pipeline drugs on an equal footing with later developed drugs products, a result that was clearly not Congress' intent. Specifically, S. 1172 would permit the holder of a patent that was in force as of 1984 and remains in force today the opportunity to seek additional patent life by filing an application with the Patent and Trademark Office (PTO). A product meeting these criteria and whose NDA was under review by FDA for at least 60 months would have its patent term restored for up to three years, assuming the PTO determined that "granting the patent restoration would not be detrimental to the public interest and the interest of "fairness" as defined through five factors set forth in the bill.⁴ These factors require a very subjective determination of what the result of a patent extension would be. These factors do not take into consideration delays in the FDA approval process that are due to the company's internal decisions (*e.g.*, Schering-Plough's decision to switch from capsule to tablet form after clinical trials were completed) or instances when FDA should fully and completely explore concerns (*e.g.*, when carcinogenicity concerns arise.) While S. 1172 is not the out-and-out grant of a three-year extension that H.R. 1598 is, S. 1172 merely sets up a few more hoops for the brand name companies to clear. One only needs to witness the vigor with which Schering-Plough is pursuing the passage of S. 1172 to determine what Schering-Plough believes the outcome for their Claritin application would be.

S. 1172 would place the responsibility for extending patent terms for the pipeline drugs with the PTO. The PTO lacks the expertise to evaluate the FDA decision-making process to determine if there was due diligence on the part of the company, and the bill does not appear to require an examination of the company records. While S. 1172 would allow for FDA consultation, NAPM believes that FDA is best equipped for any evaluation of due diligence.

S. 1172 would provide compensation to a generic applicant with an application pending at FDA for one of the pipeline drugs at the time of enactment. In fact, S. 1172 is generous enough to double the amount of compensation granted under H.R. 1598. A generic applicant would be entitled to compensation of \$2 million from the patent owner. A holder of a Type II DMF that has permitted a reference to its DMF in such an application would be entitled to compensation of \$1 million from the patent owner. The patent owner's liability would be capped at \$10 million to drug applicants and \$5 million to DMF holders. This provision is yet another thinly veiled attempt at an appearance of "fairness," but in reality there is nothing fair about this provision to the generic applicant, the DMF holder, and the consumer. The generic industry is committed to bringing quality generic medicines to the public, not receiving remuneration in exchange for "correcting" brand name companies' "unanticipated" delays.

S. 1172 offers a gesture to the generic drug industry by making modest reforms to the Orange Book. Unfortunately, these reforms are limited to the eight pipeline drugs' listings in the Orange Book, and, therefore, do little to thwart the brand name industry's abuses of the Orange Book. The bill also attempts to address the widely debated issue of granting 180 days of market exclusivity for generic drugs. S. 1172 does not begin to address the numerous and complicated fact patterns that have arisen to make this section of the Hatch-Waxman Act such a controversial matter. FDA is in the process of revising its regulation on this issue to better reflect the recent related court decisions. Thus, it may be prudent for Congress to address this issue, if necessary, after FDA attempts to clarify the procedures involved.

The extra costs to consumers and taxpayers from this legislation would be enormous. The PRIME study concludes that a three-year delay (from 2002 to 2005) in the availability of generic versions of Claritin if the legislation passes would cost American consumers \$7.36 billion from 2002 to 2012. For all eight pipeline drugs, the estimated total cost impact from delaying generic competition for three years would be \$11.15 billion from 2002 to 2012. The study projects that the government's total share of U.S. outpatient prescriptions, now at 20 percent-25 percent of all prescription expenditures, would increase to 45 percent-50 percent if a Medicare prescription drug benefit is enacted. If S. 1172 is enacted, the cost to the government would be a minimum of \$1.89 billion, with that figure rising to \$5.0 billion if a prescription drug benefit is added to Medicare.

The huge increase in costs to consumers and taxpayers from this legislation would lead to very minimal stimulation of research and development leading to the discov-

⁴The three-year restoration would be reduced by any period in which the applicant did not act with due diligence. In the years since passage of Hatch-Waxman, there has never been a determination of a lack of due diligence by a brand name company with regards to an application for an extension.

ery of the next generation of drugs. By delaying generic competition for three years, the study estimates that Schering-Plough would receive an additional \$9.64 billion from Claritin sales. Based on current research and development spending by Schering-Plough and industry trends, the study estimates that only 3.6 percent of this windfall for Schering-Plough, or \$350 million, would be used for research and development leading to the discovery of new drugs.

While the national association representing the interests of brand name pharmaceutical firms, Pharmaceutical Researcher and Manufacturers of America (PhRMA), has not, to our knowledge, supported or taken any position on this special interest legislation, Schering-Plough has been most vigorous in promoting S. 1172 because it would reap a huge unanticipated windfall by the patent extensions for its blockbuster drug, Claritin, and its cancer drug, Eulexin®. This is not their first money grab. Schering-Plough has pressed Congress on this issue on multiple occasions. Schering-Plough lobbied tenaciously to add this monopoly extension to last year's Omnibus Appropriations Act for fiscal year 1999, an effort that continued until the bitter end despite news reports exposing the provision as another infamous "special interest" rider. Schering-Plough had already attempted to add this extension onto the Omnibus Patent Act of 1997. And, at the end of the 1997 session, there was an effort to award additional market exclusivity for specific products in exchange for a 3 percent royalty payment to the National Institutes of Health, with no prohibition against the companies passing on this royalty payment to consumers.

These mostly behind-the-scenes, secret efforts to secure longer monopoly times were rightly denied by the Congress, but Schering-Plough has clearly not given up—even though it received a two-year Hatch-Waxman extension and a 22.5-month extension under the General Agreement on Trade and Tariffs (GATT), and now is reportedly poised to secure an additional six-month extension for conducting pediatric studies under the Food and Drug Administration Modernization Act of 1997—pediatric studies which the brand name drug industry refused to conduct without a pay-off to them in the form of longer monopolies. These extensions were "unanticipated" by Schering-Plough when it first began development of Claritin. Schering-Plough argues that this legislation is fair because of unanticipated delays in FDA's review of Claritin. If this is the argument, wouldn't it also be fair to reduce any new extension by the lengths of the unanticipated extensions it has already secured?

Schering-Plough has also failed to adequately address openly the reasons why Claritin's review was delayed. Schering-Plough instead has blamed FDA and the reviewers for moving too slowly. While we have no access to internal company documents nor to FDA review documents, trade press articles discussed two reasons for the length of the review time. After Claritin received an FDA advisory committee recommendation for approval on October 23, 1987, Schering-Plough decided to market Claritin in a tablet form as opposed to the capsule form used in its clinical trials. This change—which was purely a marketing decision made by Schering-Plough—raised bioequivalency questions that had to be addressed by FDA. Schering-Plough cannot possibly claim that it was unaware such questions would be raised by their internal decision that they wanted to market a tablet instead of a capsule, and this "delay" cannot be blamed on FDA. By 1991 FDA was examining carcinogenicity concerns with Claritin. Certainly even Schering-Plough cannot fault FDA for focusing on concerns as serious as cancer. FDA's mission is to ensure efficacy and safety, and carcinogenicity concerns cannot be and should not be resolved overnight.⁵

This year a House Judiciary Subcommittee heard testimony from Peter Barton Hutt, Esq., that brand name drug companies had received a maximum two-year rather than five-year patent extension for pipeline drugs under the Hatch-Waxman Act because:

- (1) It was anticipated that pipeline drugs would be approved by FDA shortly, and
- (2) "less of an economic incentive was needed to assure continued pursuit of [pipeline drugs] to final FDA approval."⁶ Mr. Hutt argued that several pipeline drugs were not approved by FDA as quickly as anticipated by the negotiators of the Hatch-Waxman Act. Yet, Mr. Hutt failed to establish that additional patent time was needed as an economic incentive to brand name drug companies to pursue final approval of these pipeline drugs. The fact is, pipeline drugs did not need more than two years of extra monopoly time because the companies making those

⁵*The Pink Sheet*, articles dated October 31, 1986, November 9, 1987, November 27, 1989, June 24, 1991, and April 19, 1993.

⁶Testimony of Peter Barton Hutt, Esq., before the Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary, U.S. House of Representatives, on H.R. 1598, at 6 (July 1, 1999).

drugs were at a point in the review process where it was highly unlikely the development of the drugs would be abandoned. The 1984 Congress obviously recognized this situation and, therefore, passed into law the language which Schering-Plough is trying to undo today. Extending these patent terms would not be consistent with Congressional intent, nor would the establishment of a sham “process” that merely purports to examine the merits of each application.

Schering-Plough claims that it only wants to set up a process. NAPM hopes that the Congress can recognize not only that S. 1172’s version of a process is a stacked deck against consumers and the generic drug industry, but also that a process was created and is still in place under the Hatch-Waxman Act. Congress should send the message now that this special interest legislation is not about intellectual property rights or about fairness and equity. Congress should send the message that it is serious about containing healthcare costs and about ensuring a competitive marketplace to the benefit of all Americans.

Perhaps the brand name drug companies are correct in labeling this issue as one of “fairness” and “equity”—it is not fair and equitable for the Federal Government and consumers, especially the elderly on fixed incomes, to continue to pay inflated prices for pharmaceuticals in a competition-free market. Congress has told Schering-Plough “no” before. Congress must tell Schering-Plough “no” again, for what will hopefully be the final time.

NAPM appreciates the opportunity to present our views.

PATENT EXTENSION OF PIPELINE DRUGS: IMPACT ON U.S. HEALTH CARE
EXPENDITURES

STEPHEN W. SCHONDELMAYER, PHARM.D., PH.D., PROFESSOR AND DIRECTOR¹

EXECUTIVE SUMMARY

Background

- HR 1598 will affect 7 drug firms and 8 drugs worth \$2.7 billion; that is 3.3 percent of U.S. Rx sales in 1998.
- Congress addressed additional exclusivity for the “pipeline drugs” when it passed the Hatch-Waxman Act.
- Pipeline drugs have already benefitted from 2 to 5 years of additional protection from generic competition.
- Drugs covered by this legislation currently have effective patent lives ranging from 6.8 to 13.8 years.

Drug Products Affected

- Claritin™ had sales of \$1.9 billion in 1998, Relafen™ had \$450 million, and Daypro™ had \$300 million.
- There are 45 million allergy sufferers and 40 million arthritis sufferers who may be affected by this bill.
- U.S. sales of Claritin™ (\$1.9 billion) in 1998 accounted for 84 percent of Claritin™ worldwide revenue (\$2.3 billion).
- Claritin™ sales provide 34 percent of Schering-Plough’s total worldwide revenue of \$7.3 billion in 1998.
- The Canadian price of Claritin™ is one-third of the U.S. price for the identical drug from Schering-Plough.
- Claritin™ 10 mg (#30) in the U.S. costs \$54.72, while the same drug costs \$18.34 in Canada (mfg price).

Cost to Consumers from Three-Year Delay in Generic Competition

- A case study of Claritin™ was done to estimate the economic impact of a 3-year delay in generic competition.
- Claritin™ sales are expected to reach \$3.46 billion by 2002 and \$3.78 billion (NPV, 2000\$) by 2005.
- Generic competition for Claritin™ is expected to begin in July 2002; with a delay, it is expected in July 2005.
- Consumer savings from generic competition for Claritin™ is estimated at \$0.70 billion (NPV 2000\$) in 2003; \$1.15 billion in 2004; \$1.55 billion in 2005; \$1.82 billion in 2006; and \$2.01 billion in 2007.
- Consumers can expect to save \$7.33 billion (NPV, 2000\$) from generic versions of Claritin™ in the first 5 years.

¹This study was funded in part by a research grant from the National Association of Pharmaceutical Manufacturers.

- A 3-year delay in competition for Claritin™ will cost consumers \$5.31 billion (NPV, 2000\$) from 2002 to 2007; and \$7.36 billion (NPV, 2000\$) from 2002 to 2012.
- The total cost to consumers from an exclusivity extension for the 8 “pipeline drugs” will be about \$11.1 billion.

Effect on Schering-Plough

- Two Schering-Plough products (Claritin™ and Eulexin™) represent 68 percent of the market value of affected product.
- Schering-Plough’s marketing, advertising & admin. expenses are above industry average (39 percent vs. 25 percent-30 percent).
- Schering-Plough’s R&D expenditures are considerably below the industry average (12.5 percent vs. 20.0 percent).
- This legislation will add \$9.64 billion to Schering-Plough revenue from 2002 to 2012.
- More than 60 percent (-\$5.83 billion) of Schering-Plough’s added revenue will go to marketing, sales, and profits.
- Less than 30 percent of R&D expenditures is typically allocated to discovery of new medicines.
- Less than 3.6 percent of the added costs to the American public is expected to go toward discovery of new drugs.

Effect on Pharmaceutical Firms

- Pharmaceutical firms had higher net profit as a percent of revenue than any U.S. industry group for 20 years.
- The profitability gap between pharmaceutical firms and the median Fortune 500 firm (America’s best corporations) has grown wider since passage of Hatch-Waxman.
- Both R&D expenditures and drug firm profits have shown dramatic growth since the Hatch-Waxman Act.
- The rate of return to pharmaceutical firms is higher than other industries in the U.S., even when risk-adjusted.
- CBO says lengthening patent periods is not the most effective means of encouraging R&D.
- Reduction of FDA review times is a more effective means of stimulating research and development.
- The FDA’s NDA review time has been reduced substantially from >30 months (1984) to 11.7 months in 1998.

Economic Impact on Consumers and Government

- The cost to American consumers from this proposed legislation exceeds \$11 billion (NPV, 2000\$).
- Medicaid will bear about \$1.34 billion of the cost, and other government programs will bear \$0.55–\$1.34 billion.
- Govt. programs will bear a cost of about \$2.5 billion, and with a Medicare drug benefit about \$5.0 billion.
- This legislation will have very real costs in terms of increased pharmaceutical expenditures for Americans.

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PATENT EXTENSION OF PIPELINE DRUGS: IMPACT ON HEALTH CARE EXPENDITURES

I. INTRODUCTION

Legislation has been proposed to extend the patents of a special set of drug entities defined under the Hatch-Waxman Act as "pipeline drugs." The Hatch-Waxman legislation specifically mentioned the set of drugs which had submitted a new drug application (NDA) to the Food and Drug Administration (FDA) prior to passage of the Hatch-Waxman Act, but which had not yet received approval to market from the FDA. When Congress defined this set of drugs, it explicitly indicated that these drugs would have their patent monopoly extended by two years. Proposed legislation (HR 1598) has been offered which would provide an additional patent extension of up to 3-years for these pipeline drugs which have already had patent extensions under the Hatch-Waxman legislation.

The implementation of this proposed legislation (HR 1598) is delegated to the U.S. Patent and Trademark Office (PTO), despite the fact that PTO does not have expertise in either FDA approval procedures or assessment of the economic impact of its actions on public health programs (e.g., Medicare and Medicaid) or consumers. In addition to the patent extension proposed in this act, these drug products have already benefitted from other legislation extending their patent monopoly or market exclusivity periods including:

- (1) Hatch-Waxman Act adding 2 years;
- (2) GATT extensions up to 3 years;
- (3) Pediatric study extensions up to 6 months; and
- (4) Other special-interest legislation extending the exclusivity of drug products (e.g., Daypro™).

Pipeline drugs have already received the benefit of 2 to 5 years of patent monopoly extension from the Hatch-Waxman Act and other legislation. Further lengthening the period of patent protected monopoly for pipeline drugs will create a barrier to the presence of a free market with competition. If legislation is passed to award additional years of patent monopoly to the pipeline drugs, American consumers would experience a delay in the opportunity for savings which result from generic competition in the pharmaceutical-market. The delay of generic competition will result in awarding a "windfall profit" to the pharmaceutical firms whose products are affected by the proposed patent extensions. In other words, pharmaceutical firms stand to benefit from extended patent monopolies, while consumers and payers in health care will experience an increase in expenditures due to lack of competition. Much of this added cost for prescription drugs will be paid by individual consumers such as senior citizens, low income families with no health insurance, and others who do not have prescription drug coverage. Insurers, managed care plans, self-insured employers and corporate sponsors of health benefit plans will also bear some of the cost of this legislation.

The consequences in the pharmaceutical market from additional patent extension for pipeline drugs will include the following:

- (1) The pharmaceutical firms marketing these drug entities will benefit from a "windfall extension" in market exclusivity time;
- (2) The pharmaceutical firms (i.e., generic firms) preparing generic versions of currently patented drug products will face delays in approval and may have added costs due to the delay in market entry; and
- (3) The consumer will have delayed access to lower-cost, generically equivalent pharmaceutical products. While each of these effects deserves substantial analysis, the focus of this study is on the added costs to consumers from a three-year delay in generic approval and market entry.

II. PIPELINE DRUGS AFFECTED BY HR 1598

Eight drug entities will benefit from additional patent monopoly granted by the proposed legislation (HR 1598). Various characteristics of these drug entities are described in Table 1. Collectively these eight drugs accounted for more than \$2.72 billion in U.S. sales at the manufacturer level in 1998 (Table 2). The \$2.72 billion represented by these special-interest drugs is 3.3 percent of the total U.S. pharmaceutical sales in 1998.

Claritin™, the best-selling of these drugs, had \$1.9 billion in 1998 sales and accounted for two-thirds of the total value of the eight pipeline drugs included in this legislation. Claritin™ is indicated for seasonal allergy symptoms. In the United

States there are approximately 45 million seasonal allergy sufferers.¹ This drug could potentially be used by one in six Americans. Claritin's™ U.S. sales of \$1.9 billion in 1998 accounted for 84 percent of the \$2.3 billion reported as worldwide sales for Claritin™. Worldwide pharmaceutical revenue for Schering-Plough Corp. was reported to be \$7.3 billion in 1998.² In other words, Claritin™ provides 34 percent of Schering-Plough's total revenue worldwide.

Relafen™ and Daypro™ are also major drugs with 1998 sales of \$450 million and \$300 million, respectively (Figure 1). Both Relafen™ and Daypro™ are non-steroidal anti-inflammatory drugs (NSAID) used for treatment of arthritis. An estimated 40 million Americans have some form of arthritis.³ Relafen™ has been the number one NSAID (by sales volume) for more than five years and had U.S. sales of about \$450 million in 1998. U.S. Relafen™ sales account for about 88 percent of worldwide Relafen™ sales. Relafen™ provided nearly 12 percent of Smith-Kline Beecham's total pharmaceutical revenue in the U.S. in 1998. Daypro™ became the second-leading NSAID in the U.S. during 1997 and in 1998 produced revenue of about \$300 million.

The other five pipeline drugs are Cardiogen-82™ (Bracco Diagnostics), Eulexin™ (Schering-Plough), Nimotop™ (Bayer), Dermatop™ (Hoechst Marion Roussel), and Penetrex™ (Rhône-Poulenc Rorer). Collectively, these drugs are estimated to have had 1998 U.S. sales of about \$170 million (Table 2). In summary, three pipeline drugs account for 93 percent, while the other five pipeline drugs account for less than 7 percent of the collective 1998 U.S. sales volume for pipeline drugs.

III. PATENT MONOPOLY PERIODS FOR PIPELINE DRUGS

A single pharmaceutical product today may have two, three, or more patents each with different implications for the manufacturer of competing products. Patents may be issued for:

- (1) The chemical composition of the drug entity or intermediate chemical entities;
- (2) One or more processes by which the drug can be made;
- (3) The formulation of the drug product or the dosage form in which the drug is delivered (e.g., a sustained release tablet); or
- (4) A specific medical indication or use of the product.

When the drug product, Tagamet™, went off patent (May 1994) with respect to the principal drug entity, the patent holder (Smith-Kline Beecham) made it known to potential generic manufacturers that it holds at least 26 other patents related to Tagamet and that it intended to vigorously enforce them.⁴ A compilation of drug products and certain related patents can be found in the Food and Drug Administration's publication titled, *Approved Drug Products with Therapeutic Equivalence Evaluations* published by the U.S. Food & Drug Administration (also known as The FDA Orange Book). Process patents are not eligible for listing in the FDA Orange Book.

Although the language of the proposed legislation refers to "patent term restoration", the additional monopoly period proposed is beyond the existing patent term. Furthermore, each of the affected pipeline drugs in this proposed legislation has already had its patent term extended by other legislation. Each of these drugs was granted a 2-year patent extension by the Hatch-Waxman Act. Three of the drugs (Claritin™, Daypro™, and Dermatop™) have also received a previously unexpected patent extension from the GATT legislation which changed the basis for calculating the patent period from 17 years after patent issue to 20 years after patent filing. Three drugs (Claritin™, Daypro™, and Relafen™) have also submitted written requests to FDA for a 6-month exclusivity extension based on the conduct of pediatric studies on the drug. One drug (Daypro™) has benefitted from additional special-interest legislation to further extend its non-patent market exclusivity period.

The pipeline drugs covered by this legislation currently have effective patent lives ranging from 6.8 to 13.8 years and some have an additional 6 months exclusivity for conducting pediatric studies. These periods of market monopoly are typical of the monopoly periods for other prescription drug products and do not suggest that these pipeline drugs have been disproportionately disadvantaged in a manner that warrants further extension of their patent monopoly period. Since each of these drugs has already benefitted from extensions of market exclusivity ranging from 2 to 5

¹ Schering-Plough, *1998 Annual Report*.

² *Ibid.*

³ NIH News Release, May 5, 1998, "Arthritis Prevalence Rising as Baby Boomers Grow Older."

⁴ *Scrip*, No. 1927, May 31, 1994, p. 16.

years, there appears to be no reason to legislate an additional 3 years of market exclusivity for pipeline drug products. Claritin™, for example, has already received about 5 extra years of patent monopoly and market exclusivity extension.

There does not appear to be any “equity” basis for the proposed legislation (HR 1598) which requests up to 3 years of additional patent monopoly beyond the 2 to 5 years of added monopoly already received by these pipeline drugs. To further extend the patent monopoly of these pipeline drugs would put other drug products on the market at a disadvantage. If this legislation is passed, then the other drug companies may request legislation to extend patents on their drug products to be “fair and equitable” compared to the deal the Hatch-Waxman pipeline drugs received.

IV. METHOD FOR ECONOMIC IMPACT ANALYSIS

The purpose of this section is to explicitly describe the methods and assumptions used to estimate the economic impact of additional patent extensions for pipeline drugs proposed by certain pharmaceutical firms. Several aspects of the methodology deserve description and comment including:

- (1) Identification of the drugs affected by the proposed legislation;
- (2) The method for calculating added years of market monopoly;
- (3) The time frame of the analysis;
- (4) The market value and the net present value used to express the cost to American consumers; and
- (5) The expected level of generic market penetration and generic pricing.

A. Pipeline Drugs Proposed for Additional Patent Extension. This analysis is a case study of Claritin™, which represents two-thirds of the economic value of the pipeline drugs covered by this proposed patent extension legislation. Since Claritin™ is such a dominant drug in terms of U.S. sales in relation to the other pipeline drugs, it is assumed that Claritin™ will be responsible for the vast majority of the economic impact of this proposed patent extension legislation. Claritin™ represented two-thirds of the U.S. sales for pipeline drugs in 1998, while the remaining seven pipeline drugs, collectively, generated only one-third of the U.S. sales for the affected drugs. Certainly a 3-year patent extension for Relafen™, Daypro™, and the other five pipeline drugs will also have an economic impact on American consumers.

B. Added Years of Market Monopoly. The legislation proposed by HR 1598 would extend the patent monopoly of Hatch-Waxman pipeline drugs for a period of up to 3 years. Claritin™ is expected to receive 3 years of additional patent monopoly if this legislation is passed.

C. Time Frame of the Analysis. If implemented, the economic impact of the added patent monopoly from this proposed special-interest legislation will be felt by American consumers well into the first decade of the 21st century. The present patent exclusivity period of pipeline drugs extends out as far as 2002. The effect of implementing a 3-year extension of the patent for these pipeline drugs will move the patent expiration date to some time in 2005. The full effect of this legislation requires assessment of the economic impact from delay of generic competition well beyond a 3-year period. The 3-year delay in generic competition means that the savings curve is shifted to the right on the time axis.

This means that the consumer savings from competing generic products will be three years behind where it would have been for every year moving out into the future (Figure 2). Note from the illustration of this effect (Figure 2) that the majority of loss in consumer savings occurs after the first three years of the delay in generic competition. Therefore, any fair evaluation of the impact of this proposed legislation must examine the effect for at least 6 to 7 years beyond the extended patent period (i.e., at least to 2011 or 2012).

Since a 3-year delay in generic competition for the affected drug products will continue to have an economic impact 6 to 7 years beyond the 3-year patent extension, the overall time frame of this analysis should be at least 9 to 10 years beyond the current patent expiration dates. Consequently, an economic impact analysis that uses a time frame of less than 10 years beyond the current patent dates would not capture the full impact of this legislation and could grossly understate the cost of this proposed legislation to the American government and public.

D. Market Value and Net Present Value of Impact. The market value of drug sales reported in this analysis is based on sales at the manufacturer level. By reporting sales at the manufacturer level, the impact of wholesale and retail mark-ups are not taken into account. The focus on sales at the manufacturer level results in under-reporting of the expected effect by about 25 percent. This approach, however,

results in a more conservative and lower estimate the cost of a 3-year delay in generic competition for pipeline drugs.

Net present value (NPV) is a means of reporting economic data over a long period of time so that dollar values are represented in comparable terms. Over time the spending power of the dollar declines. For example, it would take about \$1.42 in 2012 to have the same spending power as \$1.00 in 2000 using a 3 percent inflation rate over that time period. The dollar values reported in the analysis section of this report, unless otherwise noted, have been converted to net present value or constant dollars for the year 2000. For purposes of this analysis, the consumer price index-all items (CPI-all) for urban consumers was used as the deflator to determine the net present value for amounts from all years prior to 1998. An inflation rate of 2 percent was assumed for 1999 and 2000, and 2.5 percent for the year 2001. The inflation rate for 2002 through 2012 was assumed to be 3 percent.

E. Generic Market Penetration and Generic Pricing. Generic competition cannot begin until after each patent listed in the FDA Orange Book (including patents on the drug's active ingredient, formulation, dosage form, or indications for use) has expired, unless the patent is challenged by a generic applicant as invalid or not infringing. In many cases, generic applicants have not challenged basic patents regarding the drug's active ingredient or the indications for use, but they have challenged other FDA Orange Book patents (particularly formulation and composition patents) as invalid or not infringing. Therefore, it will be assumed that generic competition begins after the initial (or "blocking") patent expiration.

This is a conservative assumption which does not take into account other barriers which may impede generic competition, such as tactics used by the original marketer to delay the FDA in establishing a bioequivalence standard, the 6-month exclusivity period awarded to the first approved generic, contractual agreements between the initial patent holder and the first approved generic to delay marketing of that first generic and thereby blocking entry of other generic products, difficulty in obtaining a source of raw material, administrative delays in approval by the FDA, or other factors. This assumption would tend to underestimate the cost to American consumers if generic competition is delayed for several months to several years beyond the expiration of the "blocking" patent.

Two primary factors determine the savings which American consumers can realize from access to generic competition among drug products. First, the penetration of generic drug products into the original marketer's unit volume must be estimated. The generic penetration can be assessed by examining the proportion of units (tablets or capsules) of a given drug product which are filled with generic versions of the drug product. The second factor is the price of generic drug products in relation to the original marketer's price over time. This determines the amount of savings realized for each unit of the original brand which is filled with a lower-cost generic.

Empirical evidence related to these two critical factors, market penetration and pricing of generic products, was examined. An October 1994 market analysis of the generic drug market evaluated the generic pricing and unit penetration of twenty-five major drug products that had gone off patent in the previous few years.⁵ The analysis used data from IMS America, one of the leading sources of pharmaceutical market information used extensively by the pharmaceutical industry, to determine the dollar and unit sales volume for these products from 1989 to 1994. The effect of both generic unit penetration and competitive generic pricing is shown in Figure 3.

Off-patent drug products were found to have lost 3 percent of the units in the first month, 14 percent in the second month, and 21 percent by the third month after generic competition entered the market. After one year generics, averaged 45 percent of the unit volume and at two years generic penetration had grown to 52 percent. The effect of generic competition on prices was measured by examining the average price of generics in comparison to the originator product price over time. Generics entered the market at a price averaging 73 percent of the originator price. By the second month after generic competition, the price was typically at 67 percent of the originators price and at 12 months it was at 55 percent. After two years, the average generic was priced at only 39 percent of the originator's price.

Evidence from the market in the past few years suggests that generic penetration may occur even faster today than it did in 1994. While this is quite likely, use of the 1994 penetration rates would be more conservative in that it would understate the cost to consumers from delay of generic entry into the market.

⁵Jerry I. Treppel and Edward A. Neugeboren, *Generic Drug Industry Overview*, Kidder, Peabody, October 5, 1994).

V. ECONOMIC IMPACT OF PATENT EXTENSION FOR PIPELINE DRUGS

The relevant parties who stand to be significantly impacted by this proposed extension of patent monopolies include:

- (1) Individual Americans who purchase their own prescription medications (about 25 percent to 30 percent of the population);
- (2) Corporate employers who purchase managed care and insured health benefit programs that pay for prescription medicines (about 55 percent to 60 percent of the market);
- (3) Government health programs that pay for outpatient or inpatient prescription drugs including Medicaid, Medicare, the Veterans Administration, Indian Health Service, and others;
- (4) Multinational brand name pharmaceutical manufacturers with pipeline drugs; and
- (5) Generic pharmaceutical manufacturers planning to compete with the brand name product upon patent expiration.

This analysis has focused on economic impact from the perspective of those who pay for prescription medicines either individually or collectively.

A. Cost to American Consumers of Patent Monopoly Extension for Pipeline Drugs. The combined effect of generic unit penetration and competitive pricing can be used to estimate the savings that will result from generic competition in the market, and to estimate the cost to American consumers from the proposed extension of patent monopoly periods of the previously marketed pipeline drugs. The generic unit volume penetration and pricing pattern (Figure 3) was used to estimate the consumer savings expected from the availability of generics in the pharmaceutical market.

To illustrate the economic impact of a 3-year delay in generic competition as proposed in this legislation, Claritin™ was used as a case study. Claritin™ sales since introduction to the market have been quite brisk. In 1993 Claritin™ recorded \$107 million in U.S. sales and then showed a 192 percent increase to \$316 million in 1994. Since then the annual sales growth has been 92 percent in 1995, 52 percent in 1996, 37 percent in 1997 and 42 percent in 1998 (columns A and 6 of Tables 3 and 4 and Figure 4). Sales have been projected forward for Claritin™ assuming a conservative declining rate of growth curve. By the year 2002, Claritin™ should be selling \$3.46 billion (NPV, 2000\$) and by 2005 it should be up to \$3.78 billion (NPV, 2000\$) (Table 4).

The sales revenue for Claritin™ was projected forward to the year 2012 assuming that no generic competition enters the market. Patent 4,282,233 covers the use of Claritin™ for treating seasonal allergies. This patent expires June 19, 2002, but the patent monopoly period would be extended by 3 years under the proposed legislation (HR 1598). The FDA Orange Book also lists other patents with later expiration dates in connection with Claritin™. This study assumes that generic competition for Claritin™ can begin upon expiration of the 4,282,233 patent, and that other patents listed in the FDA Orange Book will not serve as impediments to generic competition.

Therefore, the savings to consumers from generic competition for Claritin™ will begin after July 2002. Savings in the first 6 months of generic competition during 2002 are estimated to be \$94 million (NPV, 2000\$). Then, annual savings will be \$0.70 billion in 2003 and will grow to \$2.52 billion in 2010 (column F of Table 4 and Figure 4). If generic competition for Claritin™ begins in 2002 as would be expected under the current Hatch-Waxman Act and other relevant patent laws, American consumers can expect to save \$7.33 billion (NPV, 2000\$) in the first 5 and ½ years (July 2002 to 2007).

Extension of the exclusivity period for Claritin™, and the consequent delay of generic competition, was evaluated next. Assuming a 3-year patent monopoly extension, as proposed in HR 1598, the impact of generic competition beginning in July 2005 was calculated (Tables 5 and 6). Initial generic competition in the last six months of 2005 would produce consumer savings of nearly \$100 million (NPV, 2000\$) and \$0.73 billion annual savings would accrue in 2006. In 2007 annual savings would be \$1.19 billion and in 2008 \$1.60 billion in annual consumer savings would be realized.

The savings lost by American consumers from a 3-year delay in competition for Claritin™ can be calculated by subtracting the savings achieved each year with a 2005 generic launch from the savings achieved each year with a 2002 generic launch. [Note: this is column F on Table 4 minus column F on Table 6.] The net present value (NPV, 2000\$) of consumer loss from this 3-year delay in generic competition would be \$94 million in the last six months of 2002. The impact will grow

to nearly \$0.70 billion in 2003, and \$1.15 billion in 2004. During the first 5 ½ years (July 2002 to 2007) after this delay of competition, American consumers would pay an additional \$5.31 billion (NPV, 2000\$) and in the next five years (2008 to 2012) will add another \$2.05 billion in cost to American consumers.

To summarize, the cost of this proposed patent extension legislation upon those who pay for prescription drugs is estimated to be \$7.36 billion (NPV, 2000\$) between the years 2002 and 2012 (Figures 5 and 6) for Claritin™ alone. Recall that Claritin™ represents only 66 percent of the market value for the pipeline drugs covered by this proposed legislation. If one extrapolates these Claritin™ findings to the other pipeline drugs covered by this proposed legislation, the total cost to American consumers could reach more than \$11.15 billion. If wholesale and retail margins were taken into account, the total cost to the American public would reach nearly \$15 billion.

B. Benefit to Pharmaceutical Firms from Patent Monopoly Extension for Pipeline Drugs. The eight drugs known to be affected by this special-interest legislative proposal are marketed by seven different firms (Table 1). Schering-Plough Corp. has two drug products affected (Claritin™ and Eulexin™). Not only does Schering-Plough have the most products affected, but these two drug products are 68 percent of the 1998 U.S. market value for the pipeline drugs affected (Table 2).

Claritin™ Sales Revenue. As noted earlier, Claritin™ had U.S. sales in 1998 estimated to be \$1.9 billion and worldwide sales of \$2.3 billion. U.S. sales of Claritin™ represent about 84 percent of Claritin™ worldwide revenue.⁶ If Claritin™ is to receive \$9.64 billion additional revenue because of a 3-year patent monopoly extension, it is reasonable to ask how is this money likely to be used (Tables 8 and 9). One can not always second guess the corporate decisions which will be made in the future, but examination of the distribution of revenue for a company over time can provide some fairly good clues about how a 3-year continuation of monopoly revenues might be used. Annual reports and market information for Schering-Plough were reviewed and the actual distribution of revenues across major expense categories were identified. The expense categories were net profit (after taxes); research and development (R&D); marketing, advertising, selling, and other administrative expense; cost of production (or cost of goods sold); and taxes and other expenses. Although there were minor variations, Schering-Plough showed a fairly consistent pattern for distribution of revenues across these expense categories for the years 1993 to 1998 (Table 7). For purposes of this study it was assumed that a similar distribution of revenues will continue by Schering-Plough in future years.

Schering-Plough Revenue Distribution. Schering-Plough Corp. retained 21.7 percent of 1998 revenues as net profit after taxes, while expenditures on research & development accounted for 12.5 percent of revenue. The cost of production was reported to be 19.8 percent, and taxes and other expenses consumed 7.1 percent of revenue. Finally, 38.9 percent of revenue was spent on marketing, advertising, selling and other administrative expense (Figure 7). It should be noted that Schering-Plough's marketing, advertising, selling and other administrative expenditures are somewhat above industry averages (38.9 percent vs. about 25 percent to 30 percent) and the R&D expenditures are considerably below the industry average (12.5 percent vs. 20.0 percent).⁷

Claritin™ Marketing and Advertising Expense. If Schering-Plough continues these expenditure trends into the future, the majority of the additional revenue (60 percent or about \$5.83 billion) from this proposed legislation will go toward marketing, advertising, selling, and administrative expense or toward corporate profits (Table 9 and Figure 8). Claritin™ was the most heavily promoted prescription drug by direct-to-consumer advertising in 1998. In 1998, alone, Schering-Plough spent an estimated \$172,802,900 on direct-to-consumer advertising and \$81,814,000 on professional promotion of Claritin™.⁸ These expenditures were an increase of 149.8 percent over the 1997 expenditures. Direct-to-consumer advertising may include television, radio, magazines, and newspapers as well as direct mail to consumers.

Claritin™ Price. The U.S. wholesale acquisition cost for a one-month supply (30 tablets) of Claritin™ 10 mg tablets in July 1999 was \$54.72 (US \$).⁹ The Canadian wholesale acquisition price of a one-month supply of the same drug entity in the same strength and the same dosage form manufactured by Schering-Plough was

⁶Schering-Plough, *1998 Annual Report*.

⁷Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Survey, 1998, Table 2, p. 91*.

⁸Taren Grom, *Medical Advertising News*, May 1999, 18(5) p.8.

⁹Price is the wholesale acquisition price for Claritin™ 10 mg tablets in a bottle of 100. PriceChek PC, First Databank, Indianapolis, IN, July 1999.

\$18.34 (US \$) in July 1999 (Table 10 and Figure 9).¹⁰ The Canadian price is just one-third of the price of the same drug product being sold in the United States. Since the cost of production for this drug product is expected to be the same for the product whether it is sold in the U.S. or in Canada, the difference in price must be from other differences in expense such as net profit, administrative expenses, or marketing and advertising expenses.

Research & Development Expense. Schering-Plough Corp. currently spends 12.5 percent of their revenue on R&D. Based on industry standards, less than 30 percent (29.1 percent) of R&D expenditures is typically allocated to research which leads to the discovery of new medicines.¹¹ This would mean that only about 3.6 percent of the additional revenue to Schering-Plough would be used for discovery of new drugs. The actual net present value of this estimate of the R&D expenditure would be as follows:

\$9.64 billion added revenue \times 12.5 percent for R&D \times 29.1 percent for discovery research = \$350 million.

If the intent of this legislation is to stimulate R&D, this is very inefficient legislation because it requires a cost to the public of \$9.64 billion to achieve \$350 million in R&D discovery.

The R&D expenditures of the pharmaceutical industry have been growing dramatically since the time of Hatch-Waxman. A review of the R&D expenditure trend does not show any adverse effect from the Hatch-Waxman legislation. The U.S. R&D expenditures of pharmaceutical firms totaled nearly \$3 billion in 1984 (Table 11 and Figure 10).¹² This expenditure rate had more than doubled by 1990 to \$6.8 billion. From 1990 to 1998 the R&D expenditure rate has again doubled reaching more than \$17.2 billion. The growth in R&D expenditures has been at a double digit rate in all but two years since 1984, the era of the Hatch-Waxman Act (Figure 11). The growth rate of R&D expenditures does not appear to raise questions about difficulty in securing private market funds for R&D investment.

The Congressional Budget Office conducted a study of the Hatch-Waxman Act.¹³ That study concluded that "reducing FDA approval times—if it is done without sacrificing safety concerns—would be much more effective in helping both the drug industry and consumers than would lengthening the patent-protection period."¹⁴ In fact, the FDA has done an excellent job of reducing the review time for new drug applications (NDAs). The average review time for an approved NDA was more than 30 months at the time the Hatch-Waxman Act was passed (1984). In 1998, the FDA averaged only 11.7 months per NDA review—a two-thirds reduction in the NDA review time.¹⁵ This notable reduction of NDA review times by FDA has done far more to provide an incentive for research and innovation than legislation such as HR 1598 would provide.

Net Profit and Return on Investment. Empirical evidence on rewards for innovation indicates that no other industry in the United States is more rewarded than the pharmaceutical industry. According to *Fortune* magazine, the pharmaceutical industry has the highest level of net profit as a percent of revenue of any industry group in the United States.¹⁶ Pharmaceutical firms have been the most profitable industry for nearly two decades, and for two decades prior to that time pharmaceuticals were the second most profitable industry (Table 12). Not only have pharmaceuticals been the most profitable industry, but the gap between pharmaceuticals and the median Fortune 500 firm (America's best corporations) has been widening in the last one and a half decades (Figures 12 and 13). Both the net profit as a percent of revenue and the return on equity have risen dramatically since the mid-1980s, while the growth of other industries has been much more modest. From the Fortune 500 measures of profitability, it would appear that the Hatch-Waxman Act had a very positive effect on the pharmaceutical industry.

Because of the risk involved in discovery and development of pharmaceutical products some analysts have argued that a comparison of profits in the pharmaceutical industry with profits in other industries should be adjusted for risk. A study

¹⁰ Price at ex-factory level provided by pharmacist at a Shoppers Drug Mart, Toronto, Canada, July 1999. Note: Claritin™ in Canada is over-the-counter, but the dosage form and strength are the same as the prescription version in the U.S.

¹¹ Cathy Spence (editor), *The Pharmaceutical R&D Compendium: CMR International/Scrip's Complete Guide to Trends in R&D*, 1997, p. 31.

¹² Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Survey*, 1998.

¹³ Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998.

¹⁴ *Ibid.*

¹⁵ Food and Drug Administration, web site.

¹⁶ Fortune 500 survey results, *Fortune*, April issue for years from 1970 to 1999.

by the Office of Technology Assessment (OTA) included an analysis which used an internal rate of return adjustment rather than the usual accounting rate of return.¹⁷ The OTA report concluded that “the economic rate of return to the pharmaceutical industry as a whole over a relatively long period (1976–1987) shows returns that were higher than returns to non-pharmaceutical firms by about 2 to 3 percentage points per year after adjustment for differences in risk among firms.” The OTA report went on to say “This is a much lower differential than is suggested by conventional comparisons of profit ratios, but it is still high enough to have made the industry a relatively lucrative investment.”¹⁸ During the period (1976–1987) studied by OTA the average difference in net profit as a percent of revenue between pharmaceutical firms and the Fortune 500 median was 5.6 percent. In the years since that study (1988–1998) the average difference in net profit between pharmaceutical firms and the Fortune 500 median grew to 10.2 percent. This growth in the profit gap between pharmaceutical and other Fortune 500 firms would suggest that return on investment in pharmaceutical firms has been even more lucrative in the past decade (the 1990s) than the OTA study indicated for the previous decade (the 1980s).

C. Cost to Consumers and Government from Patent Monopoly Extension for Pipeline Drugs. American consumers will be impacted by this proposed legislation, not only through the cost of medications directly purchased, but also through the cost of such medications to government-related health programs. The current expenditure patterns of Medicaid, and other government programs such as the Veterans Administration and the Department of Defense, indicate that the government pays directly for about 16 percent to 18 percent of outpatient prescription drugs in the United States. If one included federal and state employee health benefit plans, as well as active and retired military personnel with dependents, the government share of outpatient drug expenditures in the U.S. approaches 25 percent or more. Also, there is debate about coverage of outpatient prescription drugs for the elderly under Medicare. The elderly consume 34 percent of the outpatient prescriptions even though they represent only about 12 percent of the population.

The added cost of prescription medications from this proposed patent extension legislation would be borne proportionately by individuals and institutional payers for health care services including federal and state governments. The government has a substantial role in paying for outpatient prescription drugs at present (estimated to be 20 percent to 25 percent), and the future potential for a significant expansion in responsibility for purchase of prescription drugs with Medicare coverage of outpatient prescriptions (another 20 percent to 25 percent). If the Medicare expansion occurs, this would place the government’s total share of U.S. outpatient prescriptions as high as 45 percent to 50 percent of all expenditures.

The economic impact of this proposed legislation was estimated to be more than \$11.15 billion (NPV, 2000\$). Approximately \$1.34 billion, or 12 percent of this amount, would be borne by Medicaid (both federal and state shares). Other current government programs would bear another \$0.55 billion to \$1.34 billion (5 percent to 12 percent of the total impact). Coverage of outpatient prescriptions by Medicare could result in government being liable for an additional 20 percent to 25 percent of the cost of this legislation (\$2.23 billion to \$2.79 billion). In total, the government share of the cost of this proposed patent extension legislation will range from \$1.89 billion to as high as \$5.0 billion, if Medicare drug coverage is adopted.

VII. SUMMARY AND CONCLUSIONS

The proposed legislation sets up a patent extension process for a special set of products known as “Hatch-Waxman pipeline” drugs. At least eight drugs will receive patent extensions from this proposed legislation, purportedly due to inequities resulting from the Hatch-Waxman legislation. The effective patent life of these eight drugs appears, however, to be consistent with the effective patent life of other drugs approved at the time of the Hatch-Waxman Act. These eight drugs would have market exclusivity ranging from 7 to as much as 14 years.

Both R&D expenditures and pharmaceutical company profits have shown dramatic growth since the passage of the Hatch-Waxman Act. Consequently, it is hard to accept the argument that research-intensive pharmaceutical firms have been significantly disadvantaged by this Act. R&D expenditures over the past two decades have grown at double digit rates in most years while the economy and inflation have slowed to low single digit growth rates in recent years. The pharmaceutical industry

¹⁷Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, and Rewards*, February 1993.

¹⁸*Ibid.*, p. 104.

has been America's most profitable industry for nearly two decades. The pharmaceutical industry is more profitable than other industries even after considering a risk-adjusted rate of return. In addition, the gap in profits between pharmaceutical firms and other Fortune 500 firms (the best of corporate America) has grown wider in the last decade.

The major product (Claritin™) affected by this proposed legislation sells for a price which is three times the price of the same product in Canada. If consumers in the U.S. market had access to the same price as in Canada, American consumers would have saved \$1.2 billion in 1998. With passage of the proposed legislation, the projected cost to American consumers from patent monopoly extensions will exceed \$11 billion (NPV, 2000\$) over the next 10 years. The majority of the added cost (\$7.36 billion) will benefit one corporation (Schering-Plough). Less than 3.6 percent of this added cost to the American public is expected to go toward discovery of new drugs, while it is quite likely that more than 60 percent of the total cost (greater than \$6.6 billion) will go for marketing and advertising or for corporate profits.

This legislation would increase barriers to competition and to a free market. Without generic competitors in the market, American consumers will pay higher prices for their prescription drugs. The lower price and high market penetration of generics, when available, results in substantial savings to American consumers. These savings also benefit Medicaid, federal and state government, private insurers, managed care, employers, unions, ERISA plans, and others who pay directly for prescriptions. The cost of this patent extension legislation could add as much as \$1.32 billion in costs for the joint federal and state Medicaid programs and another \$0.55 billion to \$1.32 billion to the cost of other federal and state government health programs.

13 The extension of patent monopolies for these marketed drugs will mean that the introduction of lower cost generics will be delayed up to three years. Therefore, the American consumer will have to pay more for prescription medications. Although the patent extension may have positive benefits for those few pharmaceutical companies whose products are affected, this proposed legislation will have some very real costs in terms of increased pharmaceutical expenditures by Americans. These increased pharmaceutical expenditures will be felt by individual American citizens, by hospital and community pharmacies, by managed care and health insurance plans, and certainly by federal and state government health programs. The impact of this drug legislation will be even more dramatic if Congress adopts some form of coverage of outpatient prescriptions for Medicare recipients.

Table 1
Pipeline Drugs Affected by Proposed Legislation (HR 1598)

Drug Product Trade Name	Drug Product Generic Name	Manufacturer	Patent No.	Woman- Hatch Extension	URAA/GATT Extension	Current Patent Expiration Date	Pediatric Study Written Request	Additional Monopoly Extensions	1998 U.S. Sales	Date of FDA Approval	Years of Patent Monopoly
Claritin*	loratadine	Schering	4,282,233	2 years	22.5 months	06-18-02	6 months		\$ 1,800,000,000	04-12-83	9.2 years
Relafen*	nabumetone	SKB	4,420,639	2 years		12-13-02	6 months		\$ 450,000,000	12-24-91	11.0 years
Daypro*	oxaprozin	G.D. Searle	4,190,584	2 years	5.3 months	08-08-89	6 months	X	\$ 300,000,000	10-29-82	6.8 years
Cardiogin-82*	rubidium cl. RB-82	Bracco Diag.	4,400,368	2 years		08-23-02			\$ 83,000,000	12-29-88	12.7 years
Eulexin*	flumetide	Schering	4,328,364	2 years		05-11-01			\$ 54,000,000	01-27-89	12.3 years
Nimotop*	nimodipine	Bayer	4,408,906	2 years		08-27-02			\$ 21,000,000	12-28-88	13.8 years
Dermatop*	prednicarbate	Hechtel Merion Roussel	4,242,334	2 years	7.1 months	08-02-00			\$ 3,000,000	10-05-83	6.8 years
Penstax*	enoxacin	Rhone-Poulenc Boehr	4,359,578	2 years		11-16-01			\$ 200,000	12-31-91	9.9 years

* Data from FDA Orange Book and from various issues of Medical Advertising News.

Table 2
Market Value of Pipeline Drugs Affected by Proposed Legislation (HR 1598)

Drug Product Trade Name	Drug Product Generic Name	Manufacturer	1998 U.S. Sales	% of Pipeline Drug Market Value	Cumulative % of Pipeline Drug Total Market Value
Claritin*	loratadine	Schering	\$ 1,800,000,000	66.1%	66.1%
Relafen*	nabumetone	SKB	\$ 450,000,000	16.5%	82.7%
Daypro*	oxaprozin	G.D. Searle	\$ 300,000,000	11.0%	93.7%
Cardigan-82*	nibidium cl, RB-82	Breco Diag.	\$ 83,000,000	3.4%	97.1%
Eulaxin*	flumetide	Schering	\$ 54,000,000	2.0%	99.1%
Nimotop*	nimodipine	Bayer	\$ 21,000,000	0.8%	99.9%
Dermatop*	prednicarbate	Hechst Marion Roussel	\$ 3,000,000	0.1%	99.98%
Penetrax*	emoxacin	Rhone-Poulenc Bior	\$ 200,000	0.01%	100.0%
Total Value of Pipeling Drugs from All Marketers			\$ 2,721,200,000	100.0%	100.0%
Total U.S. Pharmaceutical Market (1998)*			\$ 81,289,200,000		
Pipeline Drugs as % of U.S. Pharmaceutical Market					3.3%

* As reported by Pharmaceutical Research and Manufacturers of America in *PhRMA Annual Survey, 1999*, Table 2, p. 81.

Table 3
Claritin™ Annual Sales With & Without Generic Competition:
 Assumes Generic Competition Begins in July 2002 (Current Year \$)

Year	Claritin™ Annual Sales (in Quasi-currency)		B	Claritin™ Sales w/ Generics (2002 entry)		D	Brand + Generic Annual Sales (2002 entry)		F
	A	Annual % Chg.		C	E				
1993	\$ 107,913,000		\$	\$ 107,913,000		\$	\$ 107,913,000		\$
1994	\$ 315,551,000	192.4%	\$	\$ 315,551,000		\$	\$ 315,551,000		\$
1995	\$ 604,236,000	91.5%	\$	\$ 604,236,000		\$	\$ 604,236,000		\$
1996	\$ 915,816,000	51.6%	\$	\$ 915,816,000		\$	\$ 915,816,000		\$
1997	\$ 1,253,869,000	36.9%	\$	\$ 1,253,869,000		\$	\$ 1,253,869,000		\$
1998	\$ 1,780,522,000	42.0%	\$	\$ 1,780,522,000		\$	\$ 1,780,522,000		\$
1999	\$ 2,320,821,011	30.3%	\$	\$ 2,320,821,011		\$	\$ 2,320,821,011		\$
2000	\$ 2,829,643,535	21.9%	\$	\$ 2,829,643,535		\$	\$ 2,829,643,535		\$
2001	\$ 3,277,866,660	15.8%	\$	\$ 3,277,866,660		\$	\$ 3,277,866,660		\$
2002	\$ 3,647,851,441	11.3%	\$	\$ 3,647,851,441	189,527,154	\$	\$ 3,547,736,209	100,115,233	\$
2003	\$ 3,985,333,508	9.3%	\$	\$ 3,985,333,508	923,563,182	\$	\$ 3,226,486,094	758,847,415	\$
2004	\$ 4,172,237,262	4.7%	\$	\$ 4,172,237,262	2,021,491,033	\$	\$ 2,879,375,581	1,292,861,672	\$
2005	\$ 4,366,259,099	4.4%	\$	\$ 4,366,259,099	1,971,774,558	\$	\$ 2,563,913,092	1,792,746,007	\$
2006	\$ 4,536,973,236	4.1%	\$	\$ 4,536,973,236	1,691,216,331	\$	\$ 2,378,964,995	2,158,008,240	\$
2007	\$ 4,714,005,298	3.9%	\$	\$ 4,714,005,298	1,474,421,256	\$	\$ 2,251,921,426	2,462,083,872	\$
2008	\$ 4,887,030,981	3.7%	\$	\$ 4,887,030,981	1,295,570,119	\$	\$ 2,111,920,726	2,775,110,265	\$
2009	\$ 5,055,774,183	3.5%	\$	\$ 5,055,774,183	974,937,574	\$	\$ 1,954,338,360	3,101,435,822	\$
2010	\$ 5,270,004,772	3.2%	\$	\$ 5,270,004,772	790,083,162	\$	\$ 1,863,181,175	3,366,740,386	\$
2011	\$ 5,379,535,744	3.1%	\$	\$ 5,379,535,744	806,930,362	\$	\$ 1,804,355,653	3,475,180,091	\$
2012	\$ 5,534,220,902	2.9%	\$	\$ 5,534,220,902	830,133,135	\$	\$ 1,959,114,199	3,575,106,702	\$
1993-1997	\$ 3,197,405,000	83.1%	\$	\$ 3,197,405,000		\$	\$ 3,197,405,000		\$
1998-2002	\$ 13,856,704,647	24.3%	\$	\$ 13,567,062,261	189,527,154	\$	\$ 13,756,589,415	100,115,233	\$
2003-2007	\$ 21,764,808,403	5.3%	\$	\$ 9,361,826,689	3,939,494,508	\$	\$ 13,300,261,197	8,464,547,206	\$
2008-2012	\$ 26,076,566,532	3.3%	\$	\$ 4,637,654,352	5,145,338,923	\$	\$ 9,782,993,275	16,293,573,257	\$
2002-2012	\$ 51,489,226,376	4.9%	\$	\$ 17,367,660,896	9,273,300,585	\$	\$ 26,650,990,681	24,856,236,695	\$
1993-2012	\$ 64,895,484,582	28.2%	\$	\$ 30,763,948,302	9,273,300,585	\$	\$ 40,037,248,887	24,856,236,695	\$

Aug. Ann. % Chg.

Table 4
Claritin™ Annual Sales With & Without Generic Competition:
 Assumes Generic Competition Begins in July 2002 (Net Present Value 2000 \$)

Year	Claritin™ Annual Sales (No Generic) Year 2000 \$	% Change in Claritin™ Annual Sales Annual % Chg	Claritin™ Sales w/ Generics (2002 entry) Year 2000 \$	Generic Annual Sales (2002 entry) Year 2000 \$	Brand + Generic Annual Sales (2002 entry) Year 2000 \$	Annual Consumer Savings Year 2000 \$
	A	B	C	D	E	F
1993	\$ 128,446,495		\$ 128,446,495	\$ -	\$ 128,446,495	\$ -
1994	\$ 364,531,126	183.8%	\$ 364,531,126	\$ -	\$ 364,531,126	\$ -
1995	\$ 680,878,046	86.8%	\$ 680,878,046	\$ -	\$ 680,878,046	\$ -
1996	\$ 1,002,930,936	47.3%	\$ 1,002,930,936	\$ -	\$ 1,002,930,936	\$ -
1997	\$ 1,335,484,134	33.2%	\$ 1,335,484,134	\$ -	\$ 1,335,484,134	\$ -
1998	\$ 1,851,801,162	38.7%	\$ 1,851,801,162	\$ -	\$ 1,851,801,162	\$ -
1999	\$ 2,367,237,431	27.8%	\$ 2,367,237,431	\$ -	\$ 2,367,237,431	\$ -
2000	\$ 2,829,643,535	19.5%	\$ 2,829,643,535	\$ -	\$ 2,829,643,535	\$ -
2001	\$ 3,197,918,693	13.0%	\$ 3,197,918,693	\$ -	\$ 3,197,918,693	\$ -
2002	\$ 3,455,222,772	8.0%	\$ 3,180,875,259	\$ 179,518,971	\$ 3,360,394,230	\$ 94,828,541
2003	\$ 3,694,935,670	6.1%	\$ 2,117,781,186	\$ 845,314,076	\$ 2,967,095,213	\$ 697,840,457
2004	\$ 3,725,061,592	1.6%	\$ 1,804,829,911	\$ 765,937,461	\$ 2,570,767,372	\$ 1,154,294,220
2005	\$ 3,776,077,841	1.4%	\$ 1,622,485,318	\$ 599,610,466	\$ 2,222,095,785	\$ 1,553,982,056
2006	\$ 3,818,178,505	1.1%	\$ 1,423,276,664	\$ 578,787,878	\$ 2,002,084,490	\$ 1,816,114,015
2007	\$ 3,851,614,852	0.9%	\$ 1,204,687,404	\$ 635,262,587	\$ 1,839,949,992	\$ 2,011,664,860
2008	\$ 3,876,686,250	0.7%	\$ 980,128,367	\$ 695,173,892	\$ 1,675,302,259	\$ 2,201,383,991
2009	\$ 3,893,731,538	0.4%	\$ 750,853,389	\$ 754,290,756	\$ 1,505,144,145	\$ 2,388,587,393
2010	\$ 3,903,120,939	0.2%	\$ 590,763,858	\$ 794,965,699	\$ 1,385,729,558	\$ 2,517,391,381
2011	\$ 3,905,248,597	0.1%	\$ 585,767,290	\$ 796,670,714	\$ 1,382,458,003	\$ 2,522,790,594
2012	\$ 3,900,625,784	-0.1%	\$ 585,078,868	\$ 795,707,280	\$ 1,380,786,128	\$ 2,519,739,657
1993-1997	\$ 3,512,270,736	87.8%	\$ 3,512,270,736	\$ -	\$ 3,512,270,736	\$ -
1998-2002	\$ 13,701,823,593	21.4%	\$ 13,427,476,080	\$ 179,518,971	\$ 13,606,995,051	\$ 94,828,541
2003-2007	\$ 18,835,868,459	2.2%	\$ 8,173,080,483	\$ 3,428,912,368	\$ 11,601,972,851	\$ 7,235,895,608
2008-2012	\$ 19,479,313,108	0.3%	\$ 3,492,611,772	\$ 3,835,808,321	\$ 7,329,420,092	\$ 12,149,893,016
2002-2012	\$ 41,770,404,339	1.9%	\$ 14,846,547,514	\$ 7,445,239,660	\$ 22,291,787,174	\$ 19,476,617,165
1993-2012	\$ 55,529,275,886	24.8%	\$ 28,605,419,071	\$ 7,445,239,660	\$ 36,050,658,731	\$ 19,476,617,165

Avg. Ann. % Chg

Table 5
Claritin™ Annual Sales With & Without Generic Competition:
 Assumes Generic Competition Begins in July 2005 (Current Year \$)

Year	A		B		C		D		E		F		G	
	Claritin™ Annual Sales (No Generics)	Curr Year \$	% Change in Claritin™ Annual Sales	Annual % Chg	Claritin™ Sales w/ Generics (2005 entry)	Curr Year \$	Generic Annual Sales (2005 entry)	Curr Year \$	Brand + Generic Annual Sales (2005 entry)	Curr Year \$	Annual Consumer Savings	Curr Year \$	Annual Less of Savings w/3 Yr. Delay	2002 to 2005
1993	\$	107,913,000			\$	107,913,000			\$	107,913,000	\$			
1994	\$	315,551,000	192.4%		\$	315,551,000			\$	315,551,000	\$			
1995	\$	604,236,000	91.5%		\$	604,236,000			\$	604,236,000	\$			
1996	\$	915,816,000	51.6%		\$	915,816,000			\$	915,816,000	\$			
1997	\$	1,253,889,000	36.9%		\$	1,253,889,000			\$	1,253,889,000	\$			
1998	\$	1,780,522,000	42.0%		\$	1,780,522,000			\$	1,780,522,000	\$			
1999	\$	2,320,821,011	30.3%		\$	2,320,821,011			\$	2,320,821,011	\$			
2000	\$	2,829,643,535	21.9%		\$	2,829,643,535			\$	2,829,643,535	\$			
2001	\$	3,277,866,660	15.8%		\$	3,277,866,660			\$	3,277,866,660	\$			
2002	\$	3,647,851,441	11.3%		\$	3,647,851,441			\$	3,647,851,441	\$			
2003	\$	3,985,333,508	9.3%		\$	3,985,333,508			\$	3,985,333,508	\$			
2004	\$	4,172,237,262	4.7%		\$	4,172,237,262			\$	4,172,237,262	\$			
2005	\$	4,355,259,089	4.4%		\$	4,024,807,029	216,890,480		\$	4,241,697,519	\$	114,561,560		100,115,233
2006	\$	4,536,973,236	4.1%		\$	2,622,204,357	1,091,298,807		\$	3,673,503,264	\$	863,489,972		758,847,415
2007	\$	4,714,005,298	3.9%		\$	2,284,161,377	969,419,136		\$	3,253,580,513	\$	1,460,424,785		1,294,538,268
2008	\$	4,887,030,981	3.7%		\$	2,099,976,368	776,135,624		\$	2,876,114,192	\$	2,010,916,789		1,001,659,087
2009	\$	5,055,774,193	3.5%		\$	1,884,769,462	766,363,851		\$	2,651,133,313	\$	2,404,640,870		764,193,466
2010	\$	5,220,004,722	3.2%		\$	1,632,843,148	860,918,778		\$	2,493,761,926	\$	2,726,242,796		640,487,580
2011	\$	5,379,535,744	3.1%		\$	1,360,242,342	964,630,416		\$	2,324,872,759	\$	3,064,662,985		420,517,105
2012	\$	5,534,220,902	2.9%		\$	1,067,346,797	1,072,049,305		\$	2,139,396,102	\$	3,394,822,799		180,283,903
1993-1997	\$	3,197,405,000	93.1%		\$	3,197,405,000			\$	3,197,405,000	\$			
1998-2002	\$	13,856,704,647	24.3%		\$	13,856,704,647			\$	13,856,704,647	\$			100,115,233
2003-2007	\$	21,764,808,403	5.3%		\$	17,088,743,534	2,237,608,533		\$	19,326,352,066	\$	2,438,456,337		6,026,090,869
2008-2012	\$	26,076,566,532	3.3%		\$	8,045,182,118	4,440,098,174		\$	12,485,280,292	\$	13,591,286,240		2,702,287,016
2002-2012	\$	51,488,226,376	4.9%		\$	28,781,777,093	6,677,706,706		\$	35,459,483,799	\$	16,029,742,577		8,828,493,118
1993-2012	\$	64,895,484,562	28.2%		\$	42,188,035,298	6,677,706,706		\$	48,865,742,005	\$	16,029,742,577		8,828,493,118

Avg. Ann. % Chg

Table 6
Claritin™ Annual Sales With & Without Generic Competition:
 Assumes Generic Competition Begins July 2005 (Net Present Value 2000 \$)

Year	Claritin™ Annual Sales (No. Generic)		% Change in Claritin™ Annual Sales		Claritin™ Sales w/ Generics (2005 entry)		Generic Annual Sales (2005 entry)		Brand + Generic Annual Sales (2005 entry)		Annual Consumer Savings		Annual Less of Savings w/3 Yr Delay	
	Year 2000 \$	Year 2000 \$	Annual % Chg	Year 2000 \$	Year 2000 \$	Year 2000 \$	Year 2000 \$	Year 2000 \$	Year 2000 \$	Year 2000 \$	Year 2000 \$	Year 2000 \$	2002 to 2005	
	A		B	C	D	E	F	G						
1993	\$ 128,446,495			\$ 128,446,495	\$ -									
1994	\$ 364,531,126		183.8%	\$ 364,531,126	\$ -									
1995	\$ 680,878,046		86.8%	\$ 680,878,046	\$ -									
1996	\$ 1,002,930,936		47.3%	\$ 1,002,930,936	\$ -									
1997	\$ 1,335,484,134		33.2%	\$ 1,335,484,134	\$ -									
1998	\$ 1,851,801,162		38.7%	\$ 1,851,801,162	\$ -									
1999	\$ 2,367,237,431		27.8%	\$ 2,367,237,431	\$ -									
2000	\$ 2,829,643,535		19.5%	\$ 2,829,643,535	\$ -									
2001	\$ 3,197,918,683		13.0%	\$ 3,197,918,683	\$ -									
2002	\$ 3,455,222,772		8.0%	\$ 3,455,222,772	\$ -									
2003	\$ 3,664,935,670		6.1%	\$ 3,664,935,670	\$ -									
2004	\$ 3,776,077,841		1.4%	\$ 3,776,077,841	\$ -									
2005	\$ 3,818,178,505		1.1%	\$ 3,818,178,505	\$ -									
2006	\$ 3,851,614,852		0.9%	\$ 3,851,614,852	\$ -									
2007	\$ 3,876,686,250		0.7%	\$ 3,876,686,250	\$ -									
2008	\$ 3,893,731,538		0.4%	\$ 3,893,731,538	\$ -									
2009	\$ 3,903,120,939		0.2%	\$ 3,903,120,939	\$ -									
2010	\$ 3,905,248,597		0.1%	\$ 3,905,248,597	\$ -									
2011	\$ 3,900,525,784		-0.1%	\$ 3,900,525,784	\$ -									
2012														
1993-1997	\$ 3,512,270,736		87.8%	\$ 3,512,270,736	\$ -									
1998-2002	\$ 13,701,823,593		21.4%	\$ 13,701,823,593	\$ -									
2003-2007	\$ 18,635,668,459		2.2%	\$ 18,635,668,459	\$ -									
2008-2012	\$ 19,479,313,108		0.3%	\$ 19,479,313,108	\$ -									
2002-2012	\$ 41,770,404,339		1.9%	\$ 41,770,404,339	\$ -									
1993-2012	\$ 55,529,275,696		24.8%	\$ 55,529,275,696	\$ -									

Avg. Ann. % Chg

Table 7
Schering-Plough Annual Claritin® Revenue with 3-year Delay in Competition
 Percent Distribution By Expense Type*: 1983 to 2012

Year	Claritin® Sales		Net Profit	R&D Expend.	Marketing Advertising & Admin. Expense	Cost of Production	Taxes & Other Expenses	Total Revenue
	Year	2005						
1993	\$	128,446,495	16.80%	13.30%	26.90%	20.90%	22.10%	100.00%
1994	\$	364,531,126	19.80%	13.30%	40.30%	20.60%	6.00%	100.00%
1995	\$	860,878,046	17.40%	12.90%	39.00%	19.70%	11.00%	100.00%
1996	\$	1,002,930,936	21.40%	12.80%	39.10%	19.10%	7.60%	100.00%
1997	\$	1,335,484,134	21.30%	12.50%	39.30%	19.30%	7.60%	100.00%
1998	\$	1,851,801,162	21.70%	12.50%	38.90%	19.80%	7.10%	100.00%
1999*	\$	2,367,237,431	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2000*	\$	2,829,643,635	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2001*	\$	3,197,918,693	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2002*	\$	3,455,222,772	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2003*	\$	3,664,935,670	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2004*	\$	3,725,061,592	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2005*	\$	3,468,769,674	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2006*	\$	2,206,767,329	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2007*	\$	1,866,291,895	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2008*	\$	1,665,828,864	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2009*	\$	1,451,585,286	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2010*	\$	1,220,915,424	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2011*	\$	987,461,512	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
2012*	\$	752,268,762	21.50%	12.50%	39.00%	19.80%	7.20%	100.00%
1993-1997	\$	3,512,270,736	20.3%	12.8%	38.8%	19.5%	8.6%	100.00%
1998-2002	\$	13,701,823,593	21.5%	12.5%	39.0%	19.8%	7.2%	100.00%
2003-2007	\$	14,951,826,160	21.5%	12.5%	39.0%	19.8%	7.2%	100.00%
2008-2012	\$	6,078,039,847	21.5%	12.5%	39.0%	19.8%	7.2%	100.00%
2002-2012	\$	24,485,088,779	21.5%	12.5%	39.0%	19.8%	7.2%	100.00%
1993-2012	\$	38,243,960,336	21.4%	12.5%	39.0%	19.6%	7.3%	100.00%

* Estimated distribution of revenue based on data reported in *Medical Advertising News*, September 1999 and Schering-Plough Statements of Consolidated Income. Assumes distribution of revenue from 1999 to 2012 will be similar to distribution in 1997 and 1998.

Table 8
Schering-Plough Annual Claritin® Revenue with 3-year Delay in Competition
 Amount Distribution By Expense Type* (Net Present Value 2000 \$): 1993 to 2012

Year	Claritin® Sales w/ Gen. in 2005						Total Revenue
	A	B	C	D	E	F	
	Year 2000 \$	Net Profit	R&D Expend.	Marketing Advertising & Admin. Expense	Cost of Production	Taxes & Other Expenses	
1993	\$ 128,446,495	\$ 21,579,011	\$ 17,083,384	\$ 34,552,107	\$ 26,845,317	\$ 28,386,675	\$ 128,446,495
1994	\$ 364,531,126	\$ 72,177,163	\$ 48,482,640	\$ 146,806,044	\$ 75,093,412	\$ 21,871,868	\$ 364,531,126
1995	\$ 680,878,046	\$ 118,472,780	\$ 87,833,268	\$ 285,542,438	\$ 134,132,975	\$ 74,896,595	\$ 680,878,046
1996	\$ 1,002,930,936	\$ 214,677,220	\$ 128,375,160	\$ 392,145,986	\$ 191,553,809	\$ 76,222,751	\$ 1,002,930,936
1997	\$ 1,335,484,134	\$ 284,458,120	\$ 166,935,517	\$ 524,845,265	\$ 257,748,438	\$ 101,496,784	\$ 1,335,484,134
1998	\$ 1,851,801,162	\$ 401,840,852	\$ 231,475,145	\$ 720,350,852	\$ 366,856,630	\$ 131,477,863	\$ 1,851,801,162
1999*	\$ 2,367,237,431	\$ 588,956,048	\$ 295,904,679	\$ 923,222,598	\$ 488,713,011	\$ 170,441,095	\$ 2,367,237,431
2000*	\$ 2,829,643,535	\$ 608,373,360	\$ 353,705,442	\$ 1,103,560,378	\$ 560,269,420	\$ 203,734,334	\$ 2,829,643,535
2001*	\$ 3,197,918,693	\$ 687,552,519	\$ 389,739,837	\$ 1,247,188,290	\$ 633,187,901	\$ 230,250,146	\$ 3,197,918,693
2002*	\$ 3,455,222,772	\$ 742,872,896	\$ 431,602,846	\$ 1,347,536,881	\$ 684,134,109	\$ 248,776,040	\$ 3,455,222,772
2003*	\$ 3,664,935,670	\$ 787,961,169	\$ 458,116,959	\$ 1,429,324,911	\$ 725,657,263	\$ 263,875,368	\$ 3,664,935,670
2004*	\$ 3,725,061,592	\$ 800,888,242	\$ 465,632,699	\$ 1,452,774,021	\$ 737,562,195	\$ 268,204,435	\$ 3,725,061,592
2005*	\$ 3,488,769,674	\$ 750,085,480	\$ 436,096,209	\$ 1,360,620,173	\$ 690,776,395	\$ 251,191,417	\$ 3,488,769,674
2006*	\$ 2,206,767,329	\$ 474,454,976	\$ 275,845,916	\$ 880,639,258	\$ 436,839,931	\$ 168,887,248	\$ 2,206,767,329
2007*	\$ 1,866,291,895	\$ 401,252,757	\$ 233,296,487	\$ 727,853,839	\$ 369,625,785	\$ 134,373,016	\$ 1,866,291,895
2008*	\$ 1,665,828,864	\$ 358,153,206	\$ 208,228,608	\$ 649,673,257	\$ 329,834,115	\$ 119,939,678	\$ 1,665,828,864
2009*	\$ 1,451,565,286	\$ 312,066,536	\$ 181,445,661	\$ 586,110,461	\$ 287,409,927	\$ 104,512,701	\$ 1,451,565,286
2010*	\$ 1,220,915,424	\$ 262,496,816	\$ 152,614,428	\$ 476,157,016	\$ 241,741,254	\$ 87,905,911	\$ 1,220,915,424
2011*	\$ 987,461,512	\$ 212,304,225	\$ 123,432,689	\$ 385,109,990	\$ 195,517,379	\$ 71,097,229	\$ 987,461,512
2012*	\$ 752,268,762	\$ 161,737,784	\$ 94,033,595	\$ 293,384,817	\$ 148,948,215	\$ 54,163,361	\$ 752,268,762
1993-1997	\$ 3,512,270,736	\$ 711,314,295	\$ 448,709,968	\$ 1,363,891,949	\$ 685,379,951	\$ 302,874,673	\$ 3,512,270,736
1998-2002	\$ 13,701,823,583	\$ 2,949,595,675	\$ 1,712,727,949	\$ 5,341,859,400	\$ 2,712,961,071	\$ 984,679,498	\$ 13,701,823,583
2003-2007	\$ 14,951,826,160	\$ 3,214,642,624	\$ 1,868,978,270	\$ 5,831,212,202	\$ 2,960,461,580	\$ 1,076,531,484	\$ 14,951,826,160
2008-2012	\$ 6,078,039,847	\$ 1,306,778,567	\$ 759,754,981	\$ 2,370,435,540	\$ 1,203,451,890	\$ 437,618,869	\$ 6,078,039,847
2002-2012	\$ 24,485,088,779	\$ 5,264,294,088	\$ 3,060,636,097	\$ 9,549,184,622	\$ 4,848,047,578	\$ 1,762,926,392	\$ 24,485,088,779
1993-2012	\$ 38,243,960,336	\$ 8,182,331,161	\$ 4,780,171,168	\$ 14,907,498,992	\$ 7,582,254,492	\$ 2,801,704,523	\$ 38,243,960,336

* Estimated distribution of revenue based on data reported in *Medical Advertising News*, September 1999 and Schering-Plough Statements of Consolidated Income. Assumes distribution of Claritin® revenue is proportional to distribution of Schering-Plough total revenue.

Table 9
Schering-Plough Additional Claritin™ Revenue from 3-Year Delay in Generic Competition
 Amount Distribution By Expense Type* (Net Present Value 2000 \$): 1993 to 2012

Year	A	B	C	D	E	F	G
	Added Claritin Sales from 3 Yr. Delay	Net Profit	R&D Expend.	Marketing Advertising & Admin. Expense	Cost of Production	Taxes & Other Expenses	Total Revenue
1993	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
1994	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
1995	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
1996	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
1997	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
1998	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
1999*	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
2000*	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
2001*	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
2002*	\$ 274,347,512	\$ 56,984,715	\$ 34,293,439	\$ 106,995,530	\$ 54,320,907	\$ 19,753,021	\$ 274,347,512
2003*	\$ 1,547,154,484	\$ 332,638,214	\$ 193,394,310	\$ 603,380,249	\$ 306,336,588	\$ 111,395,123	\$ 1,547,154,484
2004*	\$ 1,920,231,681	\$ 412,849,811	\$ 240,028,960	\$ 748,890,356	\$ 380,205,873	\$ 138,256,681	\$ 1,920,231,681
2005*	\$ 1,865,284,356	\$ 401,251,137	\$ 233,265,544	\$ 727,850,899	\$ 389,524,302	\$ 134,372,474	\$ 1,865,284,356
2006*	\$ 783,490,665	\$ 188,450,493	\$ 97,936,333	\$ 305,561,359	\$ 155,131,152	\$ 56,411,328	\$ 783,490,665
2007*	\$ 661,604,491	\$ 142,244,966	\$ 82,700,561	\$ 258,025,752	\$ 130,997,689	\$ 47,635,523	\$ 661,604,491
2008*	\$ 685,700,497	\$ 147,425,607	\$ 85,712,562	\$ 267,423,194	\$ 135,768,688	\$ 49,370,436	\$ 685,700,497
2009*	\$ 700,711,896	\$ 150,653,058	\$ 87,589,987	\$ 273,277,840	\$ 138,740,955	\$ 50,451,257	\$ 700,711,896
2010*	\$ 630,151,566	\$ 135,482,587	\$ 78,768,946	\$ 245,759,111	\$ 124,770,010	\$ 45,370,913	\$ 630,151,566
2011*	\$ 401,674,222	\$ 88,359,958	\$ 50,209,278	\$ 155,652,947	\$ 79,531,486	\$ 28,920,544	\$ 401,674,222
2012*	\$ 167,189,894	\$ 35,945,827	\$ 20,698,737	\$ 65,204,059	\$ 33,103,599	\$ 12,037,672	\$ 167,189,894
1993-1997	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
1998-2002	\$ 274,347,512	\$ 56,984,715	\$ 34,293,439	\$ 106,995,530	\$ 54,320,907	\$ 19,753,021	\$ 274,347,512
2003-2007	\$ 6,778,765,677	\$ 1,457,434,621	\$ 847,345,710	\$ 2,643,718,614	\$ 1,342,195,604	\$ 488,071,129	\$ 6,778,765,677
2008-2012	\$ 2,585,428,076	\$ 555,867,036	\$ 323,178,509	\$ 1,008,316,949	\$ 511,914,759	\$ 186,150,821	\$ 2,585,428,076
2002-2012	\$ 9,638,541,265	\$ 2,072,286,372	\$ 1,204,817,658	\$ 3,759,031,093	\$ 1,908,431,170	\$ 693,974,971	\$ 9,638,541,265

* Estimated distribution of revenue based on data reported in *Medical Advertising News*, September 1999 and Schering-Plough Statements of Consolidated Income. Assumes distribution of Claritin™ revenue is proportional to distribution of Schering-Plough total revenue.

Table 10
Price of Claritin™ 10 mg Tablets:
United States vs. Canada
(loratadine, Schering-Plough, # 30, July 1999)

Factor	U.S. Average Wholesale Price (US\$)	U.S. Wholesale Acquisition Cost (US\$)	Canada ex-factory price (US\$)*	Canada ex-factory price (Canadian \$)
	Price/pkg \$	216.87 \$	182.39 \$	61.13 \$
Tablets/pkg	100	100	100	100
Price/tablet \$	2.19 \$	1.82 \$	0.61 \$	0.90
Tablets/day	1	1	1	1
Days/month	30	30	30	30
Tablets/month	30	30	30	30
Price/day \$	2.19 \$	1.82 \$	0.61 \$	0.90
Price/month \$	65.66 \$	54.72 \$	18.34 \$	26.95

* Canadian dollars converted to U.S. dollars using an exchange rate of 1 US = \$1.4695 Canadian.

SOURCE: Based on July 1, 1999 price of Claritin 10 mg tablets, 100s (NDC 0086-0468-03) with data from PriceCheck PC (First DataBank, Indianapolis, IN) for U.S. price and July 1, 1999 price of Claritin 10 mg tablets, 100s from Shippers Drug Mart, Toronto, Canada for the Canadian price.

Table 11
**R&D Expenditures as a Percent of U.S. Ethical Pharmaceutical Sales,
 Research-Based Pharmaceutical Firms, 1980-1999**

Year	Firm-Financed U.S. R&D	Domestic U.S. Sales	U.S. Exports	Domestic U.S. Sales + Exports	U.S. R&D as a % of Sales & Exports
1970	\$ 559,600,000	\$ 4,552,500,000	\$ 344,100,000	\$ 4,896,600,000	11.4%
1971	\$ 619,600,000	\$ 5,144,900,000	\$ 382,400,000	\$ 5,527,300,000	11.2%
1972	\$ 648,000,000	\$ 5,210,100,000	\$ 377,900,000	\$ 5,588,000,000	11.6%
1973	\$ 697,500,000	\$ 5,686,500,000	\$ 565,600,000	\$ 6,252,100,000	11.2%
1974	\$ 794,500,000	\$ 6,470,400,000	\$ 734,000,000	\$ 7,204,400,000	10.9%
1975	\$ 884,500,000	\$ 7,135,700,000	\$ 751,700,000	\$ 7,887,400,000	11.3%
1976	\$ 973,600,000	\$ 7,851,000,000	\$ 894,800,000	\$ 8,745,800,000	11.1%
1977	\$ 1,053,000,000	\$ 8,650,400,000	\$ 947,600,000	\$ 9,498,000,000	11.1%
1978	\$ 1,159,100,000	\$ 9,580,500,000	\$ 1,064,700,000	\$ 10,645,200,000	10.9%
1979	\$ 1,319,800,000	\$ 10,651,300,000	\$ 1,154,800,000	\$ 11,806,100,000	11.2%
1980	\$ 1,544,100,000	\$ 11,765,600,000	\$ 1,219,300,000	\$ 13,007,900,000	11.9%
1981	\$ 1,666,200,000	\$ 12,665,000,000	\$ 1,393,800,000	\$ 14,058,800,000	13.3%
1982	\$ 2,265,600,000	\$ 14,743,900,000	\$ 1,446,300,000	\$ 16,190,200,000	14.0%
1983	\$ 2,663,000,000	\$ 16,695,000,000	\$ 1,535,700,000	\$ 18,140,700,000	14.7%
1984	\$ 2,876,400,000	\$ 19,026,100,000	\$ 1,340,800,000	\$ 20,366,900,000	14.6%
1985	\$ 3,370,700,000	\$ 20,742,500,000	\$ 1,556,900,000	\$ 22,299,400,000	15.1%
1986	\$ 3,870,900,000	\$ 23,658,800,000	\$ 2,044,200,000	\$ 25,703,000,000	15.1%
1987	\$ 4,503,200,000	\$ 25,875,100,000	\$ 2,013,300,000	\$ 27,888,400,000	16.1%
1988	\$ 5,228,700,000	\$ 28,582,800,000	\$ 2,696,200,000	\$ 31,278,900,000	16.7%
1989	\$ 6,019,300,000	\$ 32,708,600,000	\$ 3,145,800,000	\$ 35,854,400,000	16.8%
1990	\$ 6,800,100,000	\$ 38,486,700,000	\$ 3,420,600,000	\$ 41,907,300,000	16.2%
1991	\$ 7,623,600,000	\$ 44,304,500,000	\$ 3,523,900,000	\$ 47,828,400,000	16.6%
1992	\$ 9,369,100,000	\$ 48,095,500,000	\$ 4,642,700,000	\$ 52,737,600,000	17.9%
1993	\$ 10,473,000,000	\$ 48,650,900,000	\$ 3,982,700,000	\$ 52,633,600,000	19.9%
1994	\$ 11,100,800,000	\$ 50,740,400,000	\$ 3,606,100,000	\$ 54,346,900,000	20.4%
1995	\$ 11,833,900,000	\$ 57,145,500,000	\$ 3,993,300,000	\$ 61,138,800,000	19.4%
1996	\$ 13,676,400,000	\$ 64,741,400,000	\$ 3,794,400,000	\$ 68,535,800,000	19.8%
1997	\$ 15,422,000,000	\$ 71,761,900,000	\$ 4,025,900,000	\$ 75,787,800,000	20.3%
1998	\$ 17,222,500,000	\$ 81,289,200,000	\$ 4,462,000,000	\$ 85,751,200,000	20.1%
1999	\$ 20,111,800,000	\$ 91,423,300,000	\$ 4,860,200,000	\$ 96,273,500,000	20.8%

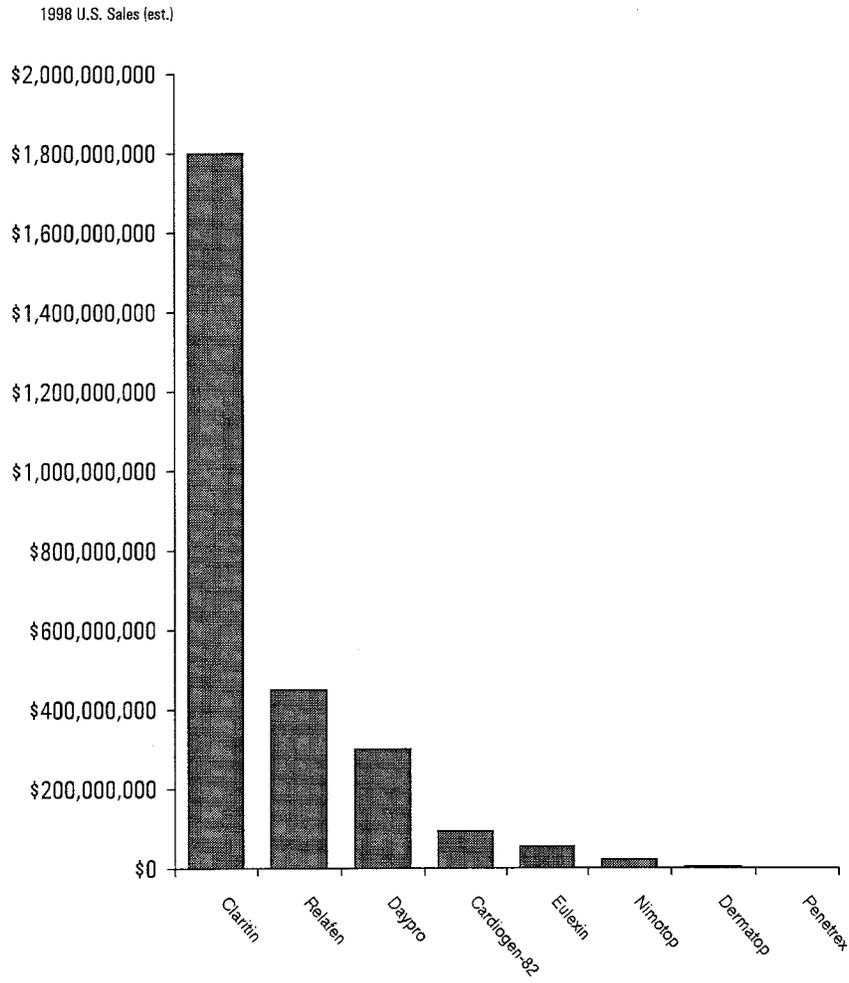
SOURCE: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Survey*, 1999, Table 2.

Table 12
Profitability of Pharmaceutical Firms and Fortune 500 Firms

Year	Profit as % of Revenue			Profit as % of Return on Equity		
	Fortune 500 All Industries	Pharma- ceuticals	Pharma- ceuticals	Fortune 500 All Industries	Pharma- ceuticals	Pharma- ceuticals
	Median	Median	Rank	Median	Median	Rank
1957	5.6%	7.8%	3	11.6%	14.7%	1
1958	4.9%	7.2%	4	8.9%	11.3%	2
1959	4.9%	8.0%	4	10.3%	12.7%	2
1960	4.4%	10.7%	2	9.1%	15.5%	2
1961	4.2%	10.5%	2	8.3%	15.8%	1
1962	4.2%	10.5%	2	8.9%	14.4%	2
1963	4.4%	10.6%	1	9.1%	14.7%	2
1964	5.0%	10.8%	2	10.5%	16.3%	1
1965	5.5%	10.3%	2	11.8%	18.0%	1
1966	5.6%	10.2%	2	12.7%	18.4%	1
1967	5.0%	9.6%	2	11.3%	18.0%	1
1968	4.8%	9.0%	2	11.7%	17.9%	1
1969	4.6%	9.2%	2	11.3%	19.1%	1
1970	3.9%	9.3%	2	9.5%	15.5%	2
1971	3.8%	9.1%	2	9.1%	15.1%	2
1972	4.1%	9.1%	2	10.3%	15.3%	2
1973	4.5%	9.4%	2	12.4%	18.1%	1
1974	4.3%	8.8%	2	13.6%	17.1%	3
1975	3.9%	8.6%	2	11.6%	16.2%	3
1976	4.6%	8.5%	2	13.3%	15.8%	4
1977	4.6%	8.5%	2	13.5%	16.7%	2
1978	4.8%	8.7%	2	14.3%	17.6%	2
1979	5.2%	8.9%	1	15.9%	18.0%	6
1980	4.8%	9.1%	2	14.4%	17.9%	5
1981	4.6%	9.1%	2	13.8%	18.0%	3
1982	3.6%	9.9%	1	10.9%	16.9%	2
1983	3.8%	10.4%	1	10.6%	17.5%	2
1984	4.5%	10.0%	1	13.6%	18.1%	3
1985	3.9%	10.4%	1	11.5%	15.6%	5
1986	4.1%	13.1%	1	11.6%	23.6%	1
1987	4.6%	13.2%	1	13.2%	22.7%	2
1988	5.5%	13.5%	1	16.2%	23.6%	1
1989	4.7%	13.0%	1	15.0%	25.5%	1
1990	4.1%	13.6%	1	13.0%	26.4%	1
1991	3.1%	12.8%	1	10.2%	26.1%	1
1992	2.4%	11.4%	1	9.0%	26.7%	1
1993	2.9%	12.5%	1	10.3%	22.0%	1
1994	4.6%	16.1%	1	13.7%	31.2%	1
1995	4.8%	14.4%	1	14.0%	30.7%	1
1996	5.0%	17.1%	1	14.1%	29.1%	2
1997	4.9%	16.1%	1	13.9%	29.3%	3
1998	4.4%	18.5%	1	13.4%	39.4%	1

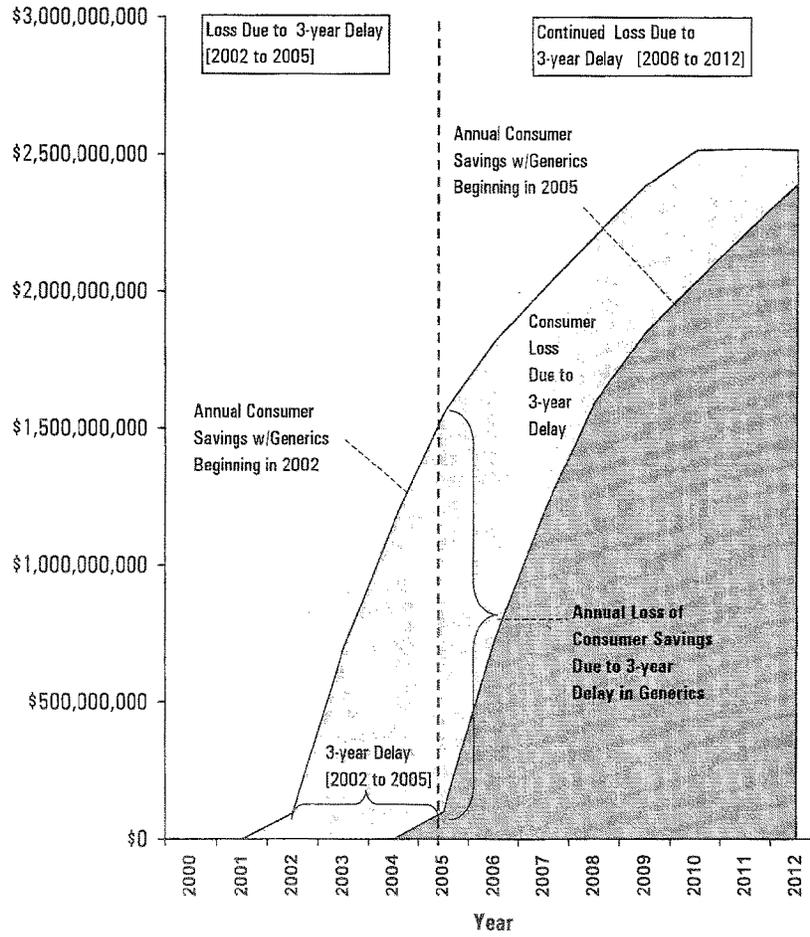
Source: Compiled by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota based on data found in *Fortune magazine*, Fortune 500 issue, 1958 to 1999

Figure 1
Pipeline Drugs Affected by
Proposed Legislation (HR 1598):
1998 U.S. Sales Volume



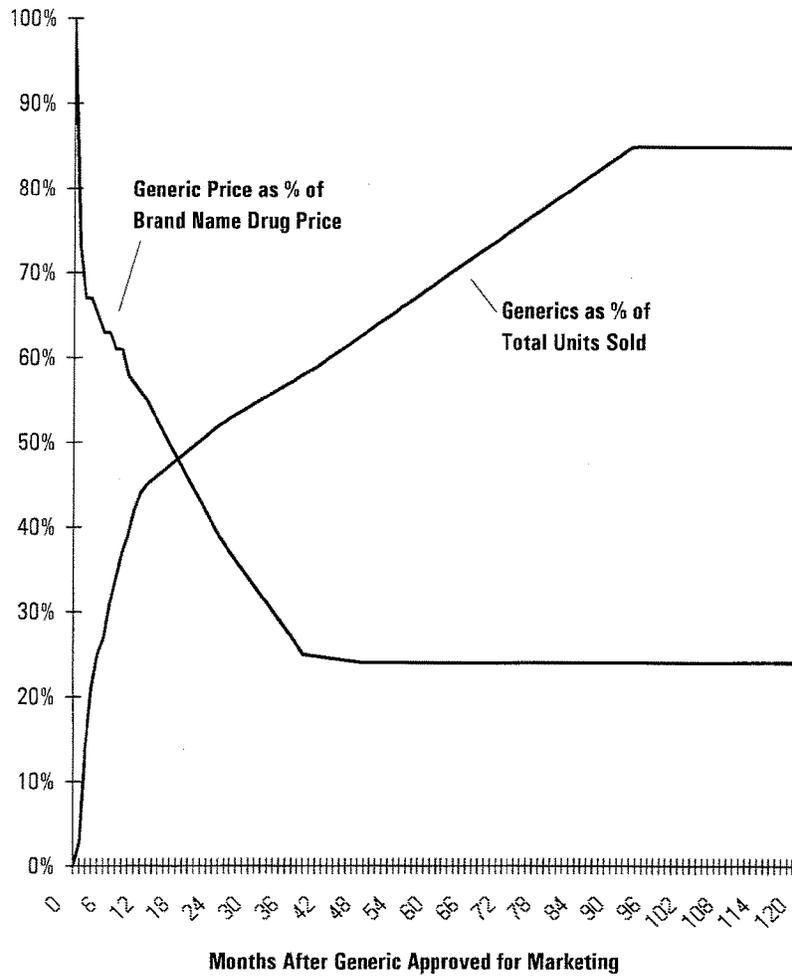
* U.S. sales estimates are at the manufacturer level and are from corporate annual reports and other market reports.
SOURCE: Compiled by the PRIME Institute, University of Minnesota

Figure 2
Annual Loss of Consumer Savings Due to
3-Year Delay in Generic Competition



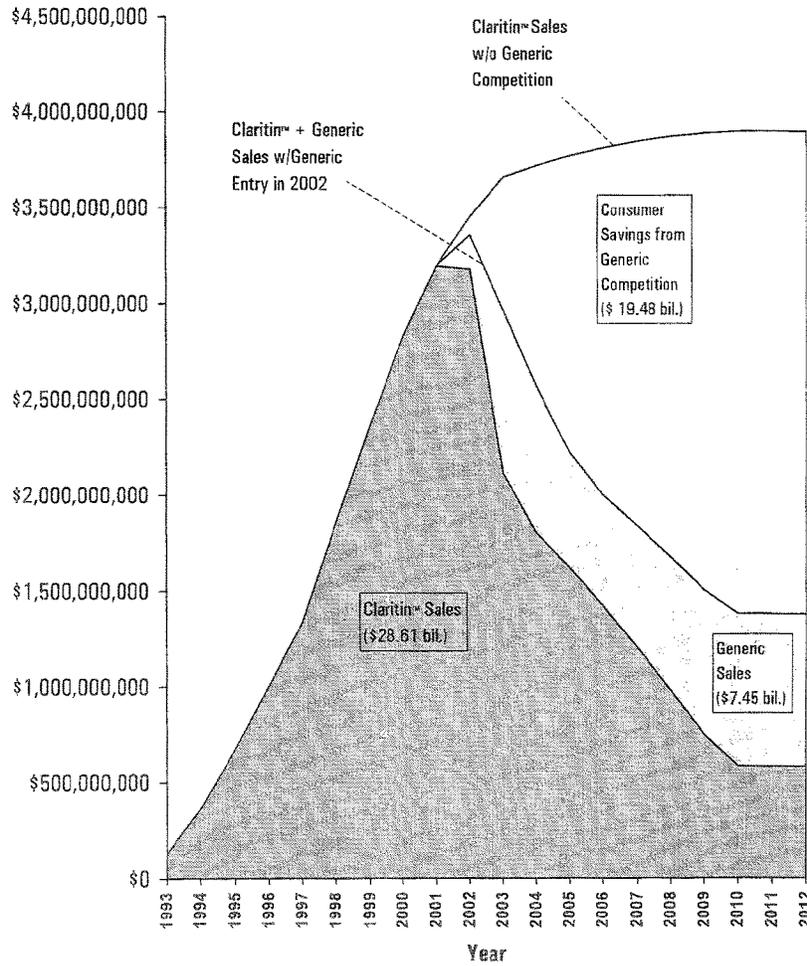
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in market reports.

Figure 3
Generic Penetration of Brand Market
by Units Sold and Price per Unit



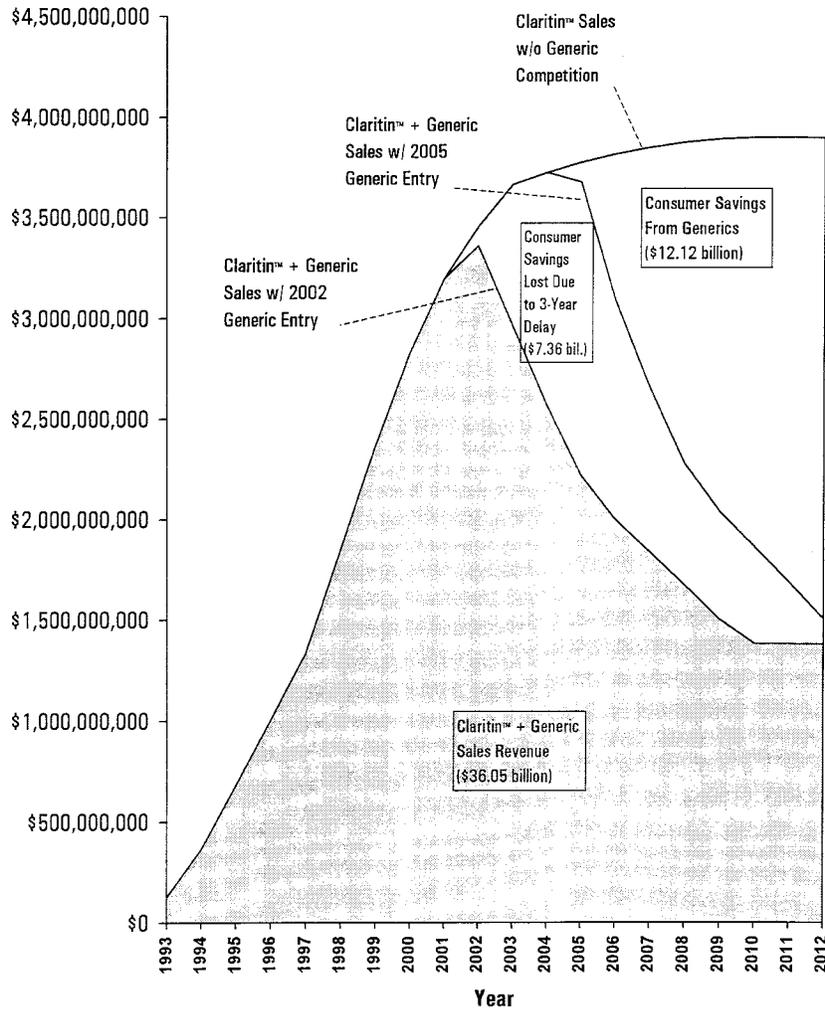
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in *Generic Drug Industry Overview*, Kidder, Peabody, Oct. 5, 1994

Figure 4
Consumer Savings From Generic Competition
for Claritin®: 1993 to 2012



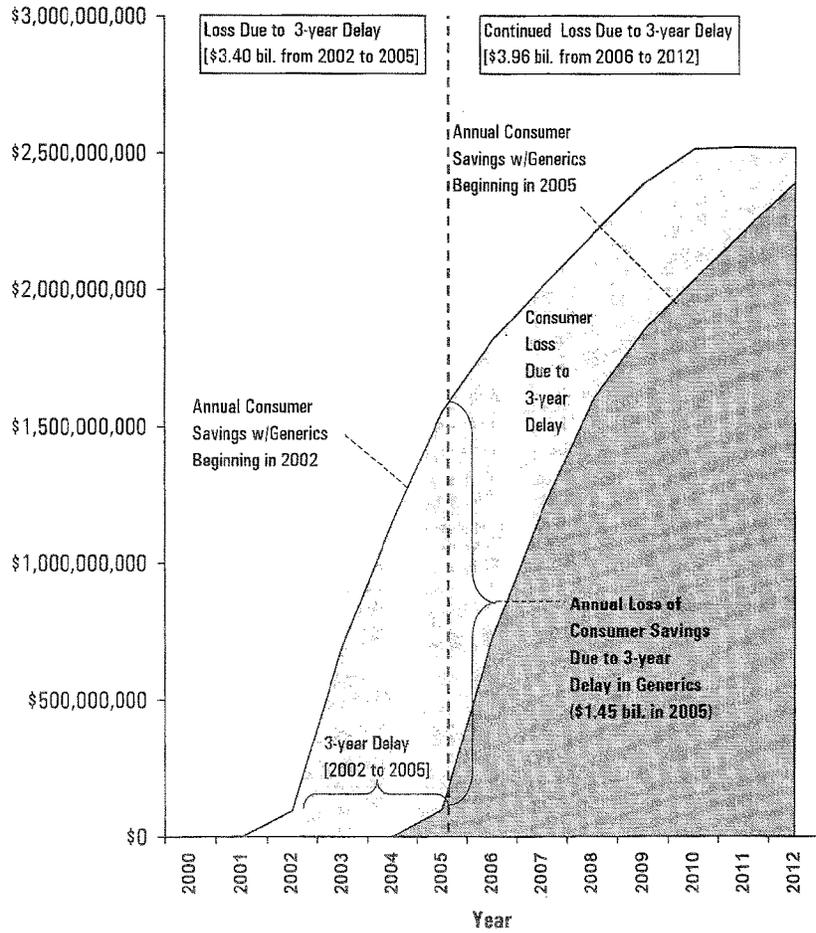
* Assumes generic competition for Claritin begins in July 2002. Reported as net present value in 2000 \$.
 SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in market reports.

Figure 5
Lost Consumer Savings Due to 3-Year Delay in Generic Competition for Claritin™



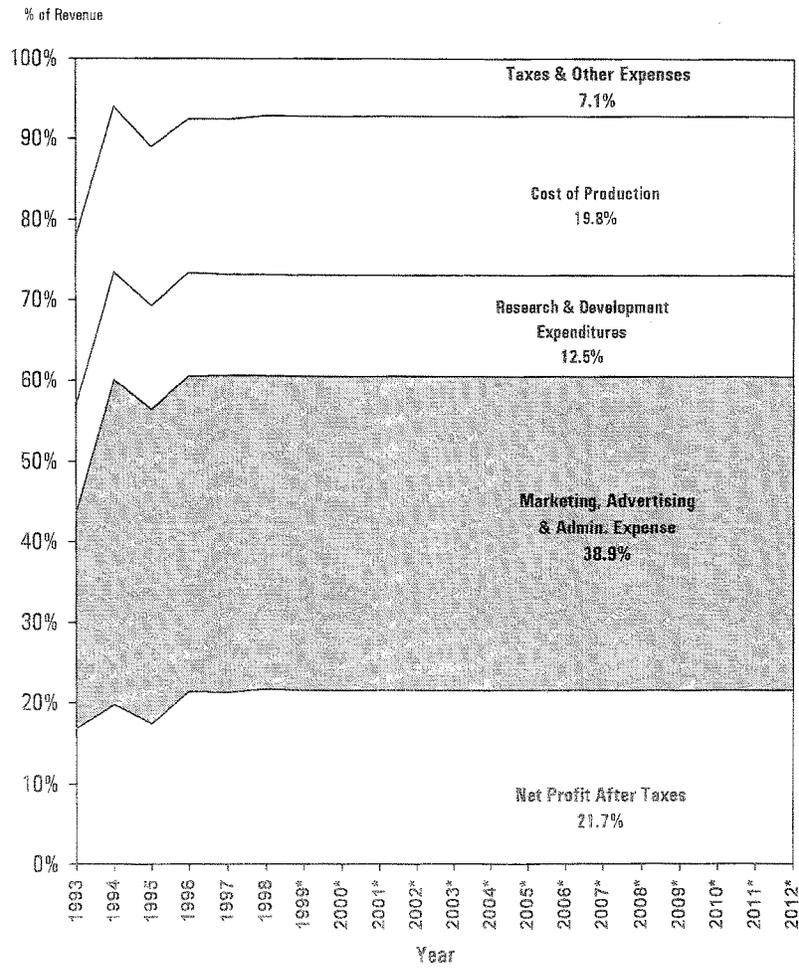
* Assumes a 3-year delay in generic entry due to proposed legislation. Reported as net present value in 2000 \$.
 SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in market reports.

Figure 6
Annual Loss of Consumer Savings Due to
3-Year Delay in Generic Competition for Claritin™



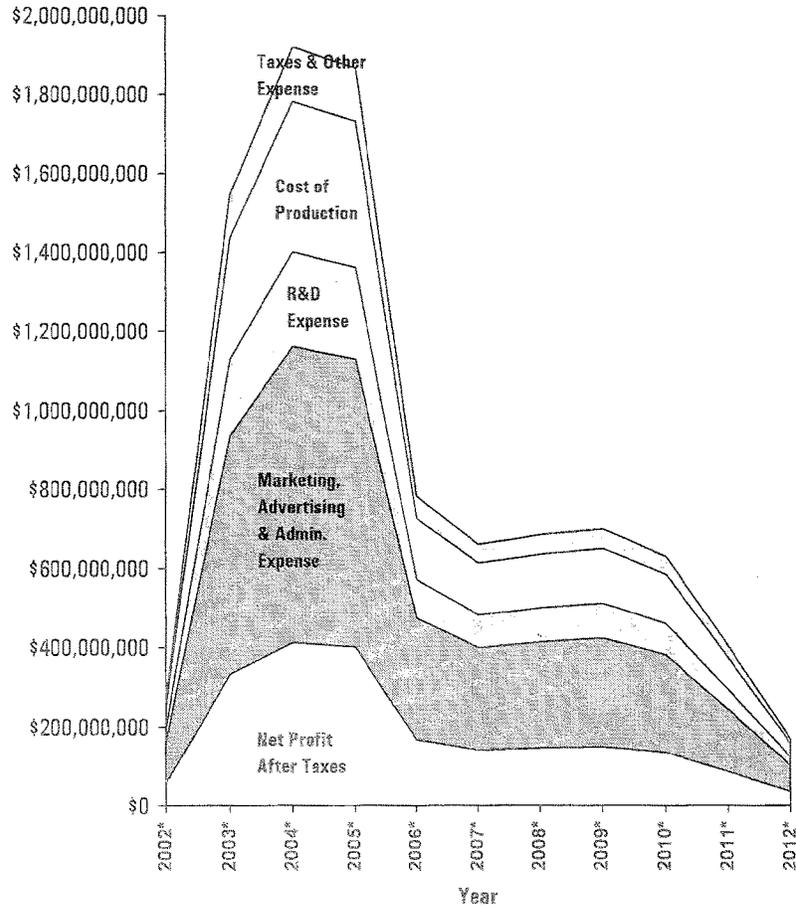
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in market reports.

Figure 7
Schering-Plough Revenue Percent Distribution
By Expense Type: 1993 to 2012*



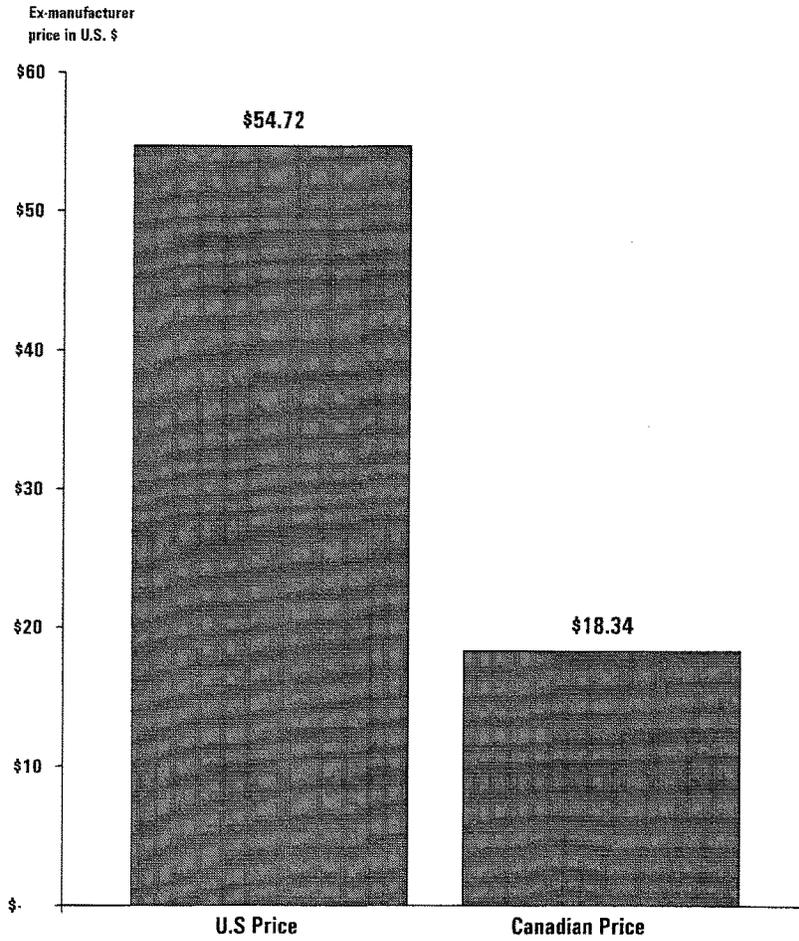
* Percents shown are for 1998. Estimates for 1999 to 2012 assume a similar distribution to the pattern in the previous years.
 SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in *Medical Advertising News*, September issues, 1991 to 1998.

Figure 8
Schering-Plough Additional Claritin™ Revenue
from 3-Year Delay in Generic Competition
Amount Distribution by Expense Type*: 2002 to 2012



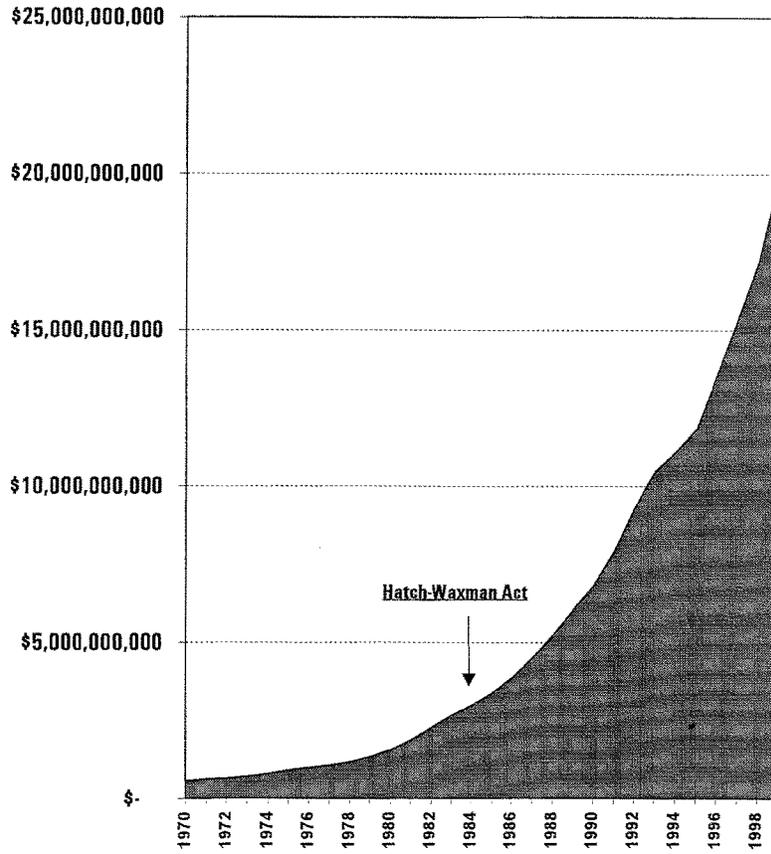
* Assumes additional Claritin™ revenue is distributed in proportion to total Schering-Plough revenue distribution.
 Reported as net present value using 2000 \$.
 SOURCE: Compiled by the PRINE Institute, University of Minnesota from data found in *Medical Advertising News*, September issues, 1991 to 1998.

Figure 9
Price of Claritin™ 10 mg Tablets:
United States vs. Canada
(loratidine, Schering-Plough, # 30, July 1999)



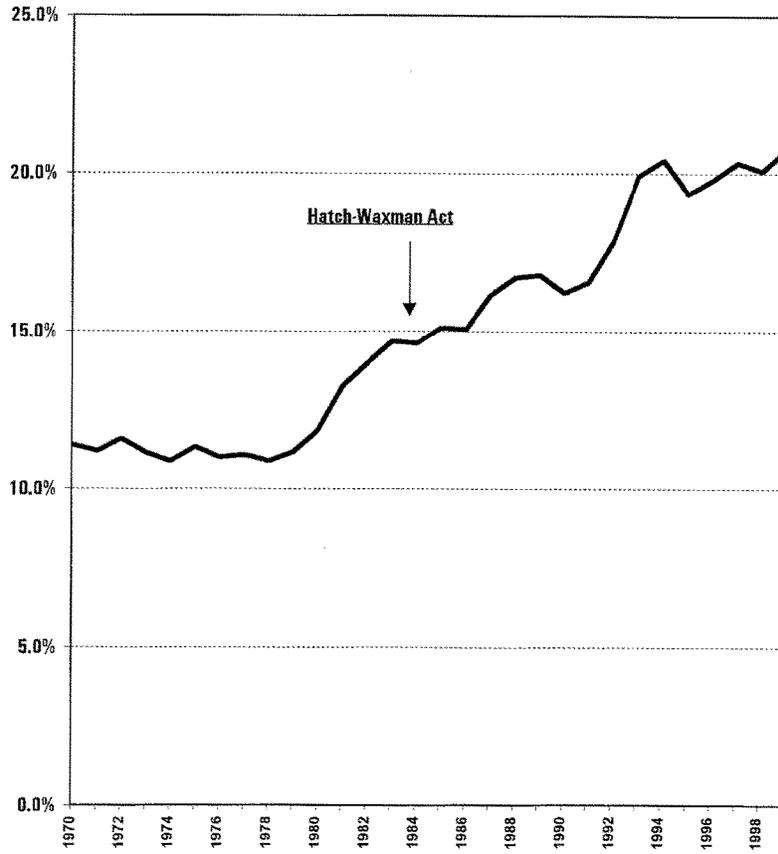
SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in PriceChek PC, First Databank, Indianapolis, IN, July 1999 and Sheppers Drug Mart, Toronto, Canada, July 1999.

Figure 10
U.S. Research & Development Expenditures
Financed by Firms: 1970 to 1999



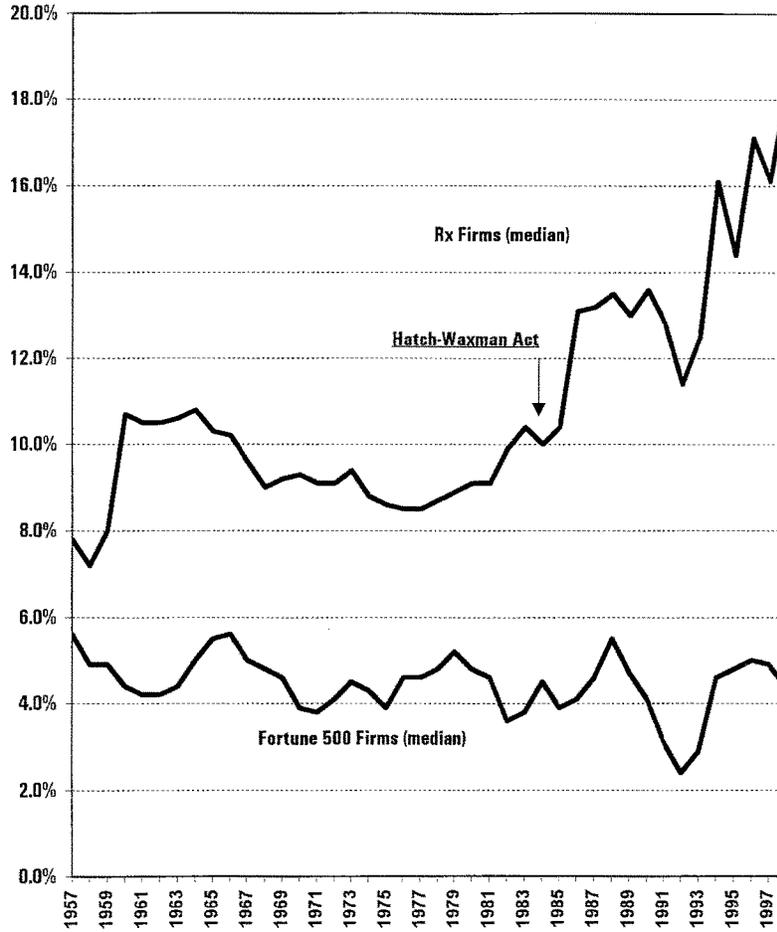
SOURCE: Compiled by PRIME Institute, University of Minnesota based on data found in *PhARMA Annual Survey*, Pharmaceutical Research and Manufacturers of America, 1999.

Figure 11
Research & Development Expenditures as a
% of Sales Revenue for Pharmaceutical Firms: 1970 to 1999



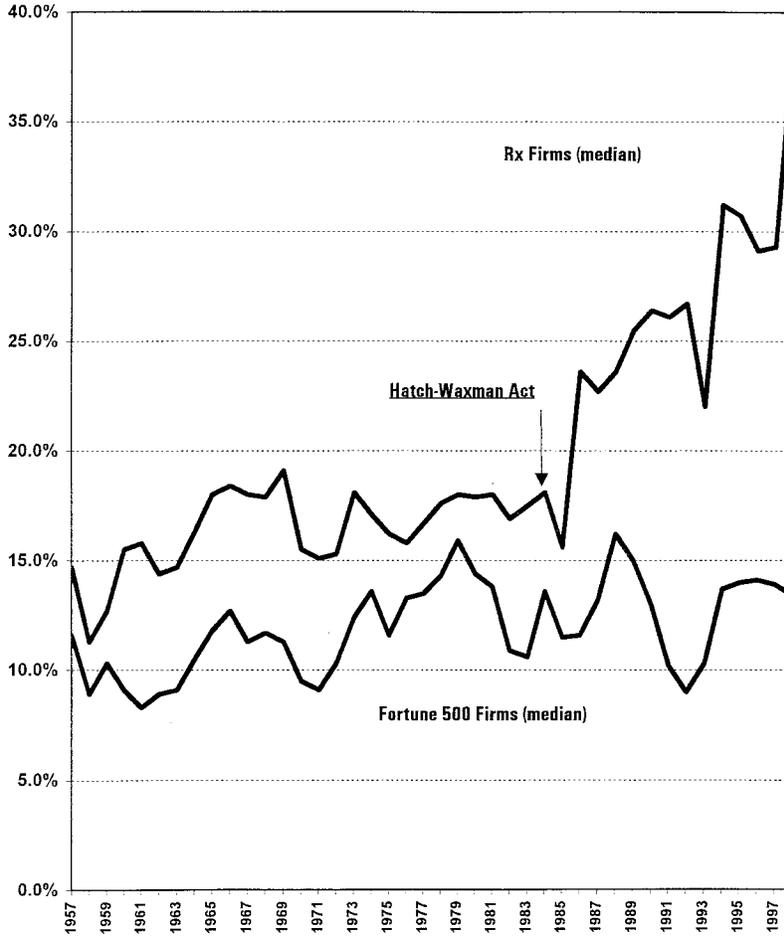
SOURCE: Compiled by PRIME Institute, University of Minnesota based on data found in *PARMA Annual Survey*, Pharmaceutical Research and Manufacturers of America, 1998.

Figure 12
Fortune 500 Firms: Profit as % of Revenue



SOURCE: Compiled by PRIME Institute, University of Minnesota based on data found in the Fortune, the Fortune 500 issue, 1958 to 1998.
 Service firms were included with industrial firms for the first time in 1984.

Figure 13
Fortune 500 Firms: Profit as % Return on Equity



SOURCE: Compiled by PRIME Institute, University of Minnesota based on data found in the Fortune, the Fortune 500 issue, 1958 to 1998. Service firms were included with industrial firms for the first time in 1994.

ALFRED B. ENGELBERG,
Palm Beach, FL, July 29, 1999.

Senator ORRIN G. HATCH,
Chairman, Committee on the Judiciary, U.S. Senate, Washington, DC.

DEAR SENATOR HATCH: I was patent counsel to the Generic Pharmaceutical Industry Association (GPIA) in 1984 and was intimately involved in drafting and negotiating the Drug Price Competition and Patent Term Restoration Act which was cosponsored by you and Rep. Henry Waxman. While I have retired from the practice of law and no longer represent GPIA or anyone else, I believe that I have an obligation to make my knowledge and experience regarding the 1984 Act available to Congress in order to preserve and protect the public's interest in affordable pharmaceuticals. Therefore, I respectfully request that this letter be considered and made part of the record in the Judiciary Committee's deliberations with respect to S. 1172, a bill which seeks to create a procedure, for granting additional patent term extensions to certain pipeline drugs.

One of the principal concerns of the research-based drug companies in the negotiations leading to the 1984 Act was to insure that the contemplated changes in the law would occur gradually and in a fashion which would not affect the near term balance sheets of those companies. Protecting pipeline drugs was critical to that process. This was not an easy task since it was also recognized that patent term extension should be perceived as providing incentives for future research investments and not as a reward to pharmaceutical companies, at public expense, for past investment. These seemingly contradictory goals were addressed by legislating a series of non-patent exclusivities in Title I of the 1984 Act which were unrelated to the patent term extension provisions of Title II. By limiting the FDA's ability to approve Abbreviated New Drug Applications (ANDAs) under certain circumstances, the potentially adverse near term economic consequences of the new law were neutralized. At the same time, as the Rep. Waxman's House Committee report shows,¹ the important concept of prospectivity was preserved by limiting patent term extensions for drugs which were in the pipeline² prior to the 1984 Act to 2 years while granting a 5 year patent extension to drugs which were first developed after the new law was enacted. The Committee's rationale for the relatively short patent term extension for pipeline drugs is succinctly stated in the Committee Report at p. 41 as follows:

The Committee established different maximum periods of extension to provide greater incentive for future innovations. By extending patents for future innovations for up to five years for products developed in the future, and by providing for up to fourteen years of market exclusivity, the Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities.

The principle profit protection mechanism which was incorporated in the earliest drafts of the 1984 Act was a so-called "transition" rule which prohibited the FDA from approving an ANDA for 10 years on any new chemical entity which was the subject of a New Drug Application (NDA) approved between December 31, 1982 and the date of enactment of the 1984 Act. This provision insured that the newest and most important drugs would have 10 years of monopoly protection irrespective of their patent expiration dates. In the late stages of the negotiations, 2 additional non-patent exclusivities were added. First, the FDA was prohibited from accepting any ANDA for any new chemical entity first approved in an NDA filed after the date of enactment of the 1984 Act for a period of 5 years thereby assuring a monopoly of at least 7 years since the ANDA review process typically takes 2 years. Secondly, the FDA was prohibited from approving any ANDA covering a new use or form of a previously approved chemical entity for a period of 3 years. The drugs for which S. 1172 now seeks additional protections have all received the benefit of these non-patent exclusivities in addition to a 2-year patent extension.

There may well be areas where the 1984 Act was flawed either as a result of poor draftsmanship or because of unforeseen circumstances.³ Those issues should be addressed by Congress. But to suggest that the parties who agreed to the 1984 Act

¹ House Committee on Energy & Commerce, Rept. 98-857, Part 1, 98th Congress, 2d Sess. The provisions of the 1984 Act with respect to pipeline drugs were originally drafted as part of H.R. 3605 and there are no Senate reports.

² A "pipeline" drug is a drug on which tests in humans had begun prior to the enactment of the 1984 Act.

³ I have addressed several such areas in my recent article entitled "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?", *IDEA, The Journal of Law & Technology*, Vol. 39, No. 3 (1999).

did not completely address the issue of protection for pipeline drugs is absurd. Assuring protection for those drugs was, in fact, at the very heart of the deal. It may well be that certain pipeline drugs did not get as much protection as others, but each company got what it felt it needed in terms of product line protection to sign on to the compromise. It is simply wrong for a new generation of legislators and lobbyists to ignore that history and seek to pile additional patent term extensions on top of the patent and non-patent exclusivities which those pipeline drugs have already received on the theory that the 1984 Act produced unintended hardships for some companies or products.

In his recent testimony before the House, Peter Barton Hutt, who represented the Pharmaceutical Manufacturers Association (PMA) in the negotiations leading to the 1984 Act has crafted a personal recollection of the rationale for the 2-year pipeline extension. Mr. Hutt states that the two-year limitation on extensions for pipeline drugs resulted from the fact that "it was felt that the pipeline drugs would be approved by FDA shortly after enactment of the 1984 legislation". No statement remotely resembling Mr. Hutt's recollection can be found in any committee report, floor statement or any other document that could be legitimately described as being a part of the official or unofficial legislative history of the 1984 Act. Moreover, prior to the enactment of the 1984 Act, Mr. Hutt was vigorously advocating for patent term extension legislation which would have provided up to seven years of extension for all pharmaceuticals at the time of their approval without regard to their "pipeline" status.⁴

In his 1982 article, Mr. Hutt states that by 1980, the testing and approval process for drugs was taking seven to thirteen years. Therefore, his current assertion that there was an expectation that these pipeline drugs would be approved shortly after enactment of the 1984 Act makes no sense. According to Senator Torricelli's testimony of July 1, 1999 on the House version of S. 1172 (H.R. 1598) there were 123 drugs in the pipeline on the day the 1984 Act became law. Some of these drugs were in the very early stages of human testing, i.e. the IND stage whereas others were either at advanced stages of clinical testing or pending before the FDA for approval. Therefore, as expected; some pipeline drugs were approved shortly after enactment of the 1984 Act while many others were not approved for many years because they were only in the early stages of development in 1984. The records of the PTO show that 2-year patent extensions were being granted for pipeline drug approvals well into the 1990's.

The testimony of Mr. Hutt and Senator Torricelli also raises serious questions regarding the timing and scope of S. 1172. If, as now alleged, pipeline drugs were improperly treated by the 184 Act, why was no broad-based remedial legislation introduced in Congress until after almost all of the patents covering pipeline drugs had expired? If, as Sen. Torricelli indicates, there were 17 pipeline drugs that had FDA review times greater than five years (as compared to an average review time of 2+ years), why is this legislation only being offered now after 10 of those 17 patents have expired? In seeking answers to these questions, the Judiciary Committee should take note of the fact that of the 7 patents potentially affected by S. 1172, 4 of them⁵ were discovered and developed in foreign countries by non-US citizens working for foreign-owned companies and were first patented in a foreign country. There is no policy rationale for granting additional patent extensions to those foreign products. Moreover, of the three US-based patents, the patent covering Eulexin provides 12.3 years of market exclusivity; and the patent covering Cardiogen provides 12.7 years of exclusivity without the additional extensions contemplated by S. 1712. According to a report issued by the Congressional Budget Office⁶ the average length of market exclusivity for drugs developed after 1984 is 10 to 11 years. Given all of these facts, it seems rather clear that the only purpose of S. 1172 is to provide Schering with an opportunity to extend its multi-billion dollar/year monopoly on Claritin. Therefore, Schering's entitlement to that relief (or lack thereof) should be directly addressed by Congress rather than creating an elaborate and unnecessary administrative process.

It is undisputed that the FDA was prepared to approve the capsule dosage form of Claritin, on which the clinical trials had been based, in October 1987 just one year after the NDA was filed. In fact, Schering publicly announced in December 1997 that Claritin would be launched during the first half of 1988. If Schering had

⁴See, Hutt "The Importance of Patent Term Restoration to Pharmaceutical Innovation", Health Affairs, Vol. 1, No 2, p. 6 (1982).

⁵The patents covering Relafen, Nimotop, Penetrex and Dermatop are all based on patents first filed in foreign countries and later filed in the United States.

⁶How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, July, 1998.

proceeded as planned, it would have enjoyed more than 14 years of market exclusivity before its basic Claritin patent expired and would be ineligible for any patent term extension under either the 1984 Act or S. 1172. However, Schering made a belated market-based decision to switch from the approved capsule form of Claritin to a tablet dosage form. Under FDA rules, the burden was on Schering to prove that its new tablet was bioequivalent to the approved capsule. It was this belated change in the NDA and subsequent technical difficulties in proving bioequivalence that apparently delayed the approval of Claritin for several years.⁷ Therefore, Schering is seeking compensatory patent extension for its own actions and not for a delay caused by the FDA.

There are those who argue that the foregoing facts are irrelevant because S. 1172 merely creates a process for determining whether Claritin is entitled to an extension without prejudging that issue. I respectfully disagree for two reasons. First, before Congress puts a process in motion which has the potential for creating billions of windfall profits for Schering at the expense of the millions of patients who take Claritin, there should at least be a prima facie case which establishes that Schering was treated inequitably and is entitled to the relief being sought. Here, the available facts and law establish that Schering's shortened exclusivity is the result of its deliberate business decision to belatedly abandon the original dosage form of Claritin for business reasons.

Second, the "process" established by S. 1172 is seriously flawed. It would only require Schering to prove that it acted with "due diligence". Schering has already received a 2-year patent extension on that theory. Additional relief should be available, if at all, only if it can be shown that the unusually long regulatory review period for Claritin was caused by improper delays by the FDA. Schering may well have acted with due diligence in seeking approval for a new dosage form but it could have marketed the capsule form of Claritin beginning in 1988 and apparently did so in many other countries. Schering should not be entitled to a patent extension for marketing time lost as a result of its business decision to refrain from marketing Claritin in the United States until it could gain approval for a more preferred dosage form. Yet, S. 1172 is not drafted in a manner which would require the PTO to examine that question of who or what caused the delay in approving Claritin. Nor does the bill prohibit the granting of an extension if the delay was caused by the applicant. Indeed, the bill does not even require an applicant for extension to publicly disclose all of the facts and proceedings relating to the approval process so that the cause of any delay can be independently determined. In short, the "process" established by S. 1172 is lopsided and essentially guarantees Schering an extension by merely asking for it.

For all of the foregoing reasons, no case has been made to support the notion that the 1984 Act erroneously short-changed pipeline drugs or that the FDA acted in a manner which improperly denied any pipeline drug the full measure of market exclusivity to which a drug was entitled. Without such evidence, it would be wrong for Congress to establish a process for providing farther patent term extensions for pipeline drugs.

I appreciate this opportunity to provide my views on this important issue and would be pleased to answer any questions that may arise from my comments or related matters.

Sincerely,

ALFRED B. ENGELBERG.



⁷The full facts with respect to the timing and events relating to the NDA review and approval process for Claritin are confidential and Schering has refused to waive confidentiality so that the process can be independently reviewed. It is unconscionable for Schering to claim that it has been wrongly treated and to simultaneously refuse to make the facts available. An adverse inference should be drawn from this conduct.