TESTIMONY OF

SENATOR HOWARD M. METZENBAUM (Ret.),

CHAIRMAN,

CONSUMER FEDERATION OF AMERICA

REGARDING

S. 1172,

THE DRUG PATENT TERM RESTORATION REVIEW PROCEDURE ACT OF 1999

BEFORE THE

COMMITTEE ON THE JUDICIARY,

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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% of U.S. health spending in 1999, up from 7.2% 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

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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.

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.

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.

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.

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 intact while the appellate process drags on.

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.