Consumer Federation of America

TESTIMONY OF

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CHAIRMAN

BEFORE THE

SENATE JUDICIARY COMMITTEE

REGARDING

LEGISLATIVE AND REGULATORY REPSPONSES TO THE FTC STUDY ON BARRIERS TO ENTRY IN THE PHARMACEUTICAL MARKETPLACE

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Good morning, Mr. Chairman, Senator Leahy and members of the Committee. My name is Howard M. Metzenbaum and I now serve as Chairman of the Consumer Federation of America (CFA).[1] This testimony is also endorsed by Consumers Union,[2] the publisher of Consumer Reports magazine. I appreciate your invitation to offer my comments regarding legislative and regulatory responses to the authoritative Federal Trade Commission (FTC) report on generic drugs issued last July. The FTC report detailed at length the many specious tactics used by drug companies to stall or thwart public access to less expensive generic drugs.

It is outrageous that the same companies that charge Americans the highest drug prices in the industrialized world would use secret payoffs, flimsy legal maneuvers and back room deals to eliminate generic competition, line their pockets and harm consumers. Every time a drug company blocks a safe, generic drug from getting into the hands of the American people, they are placing a tax on the uninsured, the poor, the sick and the elderly.

These outrageous attempts to keep drug prices high are particularly disgraceful, Mr. Chairman, because they undermine the effectiveness of one of your major achievements: the Drug Price Competition and Patent Restoration Act of 1984, also known has the Hatch-Waxman Act. You and Congressman Waxman provided great and wise leadership in drafting a law that represents a careful balancing act. It increased 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 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 has been the most profitable sector of the economy for the last thirty years.

However, in recent years, as a number of top-selling "blockbuster" drugs were due to come off patent, brand drug manufacturers have used their political muscle and legal resources in a series of increasingly desperate attempts to block generic drugs from coming to market. For example, to protect the lucrative legal monopoly on its best-selling antihistamine Claritin, drug manufacturer Schering Plough made three separate attempts in the late 1990s to sneak through riders to appropriations bills that would have extended Claritin's patent. When that failed, they attempted to pass the infamous Claritin bill, which would have made it virtually impossible for the U.S. Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office to stop a patent extension.

When these crass legislative efforts failed, the drug industry turned to their platoon of legal talent for help. They filed late patent claims just before a drug was to come off patent, sometimes on insignificant factors that had nothing to do with the therapeutic equivalence of a generic drug, such as the color or shape of a pill. They filed numerous "nuisance" lawsuits on the same drugs for violations of those late patents, triggering Hatch-Waxman's 30-month stay on the approval of the generic drug. They made secret payments to some generic companies to keep the generic alternative off the market.

All of these abuses were detailed in the FTC Report, "Generic Drug Entry Prior to Patent Expiration." I would like to provide you with the consumer perspective on the two major responses to this fine report: the recent bipartisan compromise reached on Senate legislation and a FDA rule promoted by the President that was finalized last week. These proposals overlap to some degree. In general, the bipartisan Senate compromise is much better for consumers because it deals more effectively with the range of abuses of the law that have occurred.

The Greater Access to Affordable Pharmaceuticals Act (GAAP)

Last year, the Senate passed GAAP by a wide, bipartisan margin, but the House of Representatives did not act on the bill. This year, Senators Kennedy, Gregg, McCain and Schumer have reached a bipartisan compromise on GAAP (S. 1225) that is expected to pass the Senate soon as part of Medicare prescription drug legislation. This bill has several strengths:

- **It would limit the ability of brand name drug manufacturers to prevent generic competition by triggering multiple 30-month stays on the same drugs. The bill would generally allow only one stay per drug to be granted.** The Hatch-Waxman Act sought to assure brand name drug companies that their patented products would not be infringed upon by generic drug makers who "jumped the gun" and introduced a competing product before the drug patent had expired. The law requires the FDA to stay approval of any generic drug for 30 months if the brand name company sues the generic drug maker for patent infringement. As the FTC report documents, brand name companies have improperly claimed additional patents for their products and then brought patent lawsuits to trigger 30 additional months of competition-free sales. The bill would generally allow only one stay per drug, as long as the patents are listed by the time a generic company files an Abbreviated New Drug Application (ANDA.) However, it is important to note that the restriction on multiple stays will apply to fewer patents at a later point under this compromise, than under last year's GAAP legislation (S. 812). Last year's bill only allowed a stay for patents that were already listed by a brand company at the time a new drug was approved by the FDA. The more permissive provision in S. 1225 will give brand companies a greater opportunity to manipulate the process by filing a later patent and then seeking a 30-month stay for patent infringement.

- **Generic companies would have the right to assure that their drugs are not in violation of any patent before going to market.** Under the bill, if a brand company does not bring a suit within 45 days of being notified of a generic firm's challenge to a patent, the generic "applicant" could go to court to see a declaratory judgment that no patents are being violated. Currently, the only way for a generic manufacturer to challenge an improper patent listed in the FDA's "Orange Book" is to certify that the patent is invalid or that the generic product does not infringe on the patent in question (paragraph IV certification). This action predictably leads to an infringement suit by the brand manufacturer against the generic, which automatically triggers a 30-month stay. Not only is the generic party to the suit prohibited from entering the market but the FDA is barred from approving market entry to any other generic within the same class. Strangely enough, the law enables a brand company to delay generic competition by simply not filing a patent infringement lawsuit.

By not acting, the brand company is holding out the threat of an infringement lawsuit in the future. In such a situation, most generic companies are unwilling to bring their drug to market, because they face the possibility of treble damages for patent infringement. The bill would provide a method for generic drug applicants to challenge improper Orange Book listings, resolving all outstanding legal issues with finality, without invoking a 30-month stay and stalling generic market entry.

- **It would help prevent anti-competitive contracts between brand name and generic drug companies, in which generic firms are paid by the brand-name drug company not to compete.** These "sweetheart" agreements violate the intent behind Hatch-Waxman, raise antitrust concerns and cost consumers millions of dollars a day. Such payoffs occur because Hatch-Waxman grants the first generic drug company to challenge the validity of a patent six months of "exclusivity" as the only company allowed to sell the generic version. The FTC has settled several cases in which a brand name drug manufacturer has paid a generic competitor not to market the generic alternative for the 180-day exclusivity period, allowing the brand drug to maintain its monopoly.[3] S. 1225 would require the first generic applicant to "use it or lose it." If the generic applicant fails to go to market within 60 days of final FDA approval or an appellate court decision, or fails to meet one of several other similar requirements, the company loses its six-month marketing monopoly.

- **It would take some moderate steps to reduce nuisance patent lawsuits.** Brand drug companies are required to list all patents that cover a specific drug with FDA in the Orange Book. Brand manufacturers have devised a way to keep their drug products from ever coming facing competition by filing new patents with the FDA at staggered intervals, so as one patent covering the drug product expires, it will still have patent protection.[4] The bipartisan compromise legislation would allow generic companies to challenge inappropriate patent listings, but only if they are sued first for patent infringement. It would also permit courts to consider a brand company's failure to file patent information as a basis for not awarding treble damages, which generic companies could face if found liable for a patent violation. It remains to be seen how effective these provisions will be in preventing obstructive litigation by brand companies. Both provisions are weaker than similar provisions in last year's GAAP legislation,[5] and may not provide as much of a disincentive against new frivolous patent listings with the FDA on the eve of drugs coming "off-patent."[6]

- **It would make it easier to bring several classes of generic drugs to the market.** Under the Hatch-Waxman Act, generics must prove they are "bioequivalent" to the brand name drug. Under current law, bioequivalence is determined by the absorption of a drug in a patient's blood stream, which is difficult to measure for many types of medications, such as topical ointments and inhaled medicines. While the bill would not change the FDA's current bioequivalence regulations, it clarifies existing FDA authority to amend those regulations.

The FDA's Final Generic Drug Rule

This final rule, first proposed by the President and the FDA in December, will complement the Senate bill in some ways. Overall, however, the final rule is unlikely to significantly reduce the anticompetitive tactics that I have cited today.[7] Even worse, by requiring the listing of new

categories of patents, like some product-by-process patents and some polymorph patents, it may actually encourage further abuse by brand drug companies of the patent listing process.

The rule does attempt to limit brand companies to one 30-month stay per drug if they believe a generic company has infringed on a legal patent. However, this restriction is much weaker than that in both the Senate compromise bill and last year's GAAP legislation. By allowing brand companies to seek a stay on all patents listed up until the generic drug enters the market, the FDA will allow brand companies to continue to game the system. Brand name companies will be able to list a late patent (with certain new restrictions) and then file a last-minute patent infringement lawsuit, improperly delaying consumer access to a generic drug that is about to go to market. By comparison, both the Senate compromise legislation and last years' GAAP bill would have allowed a 30-month stay only if the patent was listed much earlier in the process.

The rule's requirement that brand drug companies provide more information about the patents they are listing could help decrease the number of improper patent listings. However, while the initial rule required brand companies to submit a justification for the listing of all patents, the final rule only requires this justification for method-of-use patents. Moreover, the FDA failed to take the most significant step to minimize improper listings, which is to develop a procedure to review the adequacy of listings in the "Orange Book." In fact, the preamble of the final rule explicitly refuses to develop a "de-listing" procedure.

The FDA rule also takes a wrong turn by actually requiring certain additional patents to be listed in the Orange Book. Although this provision of the final rule is not as broad as the initial rule, it will still require new listings for some polymorph patents and some product-by-process patents. Moreover, although the final rule prohibits patents on metabolites, it does allow patents for "a method of using a drug to administer a metabolite," which could be abused. In its report, the FTC specifically highlighted the similarity of product-by-process patents to process patents, which cannot be listed in the Orange Book.[8] In fact, the FTC stated that product-by-process patents may be virtually indistinguishable from process patents. The FTC also raised serious questions about the listing of polymorph patents.[9] The FDA should not expand the scope of patents that are allowed to be listed to include these two patents. They do not fall within the three currently acceptable types of patents -- drug substance, drug product and method of use. There is a good chance that such an expansion would be abused by brand manufacturers and prove harmful to consumers' interests.

Conclusion

The pharmaceutical industry has repeatedly used improper delaying tactics to thwart access to generic drugs. This is not only a threat to the pocketbook of many Americans, but to their health. When faced with high drug costs, many people will go without needed medications or reduce the consumption of these drugs below the prescribed level. Senator Hatch and Senator Leahy, I urge you and members of the committee to support the bipartisan compromise legislation that will soon reach the Floor. Although the bill is not as strong as earlier legislation passed by the Senate, I applaud the efforts of Senators, Kennedy, Schumer, McCain and Gregg to find a compromise that will decrease drug costs and increase the flow of generic drugs to Americans in need.

Thank you for the opportunity to provide my comments.

[1] CFA is a non-profit association of some 300 pro-consumer organizations. CFA was founded in 1968 to advance the consumer interest through advocacy and education.

[2] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of Consumer Reports, its other publications and from noncommercial contributions, grants and fees. Consumers Union's publications carry no advertising and receive no commercial support.

[3] American Health Lawyers Association, *Today in Health Law, FTC Settles Complaint Alleging Drug Company Blocked Generic Competition* (Executive Briefing Wednesday, April 24, 2002 - Volume 7, Number 79).

[4] See Pfizer's "Orange Book' listings for Neurontin (generic name gabapentin). Although Pfizer's patent for the active ingredient gabapentin expired in 1998, the company still has six patents filed with the FDA in the Orange Book protecting Pfizer's market monopoly on Neurontin. A generic is not on the market and Pfizer's last patent covering Neurontin is set to expire October 25, 2017.

[5] S. 812, as passed by the Senate in 2002, required brand companies to declare that they had provided complete and accurate information on all patents. It also provided generic companies that had filed an ANDA application with an affirmative private right of action to correct improper patent listing, not just as a right to file a counterclaim if sued. It also barred patent infringement suits for brand companies that did not list the applicable patent within 30 days of being approved.

[6] See In re Buspirone Patent Litigation, 185 F.Supp.2d 340 (S.D.N.Y. 2002). Bristol-Meyers Squibb submitted a new patent to the FDA covering BuSpar the day before drug was scheduled to go "off-patent." Generic equivalents, which were scheduled to be available on the market the day BuSpar's patent expired, were delayed for months.

[7] The Consumer Federation of America and Consumers Union submitted comments to the FDA on December 23, 2002 that supported the intent of the initial FDA proposal, but detailed several serious flaws in the proposal.

[8] "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission, July 2003, pg. A-43.

[9] FTC Report at A-41.