Testimony of

The Honorable Patrick Leahy

August 1, 2003

Statement of Senator Patrick Leahy
"Examining the Senate and House Versions of
The 'Greater Access to Affordable Pharmaceuticals Act'"
Senate Judiciary Committee
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The Senate has been struggling with the myriad issues surrounding Medicare reform, and indeed the provision of quality, affordable health care generally, for years. Our latest effort is now in conference: The "Greater Access to Affordable Pharmaceuticals Act" is a critical part of the Medicare legislation, and I have high hopes for its ultimate effect on the health and lives of a great many Americans.

Like any complicated and contested bill, the Act has presented many challenges to its drafters and supporters as it has progressed through the legislative process. Now that it is in conference, the final decisions need to be made, and the last compromises worked out, so that we can continue to move forward. I sincerely hope that the tremendous quantity of time, and the heroic quality of effort, that have been put into this bill are not dissipated in conference. The stakes are too high, when we are dealing with the health and well-being of our citizenry, to risk a final bill that is anything less than a genuine improvement in our system of healthcare.

I do understand that there are more than a few differences between the House and Senate versions of the Act, and I know that feelings are running high on several of those, most notably on the declaratory judgment provision that concerns patent suits between companies anxious to enter the market with a generic version of a drug and the brand name drug companies that hold a patent on that drug. I will not enter that fray today, except to say that while we should take seriously the constitutional limitations on our actions in Congress, we should also not hesitate to legislate what is necessary within the confines of our constitutional powers and prerogatives.

One matter quite close to me is the Drug Competition Act, which was included as an amendment in the Greater Access to Affordable Pharmaceutical Act. The Drug Competition Act closes a truly problematic loophole in the current law. Under that law, the first generic manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires enjoys protection from competition for 180 days B a head start on other generic companies. In itself, that was an excellent idea, and likely to promote generic drugs in the marketplace. That was a good idea B but the unfortunate loophole exploited by a few is that secret deals can be made that allow the manufacturer of the generic drug to claim the 180 day grace period B to block other generic drugs from entering the market B while, at the same time, getting paid by the brand name manufacturer not to sell the generic drug.

The Drug Competition Act simply requires generic and brand name drug companies that enter into agreements that touch on that 180-day exclusivity period to report those deals to the antitrust enforcers at the Department of Justice and the Federal Trade Commission. Thus, it will ensure that law enforcement agencies can take quick and decisive action against companies that are driven more by greed than by good sense. The FTC and Justice can look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of that law will be allowed to stand. The Drug Competition Act accomplishes precisely that goal, and helps ensure effective and timely access to generic pharmaceuticals that can lower the cost of prescription drugs for seniors, for families, and for all of us.

Indeed, last July, the Federal Trade Commission released a comprehensive report on the barriers to entry of generic drugs into the pharmaceutical marketplace. The FTC had two recommendations to improve the current situation and to close the loopholes in the law that allow drug manufacturers to manipulate the timing of generics= introduction to the market. One of those recommendations was simply to enact our bill, as the most effective solution to the problem of Asweetheart@ deals between brand name and generic drug manufacturers that keep generic drugs off the market, thus depriving consumers of the benefits of quality drugs at lower prices. I am pleased to see Chairman Muris here this morning, and want to thank him for his support of the Drug Competition Act.

The Drug Competition Act bolsters our efforts to bring quality healthcare at lower costs to more of our citizens. It enjoyed the unqualified support of the Senate last year, and I sincerely hope that this common sense legislation is a part of any final agreement with the House on the larger drug bill. I do know that the House version has deleted the reference to the Department of Justice, limiting referrals of these secret deals simply to the FTC, but I understand that that is simply a jurisdictional issue, and not a substantive concern. I believe that the Department of Justice can be restored to its co-equal role with the Federal Trade Commission in overseeing this situation while the larger bill is in conference.

I have also heard the very thoughtful and positive suggestion that other deals that effect the 180-day period should be included, and that the bill not be limited to generic manufacturers' deals with brand name companies. Instead, it has been suggested that generic-generic deals, as well as brand name-brand name deals, be included as well in the agreements that must be reported to the antitrust enforcement agencies, and I whole-heartedly concur in that suggestion. No companies should be allowed to abuse the incentives designed to encourage the entry of generic drugs to the marketplace, and this would be a worthwhile enhancement of the Drug Competition Act's purpose in stopping such misbehavior.

I look forward to hearing what all the witnesses have to say this morning, and I thank Chairman Hatch for convening a hearing on an issue that has such an impact on the physical health and fiscal well-being of all our citizens.

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