Testimony of

The Honorable Orrin Hatch

August 1, 2003

August 1, 2003 Contact: Margarita Tapia, 202/224-5225

Statement of Chairman Orrin G. Hatch
before the United States Senate Committee on the Judiciary
Hearing on

"Examining the Senate and House Versions of the
'Greater Access to Affordable Pharmaceuticals Act'"

Good Morning. Today, we will explore important features of the Senate and House versions of the "Greater Access to Affordable Pharmaceuticals " legislation. In the Senate, this was the Gregg-Schumer Amendment to the Medicare bill, S. 1.

I seem to recall that this measure was adopted by the Senate by an overwhelming 94 to 1 vote. There is always somebody who does not get the message!

Similar, but not identical legislation was included in the House Medicare Bill, H. 1.

A chief purpose of this hearing today is to help the Medicare conferees and others evaluate the relative merits of the Senate and House provisions.

I want to commend my colleagues, Senators Gregg, Schumer, McCain, and Kennedy for all of their work on this legislation. I believe that this legislation represents a major improvement over last year's vehicle, S. 812.

I am pleased that the sponsors of this legislation have now adopted a version of the 30-month stay provision that I first suggested last May, and argued for on the floor last July. The one-and-only-one 30-month stay for all patents filed when the NDA is submitted was also a centerpiece of the Federal Trade Commission report released last summer. The proponents of this legislation were wise to reject all of the various previous legislative proposals in this area.

I want to commend again Chairman Muris and the FTC for the agency's constructive contribution to this important debate.

In addition to a recommendation pertaining to the 30-month stay, the FTC Report contained a second recommendation calling for the reporting of any potentially anticompetitive agreement between pioneer and generic drug firms to the FTC and the Department of Justice. My colleague, Senator Leahy, developed just such legislation, the Drug Competition Act, that was included in the Senate Medicare bill. I have worked with Senator Leahy in developing this bill and support it.

Today, I want to spend some time examining some key differences between the Senate and House versions of the bill. For example, there are some differences between the House and Senate versions of the Leahy language that must be ironed out.

One of the most significant differences between the Senate and House bills centers on the manner in which the declaratory judgment provisions are drafted. These provisions were the subject of a spirited written debate between two esteemed lawyers - both of whom are friends of mine - Boyden Gray, former White House Counsel and John Yoo, a former member of my staff.

Today we will hear testimony from the Department of Justice that the Administration has concluded that the Senate declaratory judgment provision is constitutionally infirm.

Moreover, the Patent and Trademark Office will tell us that the Senate language "could result in unnecessary harassment of patent owners." In addition, PTO believes that the manner in which the Senate bill treats the award of treble damages is unwise.

On the other hand, we will hear from the FTC that it believes a key feature of the House declaratory judgment provision, the right to confidential access, may not be necessary and, as a matter of policy, the Senate declaratory judgment provision may have some advantages.

Consistent with its 2002 Report, the FTC takes exception with the manner in which both the Senate and House language eliminate the current district court decision triggering mechanism for 180-day marketing exclusivity.

We will also hear from the FDA about how the provisions of these bills would interact with the agency's recently issued final rule on patent listing. The FDA disagrees with the FTC on the matter of the court trigger and supports an appellate court triggering scheme.

It is my hope that after we have heard from our panel of government experts the conferees and other interested parties will gain knowledge about the strengths and weaknesses of the House and Senate bills'. Our goal should be to forge a conference report that preserves the best features of these measures or results in the crafting of better language.

Finally, we will also hear today from a private sector expert who will talk about the ramifications of an identical section of the Senate and House bills. These are the provisions related to the award of 180-day marketing exclusivity where pioneer patents are found to be invalid or not infringed by generic competitors.

Both bills adopt a first-to-file regime. I am a proponent of what I will call a successful challenger system. It seems to me that the first successful challenger - be it the first generic not to be sued, the first to win in court, or the first to be granted a covenant not to be sued by the pioneer firm - is more deserving than a mere first filer. As I explained in my June 26th Congressional Record statement, it appears to me that the 180-day marketing exclusivity provisions in the pending legislation contain perverse incentives that may result in unfortunate, if unintended, consequences.

I plan to ask the Congressional Budget Office to review the provisions of the 180-day marketing exclusivity provisions and consider whether these new rules may actually prove costly to consumers. It is possible a consensus will emerge to revisit this issue. Frankly, it seems to me that simply adding a new forfeiture event, in cases where a challenger is not sued, succeeds in court, or obtains a covenant not to be sued, could materially improve the legislation.

It is also possible that the Medicare conference will not be the best time or place to reconsider these issues. I can accept that. But I also believe that we have not heard the last word on these new 180-day rules.

Let me close by stating that it is my hope the Congress will enact a Medicare drug benefit this year. I plan to work in a constructive fashion toward the success of this legislation. In that spirit, I hope that today's hearing will help inform the discussion of reconciling the House and Senate versions of the important provisions addressing generic drug competition.

I look forward to hearing from our witnesses today.

# # #