Testimony of

The Honorable Orrin Hatch

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"LEGISLATIVE AND REGULATORY RESPONSES TO THE FTC REPORT ON BARRIERS TO ENTRY IN THE PHARMACEUTICAL MARKETPLACE"

Today, the Committee will hold a hearing in an area of great importance to the American public - competition in the pharmaceutical marketplace.

In this Congress, we have witnessed a growing spirit of bipartisan cooperation on pharmaceutical issues. After so many years of searching for consensus, we are all encouraged that the Finance Committee has now approved by bipartisan majority the Medicare reform and prescription drug bill we are now considering in the Senate.

President Bush deserves credit for encouraging the Congress to act in the best interests of the American public on these matters. We owe a debt of gratitude as well to Senator Grassley, Chairman of the Finance Committee and a member of this Committee, and Senator Baucus, the Ranking Democrat on Finance, for their work last week.

I will give them my wholehearted support as the Senate debates the bill over the next two weeks. Having been a member of the so-called "tripartisan group" which developed and advanced the basic structure of this Medicare reform bill over a number of years, I am excited at the prospect of finally getting the job done for our seniors and disabled.

But, there are another set of issues relating to pharmaceuticals that promise to benefit the American public through increased competition in the pharmaceutical marketplace. And that is the subject of our hearing today.

This Committee held a hearing in May of 2001 on the issue of competition in the pharmaceutical marketplace. At that time, we discussed the anti-competitive behaviors made possible, in part, by the sometimes complex and admittedly confusing text of a law I coauthored - the Drug Price Competition and Patent Term Restoration Act of 1984.

Since our last hearing on this issue, much has happened.

I wish to single out both the Federal Trade Commission and the Food and Drug Administration for playing a constructive role in attempting to end several mechanisms by which some research-based and generic drug firms were attempting to game the system to avoid competition in the marketplace.

The FTC submitted a citizen's petition to the FDA in May of 2001 to urge the agency to take steps to protect the regulatory system from unscrupulous and, in fact, unlawful behavior.

As the FTC testimony will detail, the agency has succeeded in winning several consent decrees with a variety of offending firms under the existing antitrust statutes. In addition, the FTC conducted an exhaustive survey and study of how certain provisions of the 1984 Waxman-Hatch Act affected competition in the pharmaceutical industry.

The FTC study contained two major recommendations. The first addressed the use of the statutory 30-month stay granted by the 1984 law in situations where patents are challenged by generic competitors. The FTC recommended that we:

"Permit only one automatic 30-month stay per drug product per ANDA to resolve patent infringement disputes over patent listed ... prior to the filing date of the generic applicant's ANDA."

This was precisely the position that I suggested in testimony before the HELP Committee on May 8, 2002 and for which I argued in the Senate last July. I will note for the record -- and express the hope that in the post Jayson Blair-era -- that at least one enterprising reporter will take the time and effort to document and analyze how the bill that passed the Senate last year,

S. 812, was at variance with this central recommendation of the FTC report.

The second major FTC recommendation responds to those situations in which R&D and generic firms were entering into agreements not to impede generic competition. The FTC recommended that Congress:

"Pass legislation to require brand-name and first generic companies applicants to provide copies of certain agreements to the Federal Trade Commission."

Having patted myself on the back with respect to my prescience on the first FTC recommendation, it is now my turn to compliment Senator Leahy. His bill, the Drug Competition Act, (S. 946) addresses this second recommendation.

I worked with Senator Leahy on refining that bill. I supported it in Committee, and worked with him to pass it through the Senate late last year. I hope and expect that the 108th Congress will adopt this measure, although I do believe it should be passed as an amendment to the Clayton Act rather than as a statute at large.

The FTC report also contained three minor recommendations and I hope that the FTC will tell us the status of these

today.
Apart from its recommendations, the FTC study served an important purpose of cataloging the facts surrounding certain abuses of the 1984 Act. In formulating public policy, facts matter - or at least they should. In formulating legislative and regulatory responses, we need to tailor the response to the identified problems -- nothing more, nothing less.
An example of an attempt to provide a measured approach to a problem is the Bush Administration's FDA rulemaking on the 30-month stay. As the rule was finalized just last Thursday, I will not pretend to understand all the nuances and implications of this 125-page rule and preamble.
But I can say this. The final rule appears to be a good faith attempt to implement the first FTC recommendation which calls for adoption of the principle that one-and-only-one 30-month stay should be permitted and only for those patents colorably related to the approved drug product. Today, we will have an opportunity to discuss how well the final rule effectuates a fair and thoughtful one-and-only-one 30-month stay policy.
In an area this complex, no one should be surprised if we find that the agency inadvertently created new loopholes or unintentionally imposed unfair hardships. In due course, we all must assess whether further refinements to these regulations may be in order.
On balance, President Bush, Secretary Thompson, Commissioner McClellan and the FDA deserve much credit for initiating a series of regulatory changes that promises to save consumers billions of dollars over the next 10 years. Likewise, Chairman Muris - and his predecessor and colleagues at the FTC - must be recognized for taking strong enforcement measures and providing the study that underpin much of the positive developments in this area.
The FTC report was issued only one day before the Senate adopted S. 812, the "Greater Access to Affordable Pharmaceuticals Act of 2003," last July 31st . Unfortunately, the FTC study did not get the attention it merited by the Senate.
The GAAP Act, developed by Senators McCain and Schumer, proved to be a very popular initiative for reasons which are obvious. That helps explain why Senators Kennedy, Collins, Edwards helped to revise the bill dramatically and garner the support of some 78 Senators last year.
And while there is no question my colleagues were motivated by their goal of making drugs more affordable for seniors and all Americans, there were some flaws in this legislation. It is no secret that I opposed the bill. It is no secret that the Administration opposed the bill. It is no secret the House did not take up the bill.
Frankly, given the analysis and recommendations of the FTC report and recently-issued FDA final rule, the prospect of language similar to S. 812 actually being signed into law by the President is remote at best.
Since I do not want to be the one to break the growing spirit of bipartisanship on pharmaceutical issues this year, I will not take the time to repeat all the arguments that I made at some length against S. 812 last year. Instead, I will briefly mention a few of the most egregious provisions of S. 812.
The proposed legislation, in addition to creating for the first time a private right of action in the Food, Drug, and Cosmetic Act, would have resulted in the waiver of patent rights - apparently even against third parties - if pioneer drug firms did not file certain patents with the FDA and, if challenged by a generic drug applicant, pursue expensive litigation within tight time frames.
In sharp contrast to the FTC recommendation, S. 812 basically made any patents submitted to FDA after a month from the date the pioneer drug application was received at the FDA ineligible for the 30-month stay. In most cases, this is at least four years earlier than the FTC recommendation.
It is no wonder why the American Intellectual Property Law Association opposed S. 812. It is no wonder why the biotech industry worked against the bill. It is no wonder that the Statement of Administration Policy on S. 812 noted that, "(c)learly the bill would benefit from consideration by the Senate's experts on Hatch-Waxman law on the Judiciary Committee, the proper committee of jurisdiction for this bill."
But all of that is old news about last year's failed tail-wagging-the-dog approach in which a flawed Waxman-Hatch vehicle proved incapable of carrying the Medicare drug benefit.
We now come to S. 1225. Once again we have a HELP Committee bill. Once again, it is called the "Greater Access to Affordable Pharmaceuticals Act." Once again, it is cosponsored by Senators McCain, Schumer, and Kennedy. Only this time the core of the bill is much more reasonable, due in great part to the considerable influence of Chairman Gregg. While I do have some concerns over the way in which this legislation was fashioned, I must give Chairman Gregg credit for succeeding in convincing his cosponsors and colleagues on the HELP Committee to make substantial improvements in last year's bill. And I must commend sponsors of S.812 for moving in the right direction. Although we do not have the benefit of final language, my initial reaction is that S. 1225 is a vast improvement over S. 812.
The purpose of our hearing today is to discuss the FTC report and assess how the new FDA rule and new bill work and whether improvements may be needed.
Generally speaking, S. 1225 appears to attempt to enact exactly the type of one-and-only-one 30-month stay policy

that I suggested to the HELP Committee last May, and the FTC recommended in July. The bill appears to be consistent with the spirit of the FDA rule. As with the precise language of the FDA rule, we must ask whether the actual text of the bill as reported, actually achieves its intended result. Discussion is in order as to how the bill language, if adopted, would work with the new FDA rule.

I am told that some in the Administration and within industry believe that the bill as reported last Wednesday has some technical problems. This is not surprising in such a complex area. The language should be carefully vetted among the patent and FDA regulatory bars.

I am also told that the language is something of a moving target as there is under development a package of technical corrections that selected governmental and industry experts have commented upon. I have learned over the years it is often the case that one man's so-called technical correction is another's substantive change.

It is unfortunate that the PTO was unable to present a witness today, albeit on short notice, and I will continue to press the agency for comments on how the bill and final rule affect patent rights. It would have been preferable for the Committee to have the benefit of an agency official who could advise us on the patent provisions of S. 1225.

One area of special concern to me and the Judiciary Committee is the argument that some have advanced - and others refute - that the case or controversy provision of the bill raises constitutional problems. While I do not expect the Administration or the Department of Justice to give us a definitive opinion on this matter today, it is my hope that they will soon be able to make its determination on this matter. I expect DOJ to pledge to work with our Committee, the HELP Committee, and others, to help fix any constitutional shortcomings and we are appreciative of the agency for providing us with a witness today.

Yet another improvement of S.1225 over the McCain-Schumer-Edwards-Collins legislation is the abandonment of the rolling exclusivity policy in favor of a use it or lose it approach. I have long stated a preference for the consumer friendlier use it or lose it rule over the too open-ended rolling exclusivity. In fact, as I argued on the floor last year, I think it appropriate that our entire approach to the 180-day patent challenge exclusivity should be reassessed. Specifically, I do not believe it appropriate to lump together patent invalidity and patent non-infringement challenges in light of the fact that the latter may in practice extend longer than the purported 180-day award. In my view, if two or more non-infringers come forward, let them compete in the marketplace as occurs in other industries.

I think it way past time to re-examine the length of the 180-day reward for patent challengers given the fact that the nominal value of blockbuster products has grown more than 10-fold in annual sales since 1984. I hope that Senator Metzenbaum can give us his views on that topic.

Finally, I am uncertain of the policy justification for S. 1225's retention of granting the 180-day reward to the first filer rather than the first successful defendant. What was wrong with the pre-Mova decision regime? I may be old-fashioned, but I believe that there is a lot to be said for giving the reward to the actual winner in court or the first not to be sued, not just the first one to enter the Parklawn Building with the right sheaf of papers.

Let me close on a positive note. The FTC study appears to have had a positive impact on both the regulatory and legislative fronts. I hope this hearing will increase our understanding of the facts and findings of the FTC report. I also hope that the Committee will take this opportunity to question the witnesses about the manner in which the new FDA rule operates.

Finally, I hope the Committee finds these two panels able to provide valuable insights into the consideration of Senator Leahy's Drug Competition Bill and the new, and perhaps still evolving, language that Senators Gregg, Schumer and others are developing.

I have said many times that I prefer a comprehensive approach to Hatch-Waxman reform that includes a discussion of augmenting the existing intellectual property incentives and consideration of whether and how to create a fast track approval process for off-patent biologics. Nevertheless, I stand prepared - and the Judiciary Committee stands prepared - to participate fully in any effort to revise the Drug Price Competition and Patent Term Restoration Act of 1984. We must all work together to see that the American public receives both innovative and affordable medicines.

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