August 27, 2003

Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

As you requested, CBO has prepared the enclosed analysis of the changes to the Hatch-Waxman Act contain in S. 1, the Prescription Drug and Medicare Improvement Act of 2003, as passed by the Senate on June 27, 2003. In particular, the enclosure addresses section 703, the 180-day marketing exclusivity provision contained in S. 1.

If you wish further details on this analysis, we will be pleased to provide them. The CBO staff contacts are Margaret Nowak and Anna Cook.

Sincerely,

Douglas Holtz-Eakin

Enclosure

cc: Honorable Patrick J. Leahy
Ranking Democratic Member

Honorable Judd Gregg
Chairman
Committee on Health, Education,
Labor, and Pensions

Honorable Edward M. Kennedy
Ranking Member

Honorable W. J. "Billy" Tauzin
Chairman
House Committee on Energy
and Commerce

Honorable John D. Dingell
Ranking Member

CONGRESSIONAL BUDGET OFFICE

August 27, 2003

Analysis of Changes to the Hatch-Waxman Act

As contained in S.1, the Prescription Drug and Medicare Modernization Improvement Act of 2003, as passed by the Senate on June 27, 2003

COST ESTIMATE OF TITLES VII AND IX OF S.1

CBO expects that enacting the changes to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, contained in titles VII and IX of S. 1, would accelerate the availability of generic versions of prescription drugs. As a result of that increased competition, CBO estimates the provisions in those titles would lower total drug spending within the United States by $7 billion over the 2004-2013 period. Of that 10-year total, the estimated savings for existing mandatory federal programs would be $750 million, as shown in the following table.

ESTIMATED EFFECT OF TITLES VII AND IX OF S. 1, THE PRESCRIPTION DRUG AND MEDICARE IMPROVEMENT ACT OF 2003

	Outlays in Millions of Dollars, by Fiscal Year [a]											
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2004-2008	2004-2013
Changes in Direct Spending [b]	-20	-30	-30	-40	-40	-80	-110	-120	-130	-150	-160	-750
Changes in Spending Subject to Appropriation	-5	-10	-10	-10	-10	-25	-25	-25	-40	-40	-45	-200

SOURCE: Congressional Budget Office.

a. CBO estimates that titles VII and IX also would increase revenues by $200 million over the 2004-2013 period.

b. Titles VII and IX would also affect the cost of the Medicare prescription drug benefit in title I of S. 1. CBO's estimate of the net cost of the prescription drug benefit reflects a reduction of $650 million as a result of the Hatch-Waxman provisions.

The changes to the Hatch-Waxman Act also would affect spending subject to appropriation, for programs such as veterans health care, the Department of Defense health care programs, and the Federal Employees Health Benefits program for active workers. CBO estimates that savings for these programs would be $200 million over the next 10 years, assuming that appropriations are reduced accordingly.

180-DAY MARKETING EXCLUSIVITY PROVISION

This analysis focuses on the 180-day exclusivity provisions contained in section 703 of S. 1. One of the effects of these provisions would be to accelerate the availability of generic drugs in many cases. As under current law, the first company to file an abbreviated new drug application (ANDA) with a patent challenge could become eligible for a 180-day exclusivity period during which other generic drugs could not be sold. Under S. 1, generic manufacturers could file their ANDA and begin the patent challenge process much earlier with less risk of losing all or part of the 180-day exclusivity period available to the first generic applicant. This could lead to earlier commercial marketing by the first applicant under S. 1 than under current law.

At the same time, section 703 could delay first commercial marketing of a generic version of the innovator drug in some cases, because the 180-day exclusivity period would no longer automatically begin with a district court decision (brought by the first or any subsequent applicant) that the innovator drug company's unexpired patents were invalid or would not be infringed. Also, the fact that a greater number of generic firms would enjoy the full 180 days of marketing exclusivity means that competition from multiple generic drugs would be delayed for a similar period.

CBO expects that the impact of these opposing factors on drug spending would generally be offsetting.

Current Law

Under current law, the first generic applicant to a file an ANDA that contains what is known as a paragraph IV certification on a particular patent may become eligible for 180 days of marketing exclusivity—the period in which only one generic manufacturer would be permitted to compete with the original brand-name drug. (A paragraph IV certification claims that the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application has been submitted.) Because firms can qualify for the 180-day exclusivity period if they are first to file a paragraph IV certification on any patent, that 180-day period can be shared among multiple generic firms producing the same drug

product. The first applicant may be awarded marketing exclusivity if it is not sued by the brand-name manufacturer on the challenged patent or if it is sued but the court finds that the patent is invalid or not infringed.

The exclusivity period begins at the earlier of the date of a decision by a district court or when the first applicant begins marketing their product. In some cases, generally involving appellate litigation, first applicants do not begin marketing immediately upon receiving a favorable decision from a district court. First applicants also may lose part or all of the exclusivity period if they are not ready to market a generic version of the drug immediately after a subsequent generic applicant obtains a district court decision that the unexpired innovator's challenged patent(s) are invalid or not infringed. First applicants have not always realized their statutory right to the 180 days of marketing exclusivity.

Under current law, it is also possible for the 180-day exclusivity period to be "parked"—preventing subsequent applicants from obtaining FDA approval even if they have resolved the status of all challenged patents before the first applicant. This can occur, for example, if a subsequent applicant is not sued by the innovator company and cannot obtain a district court decision of noninfringment that would trigger the 180-day exclusivity period.

Proposed Changes Under Section 703 of S. 1

Section 703 would change eligibility for the 180 days of marketing exclusivity to the first generic applicant to submit an ANDA with a paragraph IV certification on any listed patent for a particular drug product. Subsequent applicants would not be entitled to the 180 days of marketing exclusivity, even if they are the first to file a paragraph IV certification on a different or subsequently listed patent for the same drug product. If multiple applicants each submit the first ANDA containing a patent challenge for a particular drug product on the same day, then each qualifies as a first applicant and eligibility for the exclusivity period is shared.

Under S. 1, the exclusivity period would begin on the date that the first generic applicant first offers the drug in the commercial market. That change would permit the first applicant to more frequently take advantage of the full 180-day exclusivity period. For example, the 180-day exclusivity period would no longer be triggered once the first applicant obtained a district court decision that a challenged patent was invalid or not infringed. If that court decision were to occur before a strong patent (such as a compound patent) expires, it would no longer start the 180-day exclusivity period during the time when the first applicant is still prevented from going to market by the unexpired strong patent. This would give generic manufacturers the incentive to file their applications earlier because there would be less risk of losing some or all of the 180 days of marketing exclusivity. To the extent that the first

applicant would enjoy the full 180 days of exclusivity under S. 1, but not under current law, competition from multiple generic firms could be delayed.

Subsequent applicants that file an ANDA with a paragraph IV certification may obtain a court decision of noninfringement on the challenged patent(s) before the first applicant. To facilitate such subsequent applicants coming to market, section 703 establishes "failure to market" conditions under which the first applicant would forfeit the period of exclusivity. For example, the first applicant would have to market the drug within 75 days after any applicant has obtained a favorable court decision on all unexpired challenged patents. The court decisions that could trigger such a forfeiture event include an appellate court ruling, an unappealed district court ruling, or a settlement order finding that all unexpired patents challenged by the first applicant are invalid or not infringed. When the brand-name manufacturer appeals a district court decision in favor of a subsequent generic applicant, those forfeiture conditions effectively change the earliest date that a subsequent applicant may enter the market from 180 days after a favorable *district* court decision under current law to 75 days after a favorable *appellate* court decision if the first applicant forfeits the exclusivity period. If the exclusivity period is not forfeited, subsequent applicants could wait up to 255 days after a favorable appellate court decision to enter the market under S. 1.

The "failure to market" forfeiture conditions also creates a way for first generic applicants to file their ANDA with a patent challenge many years in advance of the expiration of a strong patent (such as a compound patent) without risking loss of some or all of the 180-day exclusivity period. This involves challenging a strong patent as well as later expiring patents. Until all challenged patents are either shown to be invalid, not infringed, or have expired, subsequent applicants cannot trigger the forfeiture under the "failure to market" condition. By challenging a strong patent, together with other later expiring patents, the first applicant causes the forfeiture condition to hinge on the status of the strong patent, which is unlikely to be found invalid or not infringed. In most cases then, until the strong patent expires, no subsequent applicant can cause the first applicant to forfeit the exclusivity period. This will lead to earlier generic entry, because the patent challenge process is likely to begin much earlier in such cases, and the litigation is more likely to be resolved before the strong patent expires (something that has rarely occurred under current law). At the same time, brand-name manufacturers will be forced to defend their strong patents more frequently than under current law. The number of brand-name drugs facing patent challenges may not increase because of this provision, but it is much more likely that brand-name manufacturers will also have to defend at least one strong patent.

The "failure to market" conditions in section 703 do not fully address cases where the 180-day exclusivity period can be "parked" under current law—preventing subsequent applicants who have resolved the status of all challenged patents before the first applicant from coming

to market. For example, the exclusivity period could be "parked" if the brand-name manufacturer fails to pursue litigation against subsequent applicants on at least one of the patents challenged by the first applicant. If a subsequent applicant seeks a declaratory judgment and the court dismisses the case or issues a consent decree based on the brand-name manufacturer stating it will not pursue infringement litigation, that decision might not constitute a "finding that the patent is invalid or not infringed"; hence, the first applicant would not be forced onto the market (or to forfeit their exclusivity period).

The exclusivity period also would be forfeited under certain other conditions, including if all challenged patents expired or if the first generic applicant and the brand-name manufacturer of the drug enter into an agreement that violates antitrust laws. Because these provisions would prompt the first applicant to pursue FDA approval and litigation diligently, they would tend to help speed generic entry in some cases.

Under S. 1, as passed by the Senate, CBO expects that the provisions that would enable the first generic applicant to enjoy the full 180 days of marketing exclusivity would result in generic applicants filing their ANDAs earlier in some cases, thereby accelerating generic entry. However, because the 180-day exclusivity period could no longer automatically begin with a district court decision, generic entry would be delayed in some cases. Competition from multiple generic firms also would be delayed more frequently by the changes governing the 180-day exclusivity provision.

CBO expects that the savings resulting from earlier generic competition for some drugs, and the costs resulting from delayed generic competition for other drugs, including delayed competition from multiple generic firms, would be largely offsetting. Therefore, CBO estimates that there would be little net effect of these provisions on spending.

CBO STAFF CONTACTS

This analysis was prepared by Margaret Nowak and Anna Cook.