

2. Gains to the Generic Drug Industry

Innovator market share erosion is accompanied by a gain in generic market share. We estimate the 1-year increase in revenues to be \$1.120 billion. Escalating this impact by the annual increases in pharmaceutical expenditures yields a 10-year revenue gain of \$19.117 billion. Our annualized impact using a 7-percent discount rate is \$1.805 billion. These estimates are the same as in the proposed rule.

3. Benefits Not Quantified

Many important benefits associated with this final rule are difficult to quantify. The benefits to consumers from lower prices also involve favorable secondary benefits from improved access to less expensive drugs. While the economic literature indicates generic competition does not lead to significant overall increases in the quantity of drugs demanded, we nevertheless recognize this rule has favorable distributional effects for consumers who otherwise may not have been able to afford some medications. Such a benefit is consistent with the objective of improving access to affordable quality healthcare. Consumers with better access to affordable safe and effective therapies are healthier and enjoy a higher quality of life.

By addressing multiple 30-month stays, this final rule is removing a barrier to entry for generic drug firms. In principle, the removal of a barrier to entry would imply an increase in economic efficiency. The existing economic literature, however, indicates no significant increase in the quantity of drugs demanded with generic entry, implying no gain in efficiency from the removal of the barrier to entry. Thus, we do not quantify any efficiency gains in our analysis. Nevertheless, this rule encourages more and earlier market entry by generic drug firms and may impact consumption in a way not captured by the economic literature. To that extent, we believe this rule has the potential to increase economic efficiency.

The costs of allocating legal resources to defend patent protections are substantial. We do not know the extent to which this final rule will reduce such costs, but by eliminating multiple 30-month stays per ANDA and 505(b)(2) application, we are reducing the number of instances where innovator and generic drug firms would engage in such litigation. Moreover, we believe that this rule will reduce litigation because it clarifies which patents must and must not be submitted and reduces incentives

for submitting patents that may ultimately be found invalid. It logically follows that the reduction in resources devoted to litigation would result in savings to both innovator and generic drug firms.

This final rule reduces the level of uncertainty associated with drug marketing decisions. For example, the final rule diminishes incentives associated with submitting later-issued patents late in the patent life or exclusivity period of the product described in the NDA. Increasing the predictability of the generic drug entry process reduces product introduction costs faced by generic drug firms. In the final rule, we are also addressing a source of confusion over the submission of polymorph patents for listing in the Orange Book. We believe that a more predictable business environment benefits both innovator and generic drug firms.

Another important benefit of the final rule involves the balance between rewarding innovation and the availability of less expensive drugs. In striking this balance, we do not believe that the Hatch-Waxman Amendments intended to create the potential for NDA holders to obtain multiple 30-month stays to unduly delay generic competitors. We believe this balance to be important, yet find the value difficult to quantify. Nevertheless, in addressing the issue of multiple 30-month stays, we believe this action has the very valuable benefit of preserving the balance struck in the Hatch-Waxman Amendments.

4. Total Benefits of the Regulation

The total quantified benefits of this final rule include the gains in generic drug manufacturer revenues and consumer savings from earlier access to less expensive pharmaceuticals. These quantified gains to consumers and generic drug companies are the result of an economic transfer. The 1-year benefits to generic drug manufacturers and consumers are \$1.119 billion and \$2.040 billion, respectively. Escalating these base year costs over 10 years yields generic drug manufacturer revenue gains of \$19.117 billion and consumer savings of \$34.822 billion, for a total of \$53.940 billion. The 10-year annualized benefits, using a 7-percent discount rate, are \$1.805 billion for generic drug manufacturers and \$3.288 billion for consumers, for a total of \$5.093 billion.

C. Costs of the Regulation

In the proposed rule, we identified two sources of costs. Innovators lose revenues from earlier generic competition and innovators must

complete patent declarations. The loss in revenues to innovator drug companies is part of an economic transfer, but is included in this analysis with the resource costs associated with this action. We summarize the revenue loss and we assess the costs associated with the declaration requirement. In addition, we estimate the burden to industry from the requirement that, for submission of patents claiming different polymorphs of the active ingredient described in the NDA, there must be test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA.

In the proposed rule, we addressed potential concerns about the effect this action may have on innovation. After considering potential impacts, we concluded that any negative effect would be minimal. As discussed in the proposed rule, while the initial 30-month stay is part of the balance struck in the Hatch-Waxman Amendments to reward innovation, the subsequent stays are not part of this balance. According to the FTC report, most of the court rulings examined by the FTC, which involved a subsequent 30-month stay, found the underlying patent to be either invalid or not infringed. Extending market exclusivity through multiple stays is a strategy that has become popular in the last few years and is not a longstanding source of research funding. Subsequent stays could actually hinder innovation through the replacement effect, in that they provide a disincentive for an NDA holder to improve upon its own product. Moreover, to the extent that subsequent 30-month stays might be associated with increases in spending on research, these increases do not necessarily improve social welfare (see 67 FR 65460). We received no comment on our assessment of the impact on innovation and continue to believe it to be reasonable.

1. Innovator Revenue Loss

As discussed in the analysis of impacts in the proposed rule, the elimination of multiple 30-month stays per ANDA or 505(b)(2) application allows generic drugs to enter the market earlier. Upon entry, generic versions of an innovator drug gradually lower their prices and take market share from the innovator. With the loss of market share, innovator revenues are lower than they would be had the innovator been allowed to use multiple 30-month stays to delay generic entry. In the analysis in the proposed rule, we used data from instances where generics had been blocked with multiple 30-month stays and calculated the impact of a typical