

will result in a revenue loss for innovator drug companies, which will be offset slightly by a reduction in associated costs. We believe that the rule will also reduce legal fees associated with disputed patents, although we are unable to provide quantitative estimates of this effect. In addition, innovator drug companies will face a burden of completing revised

patent declaration forms. Finally, those NDA holders wishing to submit patents claiming different polymorphs of the active ingredient described in the NDA will need to have test data demonstrating "sameness." Table 2 below provides a summary of our estimates of these effects and overall net benefits. The benefits and costs are annualized at a 7-percent discount rate

over 10 years. We have chosen this time period because the Centers for Medicare and Medicaid Services (CMS), the source of the most reliable pharmaceutical expenditure estimates, projects these expenditures only for the next 10 years. We expect that this rule will generate substantial net benefits beyond this time period.

TABLE 2.—ECONOMIC EFFECTS OF THE RULE¹

Effects	Amount per year (millions of dollars)
Gains	
• Savings to consumers	3,290
• Net revenues to generic manufacturers	1,810
• Reduced legal costs	Not quantified
Losses	
• Revenue loss to innovator firms (net of associated costs)	4,870
• Costs of patent declarations and data to support polymorph patent submissions	<10
Net Benefits	220

¹ Gains and Losses include impacts of an economic transfer in addition to changes in resource costs.

These estimates are derived using methods and data similar to those described at more length in the preamble to the proposed rule published in the **Federal Register** on October 24, 2002 (see 67 FR 65448 at 65459 to 65464). In that analysis, we found that the increase in revenues to generic drug manufacturers would be \$19.117 billion over 10 years, or \$1.8 billion per year if annualized assuming a 7-percent discount rate. The benefit to consumers would be \$34.822 billion over 10 years or an annualized \$3.3 billion. We found that the reduction in revenues to innovator firms would be mitigated somewhat by the reduction in marketing expenses and that the cost would be \$51.508 billion over ten years, or an annualized \$4.9 billion. The 10-year net benefit is \$2.356 billion, and the annualized net benefit is approximately \$220 million.

With respect to the changes in market shares, the gains to consumers and generics equal the losses to innovators. An uncertainty estimate on the cost side would equal the uncertainty on the benefit side of such a transfer and would not affect our projection of net benefits. Our projection of net benefits is driven by our estimate of support costs. The primary economic impact of this action is a transfer from innovator drug firms to consumers and generic drug firms. But as innovator drug firms face a decline in revenues, they will save substantial resources used to support their products. These support costs, which include marketing, advertising, and administration, outweigh the costs associated with

polymorph testing and completing the revised declaration, so the rule is a net benefit. These support costs are based on a point estimate provided by literature that does not customarily provide confidence intervals. We cannot, therefore, provide confidence intervals about our net benefit estimate, but believe the uncertainty to be small, relative to the projected net benefit.

We received no comment on the analysis published with the proposal. We continue to believe these estimates to be reasonable and include them in the final rule. This final rule, however, contains provisions that differ from what was in the proposed rule. To account for these provisions, we have changed our analysis of the burden of providing the information required for completing the patent declaration and we assess the impact of the requirement that NDA applicants or holders or patent owners submitting patents claiming different polymorphs of the active ingredient described in the NDA. In all other major respects, however, our analysis is unchanged from the proposal, so we do not repeat here some parts of our analysis that were described in detail in the proposal (see 67 FR 65448 at 65459 to 65464).

B. Benefits of the Regulation

We have identified two principal effects from the elimination of 30-month stays. These effects are impacts associated with parties gaining in economic transfer. Generic drug manufacturers gain the market share lost by innovators. Generic revenues, therefore, would be expected to

increase. Also, to the extent that these generic drugs are less expensive than innovator drugs, consumers will benefit from saving money as a result of earlier access. Our model, as described in the proposed rule (see 67 FR 65448 at 65460 to 65462), estimates costs and benefits to consumers and innovators and generic drug firms for the first year the rule would be in effect. The projected changes in market shares and prices in the model are based on studies published in the economic literature and by FDA. We then escalate the 1-year estimates by the CMS—projected annual percentage increases in prescription drug expenditures to obtain estimates for 10 years. This 10-year stream is then annualized at a 7-percent discount rate to obtain the annualized estimate.

1. Gains to Consumers

Generic drugs are cheaper than their innovator counterparts. As a generic drug gains market share and its price falls, consumers save more money. The elimination of multiple 30-month stays per ANDA and 505(b)(2) applications and earlier market entry by generic drugs will reduce consumer expenditures on pharmaceuticals. We estimate that the 1-year savings to consumers are projected to be \$2.040 billion. We use the CMS pharmaceutical expenditure projections to escalate the base year figure results in a 10-year consumer savings estimate of \$34.822 billion for the final rule. Our annualized benefit using a 7-percent discount rate is \$3.288 billion, the same as the proposed rule.