

TABLE 6.—COSTS AND OTHER EXPECTED EXPENDITURES OF PROPOSED RULE (IN MILLIONS OF DOLLARS; 20-YEAR EVALUATION PERIOD; 7-PERCENT DISCOUNT RATE)

Industry Sector	Present Value of Costs	Annual Operating Costs at End of Period	Annualized Costs
Prescription Drugs	\$30.4	\$0.4	\$2.9
OTC Drugs	\$2.1	¹	\$0.2
Blood Products	\$0.7	¹	\$0.1
Sub-Total Manufacturers	\$33.2	\$0.5	\$3.2
Hospital Regulatory	\$6.1	(-\$0.7) ²	\$0.6
Sub-Total Private Sector Regulatory Costs	\$39.8	(-\$0.2)	\$3.8
FDA Oversight	\$13.8	\$1.3	\$1.3
Total Regulatory Costs	\$53.1	\$1.1	\$5.1
Expected Expenditures From Healthcare Sector	\$7,204.3	(-\$348.8) ²	\$680.0

¹ Less than \$0.05 million

² Hospital operating costs decrease due to fewer in-house packaging and bar coding operations.

As discussed above, we estimate the annualized public health benefit to be \$3.9 billion. This estimate includes the societal value of the avoided ADEs as well as the reduced hospital stays expected due to the earlier use of bar code reading technology. Other indirect potential benefits, such as efficient inventory control, patient tracking, electronic generation of daily reconciliation and medication reports, or other administrative gains were estimated to contribute an annualized amount of between \$451.5 and \$721.5 million in efficiency gains to hospitals. The likely distributional effects of revenue enhancement, other cost capture measures, or reduced legal costs are not completely quantified, but are likely.

If all costs and expenditures are combined, the annualized outlays total \$685.1 million. The expected annualized public health benefit of over \$3.9 billion far outweighs these outlays. Thus, the annual net benefits for the entire evaluation period are greater than \$3.2 billion. Moreover, this calculation does not account for the potential efficiency gains as described above.

N. Uncertainty and Sensitivity

We recognize that the expected impacts of the proposed rule are based on a large number of uncertain assumptions. We attempted to account for this uncertainty by examining the key assumptions in the analysis.

1. Voluntary Share of Labeling Costs

The costs attributable to the proposed rule are the incremental costs above what the industry would incur in the normal course of business. As briefly discussed earlier, many drug products change labels, on average, as often as once a year for marketing or design reasons. The ERG estimate, however, assumes that 30 percent of the required labeling costs would be attributable to

the regulation, due to the production process changes that would be required to use bar coding equipment. In addition, we believe that market driven label changes are not completely comparable to regulation required changes. We reviewed the sensitivity of this assumption by examining the impact that would occur if no required re-labeling costs were attributable to the regulation, 75 percent were attributable to the regulation, or all re-labeling costs were attributable to the regulation. These scenarios altered the current estimate of \$3.2 million in annualized costs for manufacturers, repackers, and relabelers to a range of from \$2.7 million (if all costs are considered voluntary) to \$4.2 million (if no additional labeling costs are considered voluntary).

2. Packaging Decisions

We are sensitive to industry packaging decisions and asked our contractor to specifically assess the impact of the proposal on the future of unit-dose packaging (e.g. blister packs) trends. The concern was whether bar code printing would reduce the use of unit-dose packaging because it would add more to its cost than to other formats. In general, ERG found that although the overall demand for the product is inelastic, the demand for a particular package type is more elastic in that it is affected by relative prices to a greater degree. Industry contacts, however, noted that this impact is moderated because consumers of some OTC drug product are accustomed to blister packs, and manufacturers could lose market share if they abandon this format. Also, many hospitals require drug purchases to be in unit-dose form.

ERG concluded that although a bar code requirement would increase the relative cost of the unit-dose version of a product, the cost increment would not be great enough to significantly impact the market. In fact, ERG found that the

expected reduction in hospital over-packaging could increase market demand for unit-dose products despite the cost difference. Thus, we expect that the proposed rule would not have a significant impact on product packaging choices.

3. Mortality Associated with ADEs

FDA's contractor estimated that 2.8 percent of preventable ADEs are fatal. This was derived by averaging results from several medical studies. These studies relied on relatively small samples and varying methodologies. Due to the uncertainty attached to this estimate and the major impact this assumption has on valuing public health benefits, we tested two additional mortality rates: one percent and 0.1 percent. These rates reduce the expected value of an avoided ADE from \$183,900 to \$91,500 and \$46,400, respectively, by changing the probability distribution of the expected outcomes of ADEs. The impact on the expected annualized benefits of ADE avoidance fall from \$3.9 billion to \$2.0 billion and \$1.0 billion respectively. These estimated benefits continue to exceed the costs.

4. Value per QALY

There is no precise measure of value for quality-adjusted life-year. We have used published estimates of society's implied value of a statistical life (VSL) of \$5 million derived from wage premiums required to attract employment to higher risk occupations. The life expectancy of a 35 year-old blue-collar male employee (the typical characteristics of the population for most of the wage premium studies) was adjusted for expected future bed and nonbed disability. When the implied VSL is amortized over the 41.3 years of adjusted life-expectancy, using a 7-percent discount rate, the resulting value (\$373,000) may suggest a societal willingness-to-pay for a QALY. Cost-