

the magnitude of packaging changes required to install bar coding equipment would result in manufacturer decisions to bar code entire product lines rather than incremental, specific products. We estimate that the initial investment for OTC drug manufacturers, repackers, and relabelers would total \$1.7 million over 3 years, with additional capital investments of \$0.1 million during the 11th evaluation year. The estimated annual operating costs to provide bar codes to the affected proportion of the OTC drug market are negligible (less than \$0.05 million by the third year). Overall, the PV of these costs over the 20-year evaluation period to the OTC drug industry is \$2.1 million and the estimated annualized costs are \$0.2 million.

c. Blood and Blood Products. Manufacturers of blood and blood products would also be affected by the proposed rule. Although most blood and blood product manufacturers have voluntarily applied bar coded information, this requirement would add to their costs by requiring specific machine-readable information in a consistent format. These costs would equal approximately \$0.4 million over the first 3 years, with additional capital expenditures of \$0.1 million over the following 20-year evaluation period for replacement or upgrade of equipment installed in response to the proposed rule. The annual operating costs to blood manufacturers of maintaining the equipment would be negligible (less than \$0.05 million by the third year). We estimate that the PV of these compliance costs to blood and blood product manufacturers for using machine-readable information in a consistent machine-readable format over the 20-year period is \$0.7 million and that the annualized costs are \$0.1 million.

d. Total Cost to Manufacturers, Repackers, and Relabelers. The estimated PV of regulatory costs to manufacturers, repackers, and relabelers of prescription drug products, OTC drug products, blood, and blood products is \$33.2 million. The average annualized costs to these industries are \$3.2 million.

3. Costs to Retailers and Distributors

We do not expect increased costs to retailers, wholesalers, and distributors. Currently installed scanners and readers are able to read the linear bar codes described in the proposed rule. However, if we had selected an alternative that would have required RSS symbology, independent community pharmacies, chain pharmacies, and pharmacies in chain

merchandisers or supermarkets would have had to upgrade scanners in order to take advantage of the proposed standardized information. Given the widespread reliance on bar code information in the retail sector, the currently installed stock of bar code scanners would not be affected by the proposed rule.

4. Costs to Hospitals

The proposed rule would require NDA numbers in linear bar codes on the immediate containers of affected products and machine-readable information on blood and blood products. However, because manufacturers, repackers, and relabelers are expected to find it necessary to use RSS symbology on small unit-dose packages or vials and bottles, their scanners and readers must have the ability to capture this information in a RSS format. As a result, in order for hospitals that have currently installed bar code reading systems to maintain current operating practice, their scanners may need to be replaced with scanners that are capable of reading RSS symbologies. Replacement of these scanners would not be a voluntary hospital investment, but would be necessary to maintain current operations.

These costs are somewhat mitigated for the approximately 2 percent of all hospitals (131 hospitals) that currently use bar codes in everyday practice by repackaging medications in unit-dose form and applying internally printed and generated bar codes. According to published reports and discussions with industry experts, ERG estimated that such hospitals now incur costs to apply bar codes on nearly 28 percent of dispensed medications. These 131 hospitals would avoid these expenditures under the proposed rule.

The proposed rule would result in the premature replacement of scanners used in hospital pharmacies and treatment wards. ERG has estimated that the PV of the incremental initial cost of accelerated scanner replacement or upgrade to read RSS symbologies, based on the expected remaining useful life of current equipment, is approximately \$13.7 million. The average annualized costs to hospitals of early replacement is \$1.3 million.

According to reports in the literature, it costs as much as \$0.03 per unit-dose to apply a bar code in hospital pharmacies. Avoidance of this activity will reduce costs by approximately \$0.7 million per year. The PV of this cost reduction is \$7.6 million.

Overall, we estimate the PV of regulatory costs, less the cost savings to

hospitals of the proposed rule, to be \$6.1 million, and the average annualized costs are \$0.6 million.

5. Costs to the Food and Drug Administration

According to a recent study, the number of available pharmaceutical products has increased by 500 percent in 10 years and now totals over 17,000 separate trade and generic names. With the multitude of dose strengths and packages, the total number of unique packaging units is now 178,000 separate identifiable products. Of this total, we expect 89,800 of these packaging units would need bar coded NDC numbers because we estimate that only 10 percent of all OTC drug products will be affected. Even if the recent growth rate in new products were halved (so that the number of available products increased by 500 percent in 20 years), there would be 449,000 new NDC codes over 20 years, or 22,500 per year for the evaluation period.

We expect that the requirement for notification of unique NDC numbers would require the development and maintenance of an accessible agency database. We have assumed 0.5 hours per notification to represent the cost to input and encode a specific NDC number and to maintain an accessible data base containing all NDC numbers. This implies an annual resource requirement of 11,250 hours, or approximately 5.6 full-time equivalents (FTEs). These direct resources require supervision, administration, and support. To account for these indirect resources, we multiplied direct resources by two, resulting in 11.2 annual FTEs. The most recent FDA budget documents have used a value of approximately \$120,000 per FTE. Therefore, we expect the annual costs of maintaining a system of unique NDC numbers to be \$1.3 million with a PV of \$13.8 million. Although additional regulatory requirements, such as requiring readable bar code information on product labels, would increase our compliance burden, we have not quantified that impact at this time.

6. Total Regulatory Costs

The estimated PV of the total direct regulatory costs of the proposed rule over the 20-year period is \$53.1 million, which is equivalent to an annualized cost of \$5.1 million. Table 3 illustrates the timing of the stream of investments and increased annual operating and maintenance costs expected from the proposed rule.