

TABLE 10.—DISCOUNTED ANNUAL COSTS OF OPTIONS 3 AND 4

Year 1	\$400,491,000
Year 2	\$665,290,000
Year 3	\$292,324,000
Year 4	\$273,200,000
Year 5	\$255,327,000
Year 6	\$238,624,000
:	:
:	:
Year 15	\$129,795,000
:	:
:	:
Year 30	\$47,044,000
:	:
:	:
Present Value as of Year 1	\$5,534,165,000

<sup>1</sup> Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 5: Require all components of option 4, but change the required records access time to 24 hours.

All costs for this option will be identical to those for option 4 except for

the access costs for records detailed in that section. As mentioned previously, FDA believes that 24 hours is the least amount of time allowable that would not cause any firms to need to plan for a rapid response or change their business practices. While the average access time for FDA traceback investigations is 2–3 days, we believe the same information could be provided in 1 day with the types of recordkeeping systems currently in use, including automated recordkeeping technology, and offsite storage and paper retrieval. Therefore, the difference between the cost of a 2–3 day response time and a 1-day response time is assumed to be negligible. However, the shorter response time requirements of 4 hours or 8 hours would likely impose a new burden on a number of firms. Therefore, we assume that the difference between 4 or 8 hours and 24 hours is the difference between having to preplan a response and being able to react with normal personnel in an emergency capacity. In order to estimate this cost difference, FDA assumes that no firm would incur extra planning costs detailed in option 2, and requests comments on this assumption. The marginal cost savings of extending the records access time requirement is approximately \$715,355,000.

Table 11 of this document presents the range of undiscounted costs of future compliance and Table 12 of this document presents the discounted annual costs incurred in all future years

and the present value of total costs incurred for option 5. In addition, Table 12 reports the marginal savings of option 5 with respect to option 4 as well as the discounted annual costs and the present value of total costs. The marginal savings of option 5 with respect to option 4 reflect the cost savings realized from relaxing the records access requirements from 4 and 8 hours in option 4 to 24 hours in option 5. As discussed earlier in this document, discounted computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 11.—TOTAL ANNUAL COSTS, OPTION 5

	Mean	Low	High	Average Mean Cost per Firm
Year 1	\$338,594,000	\$288,569,000	\$387,887,000	\$387
Year 2	\$567,921,000	\$481,993,000	\$659,106,000	\$649
Year 3 and later years	\$295,813,000	\$258,715,000	\$326,509,000	\$338

TABLE 12.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 5

	Discounted Annual Costs of Option 5	Marginal Savings of Option 5 With Respect to Option 4
Year 1	\$338,594,000	\$61,897,000
Year 2	\$530,767,000	\$134,523,000
Year 3	\$258,375,000	\$33,949,000
Year 4	\$241,472,000	\$31,728,000
Year 5	\$225,675,000	\$29,652,000
Year 6	\$210,911,000	\$27,713,000
:	:	:
:	:	: