

American Red Cross (Ref. 5) on the costs of conducting blood screening tests designed to ensure the safety of the blood supply. These estimates include the costs of collection (including personnel, needles, bags, and other supplies) at \$47.66 per sample; sample testing at \$25.16 per sample; and overhead at \$3.26 per sample. The estimated direct testing cost per blood sample is the sum of these amounts, or \$76 per test.

b. *Anxiety and stress associated with potential transmission of pathogens.* The psychological literature has noted that levels of anxiety and stress impact participation in public health screening programs and thereby affect physiological health (Refs. 19, 20, and 21). Also, patients who experience high levels of uncertainty due to the possibility of contracting serious, threatening diseases experience heightened levels of stress and anxiety until the results of the testing screens are negative (Ref. 20). According to one measurement scale of well-being, reduced mental lucidity, depression, crying, lack of concentration, or other signs of adverse psychological sequence may detract as much as 8 percent from overall feelings of well-being (Ref. 16) and have outcomes similar to physiological morbidity. Scaling of the relative stress caused by events shows that concerns of personal health, by themselves, are likely, on average, to contribute approximately one-sixth of the total weighting required to trigger a major stressful episode (Refs. 20, 21 and 22). Thus, FDA approximates that increased stress and anxiety concerning possible exposure to pathogens may reduce overall sense of well-being and result in health loss of approximately 1.3 percent (0.013).

As described earlier, FDA has calculated an assumed WTP of \$373,000 for a statistical QALY. This figure implies that the probability of each day of quality adjusted life has a social value of \$1,022 (\$373,000/365). If blood test results are usually obtained within 24 hours, the resultant loss of societal well-being for each test subject is valued at approximately \$13 (\$1,022 times 0.013).

c. *Benefit of test avoidance.* By combining the avoided direct cost of tests and the value of avoided anxiety and stress, FDA estimates that the societal benefit of avoiding an unnecessary blood test is \$89 per sample. During the first evaluation year, FDA expects 96,000 fewer unnecessary blood screens because of the expected reduction in defective medical gloves due to the proposed regulation. The implied societal WTP to avoid these unnecessary screens is \$8.5 million.

During the 10th evaluation year, approximately 123,000 fewer unnecessary blood screens are expected with a resultant benefit of \$10.9 million. The PV of each year's reduced cost of testing and anxiety totals \$66.5 million for the entire period (at a 7 percent discount rate) and an average annualized amount of \$9.6 million. Of the average annualized amount, \$8.2 million represents reductions in the direct testing costs and \$1.4 million represents reduced anxiety associated with possible infection by a contagious agent.

6. Total Benefits

FDA estimates that the proposed regulation would reduce the availability of defective medical gloves by over 25 percent, resulting in over 2.2 billion fewer defective gloves over a 10-year period. During this time, FDA expects that reduction in defective gloves would result in almost 7 fewer cases of chronic HBV, 7 fewer cases of HIV, and 1.1 million fewer unnecessary blood screens. Based on an implied societal WTP, the average annualized benefits of the fewer pathogen transmissions and unnecessary blood screens would equal \$12.3 million.

G. Small Business Impact—Initial Regulatory Flexibility Analysis

FDA finds that the proposed regulation would not have a significant impact on a substantial number of small entities. There are currently 417 manufacturers of medical gloves, of which 411 are foreign. Because medical gloves are almost exclusively manufactured by foreign firms, there would not be a significant economic impact on a substantial number of domestic small entities. Moreover, FDA does not expect the increased manufacturer costs to be directly passed on to end users, because the cost increases would affect only a minority of global manufacturers and, therefore, competition would require these manufacturers to absorb these costs.

H. Conclusion

FDA has conducted an analysis of the proposed regulation, using outside economic consultants. The estimated annualized costs equal \$5.2 million, while the estimated annualized benefits equal \$12.3 million. FDA certifies that the proposed regulation would not have a significant economic impact on a substantial number of small entities because medical gloves are imported from foreign manufacturers not subject to the Regulatory Flexibility Act. All six domestic manufacturers of medical gloves employ more than 1,200 workers.

The Small Business Administration designates as small any entity with fewer than 500 employees in this industry.

V. Submission of Comments and Proposed Effective Date

Interested persons may submit to the Dockets Management Branch (see ADDRESSES), written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two copies of any mailed comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA proposes that any final rule that may issue based on this proposal become effective 90 days after its date of publication in the **Federal Register**.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). No burden has been estimated for the requirements in § 800.20 because recordkeeping of tests and samples is a usual and customary business practice. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

VII. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. U.S. Centers for Disease Prevention and Control, "HIV/AIDS Fact Sheet," www.cdc.gov, 2002.

2. U.S. Centers for Disease Prevention and Control, "Surveillance of Health Care Workers With HIV/AIDS," Oct. 25, 2001.

3. U.S. Centers for Disease Prevention and Control, "Hepatitis Fact Sheet," www.cdc.gov, 2002.

4. U.S. Centers for Disease Prevention and Control, "Updated U.S. Public Health Service