

years due to the expected growth of employment in the health services industry. However, if the proposed AQL were in place, FDA forecasts the expected value of the annual transmission of HIV in health care personnel to equal 1.8 cases during the first effective year and 2.3 cases by the 10th year (based on the expected proportionate decrease in marketed defective gloves). Over the entire 10-year evaluation period, these assumptions suggest that the regulation would prevent approximately seven cases of HIV transmission to health care personnel.

b. *Reductions in HBV transmissions.* Hepatitis B transmissions to health care personnel are more common than cutaneous HIV transmissions. However, little specific data are available to identify affected patient populations. FDA has estimated that as many as 2.4 cutaneous transmissions of chronic HBV may be due to defective medical gloves each year. In the absence of this rule, this number is expected to increase to 3.1 annual transmissions within 10 years, based on the expected employment growth in the health services industry.

Implementation of the proposed regulation would decrease these transmissions by about 25 percent. Under the new standard, FDA expects 1.8 HBV transmissions during the first evaluation year, a reduction of 0.6 transmissions from baseline conditions. By the 10th evaluation year, FDA expects 2.3 chronic HBV transmissions under the proposed AQL, a total of 0.8 fewer cases. Overall, about seven transmissions of chronic HBV would be avoided due to the proposed regulation over a 10-year period.

3. Reductions in the Number of Blood Screening Tests

As the number of defective gloves marketed in the United States decreases due to this regulation, corresponding reductions would be expected in the number of unnecessary blood screens. FDA contacted several research hospitals to ascertain how frequently health care personnel identify glove failure as a reason for initiating blood screens. Respondents stated that about 5 percent of all glove failures are noticed by the user and about 1 percent of these identified failures are reported to the facility for additional screening (Refs. 9 and 10). Respondents noted that the glove failure could occur prior to patient contact. The additional screening may apply to the affected health care personnel or the patient if identified. The great majority of these screens result in negative findings.

As shown in the previous paragraphs, during the first evaluation year under the new rule, FDA projects the number of defective gloves marketed in the United States to decrease from 740 to 548 million, a reduction of 192 million defective gloves. By the 10th year, the annual number of defective gloves is expected to decrease from 955 to 709 million, a reduction of 246 million defective gloves. At the rates of potential identification (5 percent) and reports of contact with pathogens (1 percent) obtained from the research hospital sector, the proposed regulation would result in 96,000 fewer unnecessary blood screens during the first year (192 million fewer defects \times 0.05 \times 0.01). By the 10th year, 123,000 fewer annual blood screens are expected. Over the entire period, the regulation could result in 1,095,000 fewer unnecessary blood screens.

4. Value of Avoiding Blood-Borne Pathogen Transmissions

a. *Quality adjusted life-years.* The economic literature includes many attempts to quantify societal values of health. A widely cited methodology assesses wage differentials necessary to attract workers to riskier occupations. This research indicates that society is willing to pay approximately \$5 million to avoid a statistical death (Refs. 11, 12, and 13). That is, social values appear to show that people are willing to pay a significant number of dollars to reduce even a small risk of death; or similarly, to demand significant payments to accept even marginally higher risks.

Because this estimate is predominantly based on blue-collar occupations that mainly attract males between the ages of 30 and 40, FDA adjusted the life-expectancy of a 35 year-old male to account for future bed and nonbed disability (Refs. 14, 15, and 16), and amortized the \$5 million (at a 7 percent discount rate) over the resulting quality-adjusted life span. The result yields an estimate of \$373,000 per quality adjusted life-year (QALY), which implies that society is willing to pay \$373,000 for the statistical probability of a year of perfect health.

b. *Value of morbidity losses.* In theory, loss of health reduces the willingness to pay for additional longevity. Many studies have attempted to estimate the relative loss of health for different conditions of morbidity. One method utilizes the Kaplan-Bush Index of Well-Being. This index assigns relative weights to functional states, and then adjusts the resulting weighted value by the problem/symptom complex that contributed to loss of function (Refs. 16 and 17). Functional state is

measured in three areas: Mobility, social activity, and physical activity. For example, with treatment, chronic HBV may not have a major impact on any of these functions; a patient could drive a car, walk without a physical problem, and participate in work, school, housework, and other activities.

However, because a patient with HBV has an ongoing problem/symptom complex, the relative weight of this functional state is estimated at 0.7433.²

This methodology then adjusts the weighted value of the functional state by the most severe problem/symptom complex contributing to that state. In the case of HBV, the most common symptom is general tiredness, weakness, or weight loss. This complex has a derived relative weight of +0.0027, which when added to the weighted functional state value results in a relative weight of 0.7460. The loss of relative health due to HBV, therefore, is expected to equal 1.0000 minus 0.7460, or 0.2540 of perfect health. When this relative health loss is applied to the derived value of a QALY, it implies that society is willing to pay \$93,000 per year to avoid a case of HBV (\$373,000 times 0.2540). This value includes the potential costs of treatment and additional prevention, as well as any perceived pain and suffering.

FDA compared this methodology to a variety of published estimates of preference ratings of morbidity prepared by the Harvard Center for Risk Analysis (HCRA) (Ref. 17a). The published ratings of 14 studies of chronic HBV ranged from 0.75 to 1.00 (no impact). While the estimate used in this analysis (0.746) is in the low end of the collected published studies, FDA notes that most of the expressed preferences that were derived from time trade-off and standard gamble methodologies as compared to author judgment were closer to the FDA estimate. A health care worker who may contract HBV may typically have a life expectancy of approximately 40 years (as of 2000, a 40-year old female has a future life expectancy of 41.1 years (Ref. 14)). The present value of \$93,000 per year for 40 years at a 7 percent discount rate implies that society is willing to pay \$1.24 million to avoid the statistical likelihood of a case of chronic HBV in health care personnel.

Deriving society's implied WTP to avoid HIV is more complicated. The CDC has published data indicating that approximately 80 percent of all HIV infections progress to AIDS within 5 years. Of the cases of AIDS, over half

² Note: The implication is that an ideal health state is valued as 1.0000 and mortality at 0.0000.