

(approximately 60 percent) result in mortality within an additional 5 years. Thus, for a 10 year period, FDA tracked three potential outcomes: Patients who contract HIV but do not progress to AIDS (20 percent); patients who contract HIV and progress to AIDS in 5 years and survive (32 percent); and patients who contract HIV, progress to AIDS within 5 years, and then die within the next 5 years (48 percent).

HIV infection may not affect either mobility or social activity. However, such an infection may somewhat inhibit physical activity. HIV patients are able to walk, but with some physical limitations. This functional state has a relative weight of 0.6769. The main problem/symptom complex of HIV is general tiredness (as for HBV), so the selected functional weight is adjusted by +0.0027 to result in relative well-being of 0.6796. As a result, the relative societal willingness to pay to avoid the statistical probability of a case of HIV in health care personnel is estimated at approximately \$120,000 per year (\$373,000 times [1.0000 minus 0.6796]). According to the collected preference scores (Ref. 17a) in the Car's Catalog of Preference Scores, the average estimated published preference rating for HIV infection was 0.7 (range 0.3 to 1.00).

If HIV progresses to AIDS, a patient's functional state is likely to be more restricted. An AIDS patient requires some assistance with transportation, is limited in physical activity, and is limited in work, school, or household activity. The relative weight for this functional state is 0.5402. The main problem/symptom of AIDS remains general tiredness and loss of weight (as with HIV and HBV), so the adjusted health state is 0.5429. This results in a derived societal willingness to pay to avoid the statistical probability of a case of AIDS of about \$170,000 per year (\$373,000 times [1.0000 minus 0.5429]). The Car's Catalog of Preference Scores (Ref. 17a) reports average preference ratings of 0.375 for cases of AIDS with ranges from 0.0 to 0.5.

As discussed earlier, the derived societal willingness to pay to avoid a statistical mortality has been estimated to equal approximately \$5 million.

Using these estimates, the WTP to avoid the statistical probability of an HIV transmission in health care personnel is calculated as the sum of:

- 20 percent of the percent value (PV) (at 7 percent discount rate) of avoiding 40 years of HIV infection.
- 32 percent of the sum of the PV of avoiding 5 years of HIV infection plus the PV of avoiding 35 years of AIDS infection occurring 5 years in the future.

- 48 percent of the sum of the PV of avoiding 5 years of HIV infection plus the PV of avoiding 5 years of AIDS infection occurring 5 years in the future plus the discounted WTP of avoiding a statistical mortality occurring 10 years in the future.

The PV of avoiding 40 years of health loss valued at \$120,000 per year is approximately \$1.6 million (at 7 percent discount). Twenty percent of this figure equals \$320,000. The PV of avoiding 5 years of health loss to due HIV infection is equal to \$492,000. The PV of avoiding the health loss expected from 35 years of AIDS infection (valued at \$170,000 per year) is equivalent to \$2.2 million. The present value of this amount occurring 5 years in the future (at 7 percent) is \$1.6 million. When added to the PV of avoiding the health loss associated with 5 years of HIV infection (\$492,000), the total estimated present value of the societal willingness to pay to avoid a statistical case of this outcome is about \$2.1 million. Thirty-two percent of this figure equals \$660,000. The PV of avoiding the health loss expected from 5 years of AIDS infection (\$700,000) occurring 5 years in the future is equivalent to \$497,000 (at 7 percent discount rate). The PV of avoiding a statistical mortality (\$5 million) 10 years in the future is \$2.54 million (at 7 percent discount). The total societal WTP to avoid a case of HIV with mortality as an outcome, therefore, is \$3.5 million (\$493,000 plus \$497,000 plus \$2.54 million). Forty-eight percent of this figure equals approximately \$1.7 million. Summing the weighted amounts of the three expected outcomes for a case of HIV infection (\$320,000 plus \$660,000 plus \$1,700,000) equals an estimated societal willingness to pay \$2.68 million to avoid a statistical transmission of HIV.

In sum, the estimated societal values of avoiding morbidity and mortality due to the transmission of blood-borne pathogens are estimated to be equivalent to \$1.24 million per transmission of chronic HBV and \$2.68 million per transmission of HIV. FDA notes that other recent cost-effectiveness research (Ref. 18) has reported cost-effectiveness estimates (excluding pain and suffering) of \$2.1 million per avoided case of HIV.

FDA believes the methodology to estimate the value of avoided HBV and HIV infection is reasonable and supportable. Nevertheless, comparison with reported published preferences show some estimates to place higher values on avoidance and some lower than the average collected weight. FDA acknowledges these differences and solicits comment on other appropriate measures for estimating the societal

value of avoiding blood-borne infections.

*c. Benefits of morbidity and fatality avoidance.* The proposed regulation would reduce both HBV and HIV transmissions by reducing the prevalence of defective medical gloves used as barrier protection. During the first evaluation year, the regulation would result in 0.6 fewer chronic HBV transmissions to health care personnel. Applying the assumed societal WTP of \$1.24 million to avoid the statistical probability of one chronic HBV infection, the expected benefit of avoiding these transmissions is \$0.7 million. By the 10th evaluation year, 0.8 annual transmissions would be avoided at a value of \$1.0 million. The PV of avoiding almost seven chronic HBV transmissions over a 10 year period equals \$6.1 million (at a 7 percent discount rate), which is equivalent to an average annualized value of \$0.9 million for the entire 10-year evaluation period.

Also, in the first evaluation year, FDA expects that the proposed regulation would result in the probability of 0.6 fewer transmissions of HIV caused by defective gloves. Assuming that society is willing to pay \$2.68 million to avoid the probability of a single HIV transmission, the benefit of avoiding these transmissions equals \$1.6 million. By the 10th evaluation year, FDA expects the proposed regulation to result in 0.8 fewer HIV transmissions, which are valued at over \$2.1 million. The societal PV of avoiding seven transmissions of HIV over the 10-year evaluation period is \$12.9 million (at 7 percent discount rate) and is equivalent to an average annualized benefit of \$1.8 million.

In sum, FDA estimates that the reduction in blood-borne pathogen transmissions due to this proposed rule would produce health benefits valued at \$2.7 million per year. Much of this benefit (almost 67 percent) is attributable to reducing the incidence of HIV.

##### 5. Value of Avoiding Unnecessary Blood Screens

The expected decline in the number of defective medical gloves would lead to a smaller number of unnecessary blood screens and thereby provide two potential benefits. First, the direct cost of conducting screens to determine whether the pathogen was transmitted to health care personnel would fall. Second, the psychological anxiety and stress that accompanies the possibility that a pathogen was transmitted to an individual would decrease.

*a. Cost of conducting blood screens.* FDA has collected data from the