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THE LAST WORD

A REAL CHANCE FOR BIOTECHNOLOGY

Within the relatively short span of 5 years, the acquired immunodeficiency syndrome (AIDS) has become a global epidemic. Over 30,000 cases of AIDS have been officially reported from 73 countries in 5 continents.

Despite these alarming numbers, we now know that AIDS only represents a small part of the clinical spectrum of infection with the etiologic agent, the human immunodeficiency virus (HIV), which causes a life-long infection. From seroprevalence studies, it is now estimated that over 5 million people worldwide have already been infected with HIV. Many of them will unknowingly transmit the disease, develop chronic debilitating diseases, or eventually succumb to AIDS. Given the present lack of an effective curative therapy or vaccine, this disease now represents one of the most serious epidemics of this century.

Like so many other infectious diseases, HIV infection and AIDS have become firmly established in Africa. Possibly originating in Central Africa, HIV infection has rapidly spread to the general population of that region and to a lesser degree to adjacent sub-Saharan East and West African countries.

Preliminary surveillance reports in several cities in Central Africa estimate annual incidence of 550-1,000 cases of AIDS per million population. Affecting the general heterosexual population of Africa, with a 1:1 male-tofemale ratio among affected cases, these incidence rates exceed those documented in New York City and San Francisco, where AIDS has become endemic among certain risk groups, such as homosexually active men and intravenous drug abusers.

HIV infection in the Third World is predominantly transmitted by heterosexual activity, perinatally from infected mothers to newborn infants, and parenterally through blood transfusions and exposure to unsterilized needles. HIV infection rates have been documented to be as high as 27–88 percent among men attending sexually transmitted disease clinics who have sex with prostitutes. With dissemination of the AIDS virus into the general heterosexual population, nearly 10 percent of pregnant women are now positive for the AIDS virus. It can be anticipated that nearly half of the children born to these infected mothers will die from AIDS before age 2 due to perinatal transmission of HIV infection.

Between 5 and 15 percent of blood donors in Central Africa have also been found to be infected with the AIDS virus. These rates are several hundred times greater than that in the U.S. where the rate of infection is 0.04 percent among blood donors. Unfortunately, in contrast to the efficient and effective blood bank screening program in the United States, Africa lacks screening of blood transfusions for HIV, mainly because these serologic tests are expensive. Thus, even if a child is fortunate enough to be born to a seronegative mother, that child will have about a 10 percent chance of acquiring HIV infection for each blood transfusion he receives for treatment of anemia induced by malnutrition, parasitic infections, or other endemic diseases.

Fortunately there is at least one area where biotechnology can make an immediate difference in limiting the

spread of HIV infection and AIDS. With the present state of biotechnology, scientists have not only been able to isolate and purify the causative agent, but they have been able to clone it, sequence its entire genome, produce purified viral proteins, synthesize viral oligopeptides, produce monoclonal antibodies, and develop a vast array of prototype vaccines. A first product of this technology was the production and licensing of commercial enzymelinked immunosorbent assays (ELISA) for the detection of antibody to the virus in infected individuals. These assays were immediately implemented in blood screening programs throughout the developed world, but because of initial high costs, none of these diagnostic assays have been utilized in the Third World. At an annual cost of \$60 million the blood screening program has been extremely successful in the United States, but it is totally unrealistic to expect Third World countries to be able to support such an expense where the average per capita expenditure for health care is \$4.00. However, with the availability of cloned and sequenced viral proteins, simple colorimetric diagnostic assays suitable for use in developing countries can be inexpensively produced and rapidly implemented.

While the marketing executives of biotechnology firms may not envision an immediate return on this capital investment, the possible endorsement and utilization of such an assay for screening millions of blood donations daily throughout the world would eventually affect the sales of not only this product, but many others. Quite apart from the modest profit that might be realized, the ethical and moral respect that would be gained is enormous. HIV screening assays could be implemented in blood banks worldwide and potentially prevent the transmission of hundreds of thousands of cases of HIV infection and AIDS within the next year.

Beyond this short-term, and easily realized goal, scientists in developed countries, who are making almost daily advances in understanding the AIDS virus, must work to extend their biotechnical advances into the Third World. By 1991, the U.S. Public Health Service estimates that over 270,000 people will develop AIDS in the United States. For Africa and other developing countries that number has probably already been surpassed, and millions of people are presently at risk. HIV infection and AIDS represent an unprecedented challenge, and now is the time for biotechnology companies, international health agencies, scientists and public health officials to commit their resources in an effort to limit the spread of the disease.

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