

S. 1138, The Prize Fund for HIV/AIDS Act

S. 1138 supports sustainable innovation and access to new drugs for AIDS by de-linking markets for products from markets for innovation.

The Need for Innovation. Every patient receiving HIV drugs struggles with their side effects, and a life long battle with drug resistance. Since 1996, the rate of innovation for new AIDS drugs has been steady, but fairly slow. For most patients, the newer drugs do a better job of fighting AIDS with fewer side effects, and easier methods of delivery.

Costs of Antiretroviral Drugs. The United States is now spending on average more than \$9 thousand annually on antiretroviral drugs for each of the 1 million persons living with HIV in the United States, a number that would be far higher if a larger percentage of persons living with HIV were receiving treatment or taking newer drugs. The high cost of AIDS drugs has a negative impact on access everywhere. The U.S. federal and state subsidized AIDS Drug Assistance Programs are facing a funding crisis, reporting waiting lists for enrollment of 8,689 patients as of July 14, 2011, compared with just 540 as of January 15, 2010.

The Prize Fund for HIV/AIDS (The Prize Fund). The Prize Fund would reward useful investments in R&D for new treatment and manufacturing processes, and would lower the overall costs of treatments for HIV/AIDS by allowing introduction of generic medicines for HIV/AIDS as soon as they enter the market. The Prize would be co-funded by the federal government and private health insurance programs at 0.0002 of the GDP of the United States, equaling more than \$3 billion per year at current levels. Patents would still be available for HIV/AIDS inventions, and valuable in making claims against the Prize Fund, but could not be used to block generics entering the market. Generic competition among competitive suppliers is expected to lower the cost of drugs by more than \$7 billion per year for the U.S. domestic market, with the saving shared by health insurers (both public and private) and patients.

End Product Prizes. Suppliers of new innovations would compete against each other for shares of the prize fund money. Products or processes would eligible to participate in the prize fund for 10 years. Awards would be made to the first person or company that registers a qualifying treatment, a drug or a biological product, or a new manufacturing process for such product.

In considering claims against the fund, the Prize Fund Director would take into account among other factors: the number of patients who benefit from the treatment, the needs of special populations, the incremental therapeutic benefit as compared to existing treatments, and the improved efficiency of manufacturing processes.

Additional provisions. Awards would be made to reward the open, non-discriminatory and royalty free sharing of knowledge, data, materials and technology that has contributed to the development of the new medicines or manufacturing efficiencies that qualified for the end product prizes. Additionally, the legislation provides for a system of competitive intermediaries to reward interim and translational development activities. Finally, awards out of a new Donor Prize Fund would be made for products that permit open competition in developing countries, either by not patenting products, providing non-discriminatory royalty free open licenses to all patents on at least a field of use for the treatment of HIV/AIDS in developing countries, or through licenses to the Medicine Patent Pool.