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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)							DATE February 2000			
BUDGET ACTIVITY 3 - Advanced Technology Development				PE NUMBER AND TITLE 0603105A Military Human Immunodeficiency Virus (HIV) Research				PROJECT DH29		
COST (In Thousands)	FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost	
DH29 Military HIV	5497	5931	5899	5911	6050	6818	6838	Continuing	Continuing	
<p>A. <u>Mission Description and Justification:</u> This program element supports research to provide concept exploration of candidate prevention vaccines to include safety and efficacy in model systems to prepare and conduct clinical studies. It funds Acquired Immune Deficiency Syndrome (AIDS) research to control the infection in military environments, protect the military blood supply and protect military personnel from unusual risks associated with infection. AIDS research is focused on the following thrust areas: diagnosis, natural history, epidemiology, and vaccine development. Efforts are directed to answer militarily unique questions affecting manning, mobilization, and deployment. This program is managed primarily by the U.S. Army Medical Research and Materiel Command. The major contractor is the Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Additional AIDS related research is conducted within the following projects: 0601102A, project S17; 0602787A, project 873; 0603105A, project H29; 0603807A, project 811; and 0604807A, project 812.</p> <p>FY 1999 Accomplishments:</p> <ul style="list-style-type: none"> • 5497 Conducted Phase 1 clinical trial of subtype B HIV vaccine candidates (subtype B is predominant in the U.S.) and demonstrated that prime boost regimens of these two candidates are immunogenic, though the study is ongoing and all conclusions are preliminary. Completed Phase 1 clinical trial of a DNA candidate vaccine against subtype B HIV and determined that this first-generation product was safe but did not induce sufficient immune response. Completed testing of subtype E HIV vaccine candidates (subtype E is predominant in Southeast Asia and Africa) in mice and determined that they were safe and immunogenic. Completed a Phase 1 trial demonstrating the feasibility of immune reconstitution, that is, removing immune cells from an HIV-infected individual, stimulating those cells and then reinfusing the stimulated cells into that patient. <p>Total 5497</p> <p>FY 2000 Planned Program:</p> <ul style="list-style-type: none"> • 5771 Conduct clinical studies to slow progression and prevent immune deficiency related to HIV infection. Develop a vaccine process to prevent HIV infection of all genotypes of HIV-1. Establish the genetic and phenotypic correlates of drug resistance as a clinical tool. • 160 Small Business Innovative Research/Small Business Technology Transfer Research Programs. <p>Total 5931</p> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 5889 Transition to advanced development a test for simple and rapid forward diagnosis of HIV infection. Conduct a Phase 0/1 study of a novel vaccine vector for the prevention of HIV-1. Conduct Phase 0/1 study of oligomeric protein vaccines. Conduct clinical evaluation of novel methodologies for detection of antiretroviral drug resistance. Both Phase 0/1 trials are necessary before proceeding to Milestone 1 for advanced development. 										
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Total 5889

B. Program Change Summary	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget (FY 2000/2001 PB)	5672	5976	5926
Appropriated Value	5710	5976	
Adjustments to Appropriated Value			
a. Congressional General Reductions	-38		
b. SBIR / STTR	-151		
c. Omnibus or Other Above Threshold Adjustments		-24	
d. Below Threshold Reprogramming			
e. Rescissions	-24	-21	
Adjustments to Budget Years Since <u>FY 2000/2001</u> PB			-37
Current Budget Submit (FY 2001 PB)	5497	5931	5889