Exhibit R-2, RDT&E Budget Item Justification: PB 2013 Defense Advanced Research Projects Agency	DATE: February 2012
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 2: *Applied Research*	R-1 ITEM NOMENCLATURE PE 0602115E: *BIOMEDICAL TECHNOLOGY*

COST ($ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
Total Program Element	-	95.000	110.900	-	110.900	97.069	104.742	121.603	127.881	Continuing	Continuing
BT-01: *BIOMEDICAL TECHNOLOGY*	-	95.000	110.900	-	110.900	97.069	104.742	121.603	127.881	Continuing	Continuing

A. Mission Description and Budget Item Justification

This Program Element is budgeted in the applied research budget activity because it will focus on medical related technology, information, processes, materials, systems, and devices encompassing a broad spectrum of DoD challenges. Biowarfare defense includes the capability to predict and deflect pathogen evolution of natural and engineered emerging threats and therapeutics that increase survivability within days of receipt of an unknown pathogen. Continued understanding of infection biomarkers will lead to developing a detection device that can be self-administered and provide a faster ability to diagnose and prevent widespread infection in-theater. Other battlefield technologies includes a soldier-portable hemostatic wound treatment system, capability to manufacture field-relevant pharmaceuticals in theater, and a rapid after-action review of field events as a diagnostic tool for improving the delivery of medical care and medical personnel protection. Improved medical imaging will be approached through new physical properties of cellular metabolic activities. New neural interface technologies will reliably extract information from the nervous system to enable control of the best robotic prosthetic-limb technology. To allow medical practitioners the capability to visualize and comprehend the complex relationships across patient data in the electronic medical record systems, technologies will be developed to assimilate and analyze the large amount of data and provide tools to make better informed decisions for patient care. In the area of medical training, new simulation-based tools will rapidly teach increased competency in an open and scalable architecture to be used by all levels of medical personnel for basic and advanced training. Advanced information-based techniques will be developed to supplement warfighter healthcare and the diagnosis of post-traumatic stress disorder (PTSD) and mild traumatic brain injury (mTBI). This project will also pursue the applied research efforts for dialysis-like therapeutics.

B. Program Change Summary ($ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total
Previous President's Budget	-	110.000	95.400	-	95.400
Current President's Budget	-	95.000	110.900	-	110.900
Total Adjustments	-	-15.000	15.500	-	15.500
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-15.000			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• TotalOtherAdjustments	-	-	15.500	-	15.500

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Change Summary Explanation

FY 2012: Decrease reflects reductions for unsustained funding.

FY 2013: Increase reflects consolidation of all budget activity 2 medical efforts into this PE.

C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
Title: Unconventional Therapeutics*	-	8.716	3.000
Description: * Previously funded in PE 0602383E, Project BW-01 This thrust is developing unique and unconventional approaches to ensure that soldiers are protected against a wide variety of naturally occurring, indigenous or engineered threats. This program will develop approaches to counter any natural or man-made pathogen within one week. This includes development of countermeasures that do not require prior knowledge of the pathogen and are broadly applicable to multiple unrelated bacterial and/or viral infectious agents. The integration of academic research programs with pharmaceutical development efforts will result in reducing the traditional drug development cycle timeframe. ***FY 2012 Plans:*** - Demonstrate various technologies that can increase the median infectious dose of a given pathogen by 100-fold in an animal model compared to the untreated control in order to prevent infection. - Demonstrate a 4-fold increase in survival time after a lethal dose challenge of a given pathogen in an animal model due to administered technology. - Demonstrate 95% survival against a first lethal dose challenge of a given pathogen in an animal model using a therapy developed within 7 days of receipt of an unknown pathogen. - Demonstrate 95% three week survival after three lethal dose challenges of a given pathogen in an animal model spaced 1 week apart. ***FY 2013 Plans:*** - Demonstrate 95% survival after three lethal dose challenges of an unknown pathogen in two-animal models. - Transition good laboratory practice approved technology to U.S. pharmaceutical company for clinical development.			
Title: Pathogen Defeat*	-	19.000	16.500
Description: *Previously funded in PE 0602715E, Project MBT-02 Pathogens are well known for the high rate of mutation that enables them to escape drug therapies and primary or secondary immune responses. The Pathogen Defeat thrust area will provide capabilities to predict and deflect future threats. Pathogen Defeat focuses not on the threats that are already known but rather on the threats of newly emerging pathogens and future mutations, allowing pre-emptive preparation of vaccine and therapy countermeasures.			

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
FY 2012 Plans: - Develop a platform to reproducibly demonstrate the evolutionary pathway of a virus under multiple selective pressures. - Validate predictive algorithms against selected experimental pressures on viral evolutionary pathways. - Use algorithm to investigate virus mitigation and frequency globally to predict the timing and geographic location of reassortment events. - Model processes to accurately predict the drift and shift of virus in pre-human, animal reservoirs. - Develop first-ever system for anticipating evolution of clinical drug resistance through the use of an in vitro viral-evolution reactor. - Demonstrate novel sequencing technologies to reduce error rate. - Demonstrate evolution in microdroplet cell-viral infection systems. ***FY 2013 Plans:*** - Predict timing of antiviral failure in chronically infected viral host (animal) model. - Predict location(s) of genetic mutation responsible for antiviral failure in a chronically infected viral host (animal) model. - Predict number of viral generations necessary to achieve antiviral resistance in a chronically infected viral host (animal) model. - Predict location of genetic mutation(s) responsible for resistance to subunit vaccine (such as hemagglutinin or recombinant protective antigen.) - Correlate influenza vaccine failure in syngeneic/specific pathogen-free poultry with pathogen evolution in the natural ecologies of Asia. - Use in vitro evolution reactors to predict emergence of novel, variant influenza strains from within-reservoir species. - Use in vitro evolution reactors to predict emergence of dengue virus mutations in a region where dengue has recently appeared. - Use in vitro evolution reactors to predict host resistance to candidate pathogens.			
Title: Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT)*	-	10.508	15.500
Description: *Previously funded in Synthetic Biology in PE 0601101E, Project TRS-01 The overarching goal of the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program is to increase our ability to rapidly respond to a disease or threat and improve individual readiness and total force health protection by providing centralized laboratory capabilities at non-tertiary care settings. ADEPT will focus on the development of Ribonucleic Acid (RNA)-based vaccines, potentially eliminating the time and labor required for traditional manufacture of a vaccine while at the same time improving efficacy. ADEPT will also focus on advanced development of key elements for simple-to-operate diagnostic devices. A companion basic research effort is budgeted in PE 0601117E, Project MED-01. ***FY 2012 Plans:***			

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
- Increase stability of RNA-based vaccines. - Demonstrate efficacy of RNA-based vaccines in a small animal model. - Develop advanced instrumentation approaches for sample preparation for diagnostics. - Develop advanced instrumentation approaches for detector elements of autonomous diagnostics devices. ***FY 2013 Plans:*** - Demonstrate increased humoral and cellular responses with RNA-based vaccines as compared to benchmark vaccines in vivo. - Demonstrate increased efficacy of RNA-based vaccines in vivo in small and large animal models. - Demonstrate quantitative performance metrics for developed instrumentation approaches for diagnostic sample preparation. - Demonstrate quantitative performance metrics for developed instrumentation approaches for detector elements of autonomous diagnostic devices.			
Title: Tactical Biomedical Technologies*	-	16.676	18.500
Description: *Previously funded in PE 0602715E, Project MBT-02 The Tactical Biomedical Technologies thrust will develop new approaches to deliver life-saving medical care on the battlefield. Uncontrolled blood loss is the leading cause of preventable death for soldiers on the battlefield. While immediate control of hemorrhage is the most effective strategy for treating combat casualties and saving lives, currently no method other than surgical intervention can effectively treat intracavitary bleeding. A focus in this thrust is the co-development of a materials-based agent(s) and delivery mechanism capable of damaged tissue-targeted hemostasis and wound control. This system will effectively treat compressible and non-compressible wounds regardless of geometry or location. Additionally, rapid response to emerging biological threats on the battlefield is impacted by logistical delays of delivering the necessary therapeutics. Creating a "pharmacy on demand" will enable far-forward medical providers to manufacture and produce small molecule drugs and biologics in order to ensure that the therapeutics are available when they need them. This project will also develop new algorithms, protocols, and methods to allow registration and comparison of disparate sources of data in biology (across species, experimental systems, hierarchies and populations). ***FY 2012 Plans:*** - Demonstrate hemostasis agent stability consistent with operational requirements. - Demonstrate hemostasis in less than four minutes on a non-compressible injury model. - Demonstrate that hemostatic material does not induce intracavitary fibrosis within 28 days when left at the wound site. - Design scale-up for large-volume hemostasis agent synthesis. - Initiate discussions for wound stasis system FDA approval.			

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
- Synthesize active pharmaceutical ingredients (APIs) in continuous flow, and design and test drug product crystallization and formulation for pharmaceuticals for the battlefield. ***FY 2013 Plans:*** - Demonstrate a combined hemostasis agent and delivery mechanism that achieves hemostasis in less than four minutes, and does not interfere with standards of care. - Finalize a plan for wound stasis system FDA approval. - Demonstrate continuous flow synthesis and manufacturing of multiple pharmaceuticals using integrated platform. - Synthesize in continuous flow APIs in multiple pharmaceuticals. - Design and test drug product crystallization and formulation in multiple pharmaceuticals. - Engage the FDA for input on process analytical technologies (PAT) and current good manufacturing practice (cGMP). - Develop prototype device for treatment of intracranial hemorrhage using laser energy through the skull and tissues. - Develop advanced techniques to extract and evaluate both lexical and prosodic features from speech data collected from individuals linked to suicide risk in previous studies, and begin developing predictive models for depression and suicide assessment using speech biomarkers.			
Title: Military Medical Imaging* ***Description:*** *Previously funded in PE 0602715E, Project MBT-02 The Military Medical Imaging thrust will develop medical imaging capabilities to support military missions and operations. The emergence of advanced medical imaging includes newly recognized physical properties of biological tissue, or metabolic pathway, or physiological function in order to map it into an image of diagnostic utility and performance. This need is ever increasing as researchers and scientists seek to better understand anatomical, functional and cellular level interactions. This thrust will also address how to improve the delivery of medical care and medical personnel protection by building a simulated environment for rapid after-action review of field events generated from current military systems. The advanced development of these tools will provide a formidable arsenal of diagnostic tools for warfighter performance and care. ***FY 2012 Plans:*** - Develop software to convert disparate data formats into a common language, enabling visual display and integration for processing queries. - Demonstrate ability to automatically detect, track, and analyze similar events and incidents in temporal and physical space. - Focus x-rays with orbital angular momentum (OAM) through a model of skin and bone to a depth of 5 cm to continue work on new imaging technology comparable to magnetic resonance imaging, but not requiring a magnet. - Develop high efficiency x-ray optics appropriate for broadband, bench top x-ray sources.	-	7.334	6.900

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
- Increase signal-to-noise ratio using arrays of OAM photon beams and new signal detection approaches. ***FY 2013 Plans:*** - Obtain hydrogen and carbon-13 spectra from animal tissue using quantum orbital resonance spectroscopy (QORS) with potential applications for military medical use (i.e. analysis of traumatic brain injury utilizing imagery and spectroscopy information). This technique does not use a large magnet to hyperpolarize the nuclei, and may yield image and chemical information superior to an MRI, but with portability. - Design a compact prototype device for performing novel MRI-like imaging and spectroscopy using QORS in military medical environments.			
Title: Reliable Neural-Interface Technology (RE-NET)*	-	24.000	12.500
Description: *Previously funded in PE 0602715E, Project MBT-02 Wounded warriors with amputated limbs cannot fully exploit recent advances in prosthetic-limb technology because the neural interfaces used to extract limb-control information are low-performance and unreliable. The goal of the Reliable Neural-Interface Technology (RE-NET) program is to develop the technology and systems needed to reliably extract information from the nervous system at the scale and rate necessary to control state-of-the-art high-performance prosthetic limbs. The program will increase the channel-count (amount information) of reliable peripheral-nervous-system interfaces and increase the operational lifetime (reliability) of central-nervous-system interfaces. In support of these efforts, the RE-NET program is developing methods to quantitatively assess, model, predict, and accelerate the leading causes of neural interface degradation and failure. Through this focus on reliability, the RE-NET program will enable clinically relevant technology transitions in support of wounded warriors. ***FY 2012 Plans:*** - Develop a tactor-array system for use in veterans with upper-limb amputations. These systems will be provided to U.S. veterans for long-term daily use in order to incorporate touch percepts from the prosthetic fingertips into the body schema. This effort aims to dramatically increase the functionality and use of existing advanced prosthetic systems by creating a reliable sensory-feedback interface. - Develop wearable sensor arrays that detect bioelectrical signals from muscle activity associated with hand grasp and motor activity in amputees. Develop sophisticated decoding algorithms based on sparse principal-component analysis and probabilistic modeling via Markov random fields. By selecting the optimal signal vectors, muscle-activity classification is expected to achieve very high accuracy. - Develop a peripheral-nerve interface that will form a long-term and reliable connection between the severed motor and sensory fascicles of an amputee and the electrical recording devices that will drive a robotic prosthetic limb. Decoding motor and sensory algorithms will be developed to translate control and sensation signals across the interface.			

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
- Develop peripheral nerve recording interfaces and control algorithms that capture motor intent signals from the residual nerves in amputees. - Develop sophisticated real-time classification algorithms designed to operate dextrous control of an upper limb neuroprosthetic using electroencephalogram and other signals captured entirely from non-invasive, non-penetrating, sources. - Develop biotic/abiotic neural interface technology to overcome known failure mechanisms. - Replace linear and low-order, non-linear decoding techniques with sophisticated statistical and non-linear algorithms. - Develop a novel neural interface that will be implanted via a minimally invasive intravascular approach. - Enlist commercial neural interface manufacturers to develop tools to allow users to evaluate probe reliability in situ, helping them to pinpoint the source of failure should it be due to flaws in the probe design or manufacture. - Develop techniques and standards to evaluate the long-term biocompatibility of advanced neural interface materials. Collaborate with FDA and American National Standards Institute (ANSI) to adapt biocompatibility safety standards for neural interfaces. ***FY 2013 Plans:*** - Demonstrate a tactor-array system capable of driving neural plasticity and sensory percept reorganization through remapping of fingertip touch percepts to amputee residual limbs. - Demonstrate wearable bioelectric sensor array with 32 active differential channels capable of controlling a standard myoelectric prosthetic hand. Extend sophisticated electromyography (EMG)-decoding algorithms to adapt to real-world artifacts and to infer user intent. - Develop clinically viable self-contained implantable EMG-recording sensors that would have a direct and immediate impact on traditional myoelectric prostheses and transplanted muscle re-innervation patients by substantially increasing the number of controllable independent degrees of freedom. - Demonstrate the biological stability, durability, and reliability of a peripheral nerve interface through motor, sensory, and closed-loop behavioral activities in a freely moving animal model. - Initiate clinical trials for peripheral nerve recording interfaces that capture motor control signals from the endogenous residual nerves. - Demonstrate an electroencephalogram-based fully non-invasive, non-penetrating, neural-interface system capable of providing prosthetic limb control for human users. - Demonstrate the improved reliability of newly developed neural probe technologies designed specifically to overcome known failure mechanisms. - Demonstrate use of best-of-breed statistical and non-linear decoding algorithms and quantify the improvements in accuracy and reliability.			
Title: Dialysis-Like Therapeutics	-	5.000	11.500

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
Description: Sepsis, a bacterial infection of the blood stream, is a significant cause of injury and death among combat-injured soldiers. The goal of this program is to develop a portable device capable of controlling relevant components in the blood volume on clinically relevant time scales. Reaching this goal is expected to require significant advances in sensing in complex biologic fluids, complex fluid manipulation, separation of components from these fluids, and mathematical descriptions capable of providing predictive control over the closed loop process. The envisioned device would save the lives of thousands of military patients each year by effectively treating sepsis and associated complications. Applied research under this program further develops and applies existing component technologies and then integrates these to create a complete blood purification system for use in the treatment of sepsis. Included in this effort will be development, integration and demonstration of non-fouling, continuous sensors for complex biological fluids; implementation of high-flow microfluidic structures that do not require the use of anticoagulation; application of intrinsic separation technologies that do not require pathogen specific molecular labels or binding chemistries; and refinement of predictive modeling and control (mathematical formalism) with sufficient fidelity to enable agile adaptive closed-loop therapy. The basic research part of this program is budgeted in PE 0601117E, Project MED-01. ***FY 2012 Plans:*** - Evaluate existing sensing, microfluidic flow, and intrinsic separation component technologies for use in an integrated blood purification system and initiate research plan to achieve significant improvements in line with the overall program goals. - Develop integration plan for component technologies developed in the basic research aspect of this program. - Develop regulatory pathway leading to an approved integrated device. ***FY 2013 Plans:*** - Refine integration strategy, develop a bread-board system, and demonstrate bread-board system in a small animal model. - Confirm regulatory plan and begin regulatory approval process for the integrated device.			
Title: Warrior Web ***Description:*** Warrior Web, previously funded in the Maintaining Combat Performance Thrust in PE 0602715E, Project MBT-02, will develop an adaptive, compliant, nearly transparent, quasi-active joint support system to mitigate acute injuries caused by physically demanding events common to missions such as airborne and air assault insertions. Warrior Web represents an expansion of capability beyond "lightening the load." Warrior Web's capability space is between biomechanics, robotics, physiology, and combat clothing. This program will result in technology that reduces the injuries sustained by soldiers. Allowing soldiers to perform their missions with reduced risk for injuries will have immediate effects on mission readiness, soldier survivability, and mission performance.	-	-	10.250

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
Component technologies will be in areas such as regenerative kinetics at joints and energy harvesting to offset power/energy demands; human performance, system, and component modeling; novel materials and dynamic stiffness; actuation; controls and human interface; and power distribution/energy storage. The final suit is planned to weigh no more than 20 pounds and require no more than 100W of external power. ***FY 2013 Plans:*** - Conduct core technologies Preliminary Design Review. - Completion of preliminary core technology efforts: subsystem testing, analysis, and validated modeling. - Initiate design of suit combining core technologies. - Integrate core technologies into suit design. - Begin critical design towards a prototype.			
Title: Detection and Computational Analysis of Psychological Signals (DCAPS) - Medical* ***Description:*** *Formerly Healing Heroes - Medical. Previously funded in PE 0602304E, Project COG-03. The Detection and Computational Analysis of Psychological Signals (DCAPS) program will develop automated information systems that identify group and individual trends indicative of post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI), anomaly detection algorithms to identify emerging physical and psychological crises, and provide guided access to information and educational materials. This will complement commercial on-line resources, interactive media, and social networks that supplement traditional healthcare options but have not focused on issues specific to the warfighter. DCAPS recognizes that security and privacy are critical to user acceptance and Health Insurance Portability and Accountability Act (HIPAA) compliance and so will incorporate strong authentication and other security mechanisms as needed to protect patient data. The program will also develop partnerships with key DoD organizations working in this area, including the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, the Defense Medical Research and Development Program, the Army Telemedicine & Advanced Technologies Research Center, and the National Center for TeleHealth and Technology. ***FY 2013 Plans:*** - Operationalize/harden system software and obtain approvals to conduct user trials. - Perform user trials of mobile psychological health and telehealth applications in coordination with transition partners. - Modify and optimize mobile psychological health and telehealth applications based on the results of user trials. - Obtain final certifications and accreditation and deliver technology to military health community transition partners.	-	-	9.000
Title: Revolutionizing Prosthetics* ***Description:*** *Previously funded in PE 0602715E, Project MBT-02.	-	-	7.250

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2011	FY 2012	FY 2013
The goal of this thrust is to radically improve the state of the art for upper limb prosthetics, moving them from crude devices with minimal capabilities to fully integrated and functional limb replacements. Current prosthetic technology generally provides only gross motor functions, with very crude approaches to control. This makes it difficult for wounded soldiers to re-acquire full functionality and return to military service if so desired. The advances required to provide fully functional limb replacements will be achieved by an aggressive, milestone driven program combining the talents of scientists from diverse areas including: medicine, neuroscience, orthopedics, engineering, materials science, control and information theory, mathematics, power, manufacturing, rehabilitation, psychology and training. The results of this program will radically improve the ability of combat amputees to return to normal function. ***FY 2013 Plans:*** - Complete demonstration of neural control of arms with closed-loop feedback by spinal cord injured patients. - Demonstrate safety and stability of sensory feedback over multiple month periods. - Finalize and submit complete FDA package to obtain approval for commercial production of neural interface devices. - Support transition efforts of neural recording and stimulation devices.			
Title: Preventing Violent Explosive Neurologic Trauma (PREVENT) ***Description:*** The Preventing Violent Explosive Neurologic Trauma (PREVENT) program seeks to understand the causes of blast-induced traumatic brain injury (TBI), an injury that while previously described in the warfighter population, has been referred to as a potential "hidden epidemic" in the current conflict. PREVENT will use a variety of modeling techniques based on in-theater conditions to assess potential TBI caused by blast in the absence of penetrating injury or concussion. Research will create a model that can be directly correlated to the epidemiology and etiology of injury seen in returning warfighters, and attempt to determine the physical and physiological underpinnings and causes of the injury. The program will combine raw data collected from in-theater blast gauges with medical and event reports to conduct a complete analysis. As part of the mitigation and treatment strategy, candidate therapeutics are being tested in order to alleviate inflammation from both acute and chronic injury. This program continues efforts previously funded in PE 0602715E, Project MBT-02. ***FY 2012 Plans:*** - Continue longitudinal study on warfighters pre- and post-deployment in order to relate specific in-theater blast exposure to evidence and rates of blast TBI. - Further examine mechanisms of blast TBI by expanding porcine population and conducting analysis of imaging, proteomics and histopathology and showing relevancy to observed warfighter injuries. - Transition and support studies of therapeutic strategies to military medical community.	-	3.766	-
Accomplishments/Planned Programs Subtotals	-	95.000	110.900

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D. Other Program Funding Summary ($ in Millions)

N/A

E. Acquisition Strategy

N/A

F. Performance Metrics

Specific programmatic performance metrics are listed above in the program accomplishments and plans section.