Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Army

**R-1 ITEM NOMENCLATURE** 

2040: Research, Development, Test & Evaluation, Army

APPROPRIATION/BUDGET ACTIVITY

PE 0603807A: Medical Systems - Adv Dev

DATE: February 2011

BA 4: Advanced Component Development & Prototypes (ACD&P)

|  | <i>- - - - - - - - - -</i> | 101) 600 (1.0 | /               |                |                  |         |         |         |         |                     |            |
|--|----------------------------|---------------|-----------------|----------------|------------------|---------|---------|---------|---------|---------------------|------------|
| COST (\$ in Millions)  | FY 2010                    | FY 2011       | FY 2012<br>Base | FY 2012<br>OCO | FY 2012<br>Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Cost To<br>Complete | Total Cost |
| Total Program Element  | 32.851                     | 28.132        | 34.997          | -              | 34.997           | 23.291  | 18.736  | 18.894  | 21.191  | Continuing          | Continuing |
| 808: DOD DRUG & VACC AD                                      | 6.655                      | 7.225         | 11.569          | -              | 11.569           | 9.354   | 9.240   | 9.459   | 11.902  | Continuing          | Continuing |
| 811: MIL HIV VAC&DRUG DEV                                    | 1.410                      | 2.923         | 2.348           | -              | 2.348            | 1.188   | 0.808   | 0.824   | 0.835   | Continuing          | Continuing |
| 836: Field Medical Systems<br>Advanced Development           | 20.011                     | 17.984        | 19.465          | -              | 19.465           | 11.572  | 8.233   | 8.611   | 8.454   | Continuing          | Continuing |
| CS4: MEDICAL SYSTEMS ADV<br>DEV INITIATIVES (CA)             | 4.775                      | -             | -               | -              | -                | -       | -       | -       | -       | Continuing          | Continuing |
| VS7: MEDEVAC MISSION<br>EQUIPMENT PACKAGE (MEP) -<br>ADV DEV | -                          | -             | 1.615           | -              | 1.615            | 1.177   | 0.455   | -       | -       | 0.000               | 3.247      |

## Note

## A. Mission Description and Budget Item Justification

This program element (PE) funds development of medical materiel at the start of an official program of record, within the early system integration portion of the System Development and Demonstration phase of the acquisition life cycle using 6.4 funding. Program efforts support transition of promising Science and Technology candidate medical technologies (drugs, vaccines, medical devices, diagnostics, and mechanisms for detection and control of disease carrying insects) to larger scale testing in humans for safety and effectiveness. Programs are aligned to meet Future Force (F2) requirements stressed within concept documents and organizational structures. The PE provides funding for Food and Drug Administration (FDA) regulated human clinical trials to gain additional information about safety and effectiveness on the path to licensure for use in humans. The Projects supported by this PE are:

(PROJ 836) funds the demonstration and validation of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project also funds the human clinical trials that test the safety and effectiveness of biologics, devices and demonstration. Clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations. Products from this project will transition to 832.

(PROJ 808) funds development of candidate medical countermeasures for infectious diseases of military relevance. Efforts include vaccines, drugs, diagnostic kits/ devices, and insect control measures. These funds support human clinical efficacy trials of the drug/vaccine in a larger group that are designed to assess performance and to continue safety assessments in a larger group of volunteers. Products from this project will transition to 849.

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Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Army **DATE:** February 2011 R-1 ITEM NOMENCLATURE

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

(PROJ 811) funds the development of military relevant human immunodeficiency virus (HIV) medical countermeasures. It provides funding for planning and conducting of human clinical trials in a group of healthy volunteers to assess the drug/vaccine for safety, tolerability, how the drug/vaccine is distributed, metabolized, and excreted from the body, and investigate the appropriate dose for therapeutic use. Products from this project will transition to Project 812.

(PROJ VS7) program upgrades, retrofits, trains, and sustains the 256 Medical Evacuation legacy helicopters that continue to play a major role in Iraq and Afghanistan. The force design will increase the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operation needs. Products from this project will transition to VS8.

This program is managed by U.S. Army Medical Materiel Development Activity (USAMMDA) and U.S. Army Medical Materiel Agency (USAMMA) of the US Army Medical Research and Materiel Command

| B. Program Change Summary (\$ in Millions)            | FY 2010 | FY 2011 | <b>FY 2012 Base</b> | FY 2012 OCO | FY 2012 Total |
|---|---------|---------|---------------------|-------------|---------------|
| Previous President's Budget                           | 35.886  | 28.132  | 37.128              | -           | 37.128        |
| Current President's Budget                            | 32.851  | 28.132  | 34.997              | -           | 34.997        |
| Total Adjustments                                     | -3.035  | -       | -2.131              | -           | -2.131        |
| <ul> <li>Congressional General Reductions</li> </ul>  |         | -       |                     |             |               |
| <ul> <li>Congressional Directed Reductions</li> </ul> |         | -       |                     |             |               |
| <ul> <li>Congressional Rescissions</li> </ul>         | -       | -       |                     |             |               |
| <ul> <li>Congressional Adds</li> </ul>                |         | -       |                     |             |               |
| <ul> <li>Congressional Directed Transfers</li> </ul>  |         | -       |                     |             |               |
| <ul> <li>Reprogrammings</li> </ul>                    | -2.099  | -       |                     |             |               |
| SBIR/STTR Transfer                                    | -0.936  | -       |                     |             |               |
| <ul> <li>Adjustments to Budget Years</li> </ul>       | -       | -       | -2.131              | -           | -2.131        |

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| Exhibit R-2A, RDT&E Project Just  | ification: PB | 3 2012 Army |         |           |             |             |                   |            | DATE: Febr | uary 2011  |            |  |
|-----------------------------------|---------------|-------------|---------|-----------|-------------|-------------|-------------------|------------|------------|------------|------------|--|
| APPROPRIATION/BUDGET ACTIV        |               |             |         |           | OMENCLA     |             | PROJECT           |            |            |            |            |  |
| 2040: Research, Development, Test |               |             | 5.05    | PE 060380 | 7A: Medical | Systems - A | 808: <i>DOD E</i> | ORUG & VAC | CC AD      |            |            |  |
| BA 4: Advanced Component Develo   | pment & Pro   | totypes (AC | D&P)    |           |             |             |                   |            |            |            |            |  |
| COST (\$ in Millions)             | EV 0040       | EV 0044     | FY 2012 | FY 2012   | FY 2012     | EV 0040     | EV 0044           | EV 0045    | EV 0040    | Cost To    | T-4-1 04   |  |
| ,                                 | FY 2010       | FY 2011     | Base    | oco       | Total       | FY 2013     | FY 2014           | FY 2015    | FY 2016    | Complete   | Total Cost |  |
| 808: DOD DRUG & VACC AD           | 6.655         | 7.225       | 11.569  | -         | 11.569      | 9.354       | 9.240             | 9.459      | 11.902     | Continuing | Continuing |  |
| Quantity of RDT&E Articles        |               |             |         |           |             |             |                   |            |            |            |            |  |

### A. Mission Description and Budget Item Justification

B Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)

This project funds development of candidate medical countermeasures for infectious diseases of military relevance. These efforts are in: vaccines, drugs, diagnostic kits/devices, and insect control measures. These funds support human clinical efficacy (capacity to produce a desired size of an effect under ideal or optimal conditions) trials of the drug/vaccine in larger groups that are designed to assess how well the drug/vaccine works, and to continue safety assessments in a larger group of volunteers. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of medical diagnostic kits and devices. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. All clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations, a mandatory obligation for all military products placed into the hands of medical providers or service members. Product development priorities are determined based upon four major factors: (1) the extent and threat of the disease within the Combatant Commands theater of operations, (2) the clinical severity of the disease, (3) the technical maturity of the proposed solution, and (4) the affordability of the solution (development and production).

EV 2010

| B. Accomplishments/Flanned Frograms (\$ in Millions, Article Quantities in Each)  | FY 2010 | FY 2011 | FY 2012 |
|---|---------|---------|---------|
| Title: DoD Drug and Vaccine Advanced Development  | 6.655   | 7.225   | 11.569  |
| Articles:   | 0       | 0       |         |
| Description: Funding is provided for the following effort   |         |         |         |
| FY 2010 Accomplishments:  For Tafenoquine product, down-selected to best site for human safety/efficacy trial and continued laboratory assay development/ validation to understand the human body's immune responses when infected with malaria parasites and as tool for determining future clinical trial enrollment size, and transition the entire Tafenoquine program to project 849. Monitored progress of a new military topical insect repellent candidate in project 810 to determine its suitability for entry into advanced development. For the Infectious Disease Diagnostic (multiple candidates), conducted market research of selected developmental and commercial diagnostic platforms for select infectious diseases of military interest to determine suitability for entry into advanced development. The Dengue Tetravalent Vaccine (DTV) vaccine continues FDA required vaccine potency and stability testing and all other DTV activities are transitioned to project 849 [Dengue is a severe debilitating disease caused by a virus and transmitted by a mosquito]. For the Topical Antileishmanial Cream [Leishmania is a skin-based disease caused by a parasite and transmitted by sand flies], |         |         |         |
| continued a human treatment protocol in the U.S., the partner continued stability testing and produced new clinical drug lots, and project 849 supported the overseas human clinical trials activities of this topical cream. For Leishmania Skin Test (LST),   |         |         |         |

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army PE 0603807A: Medical Systems - Adv Dev

BA 4: Advanced Component Development & Prototypes (ACD&P)

dv Dev 808: DOD DRUG & VACC AD

7.225

11.569

6.655

## B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) **FY 2010** FY 2011 FY 2012 completed the final report for the expanded human safety dose ranging sensitization trial in the U.S., and conducted pre-trial activities for a large scale (>200 subjects) human safety/efficacy trial in a Leishmania endemic region. FY 2011 Plans: Prepare to accept transition of a new military topical insect repellent from project 810 at Milestone B into Engineering & Manufacturing Development phase. If candidate is ready transition new malaria vaccine candidate from project 810 into Engineering & Manufacturing Development phase. For the Infectious Disease Diagnostic (multiple candidates), prepare to accept transition of project into the Engineering & Manufacturing Development phase of advanced development. The DTV vaccine will continue FDA required vaccine potency and stability testing and all other DTV activities are transitioned to project 849. For Topical Antileishmanial Cream, continue a human treatment protocol in the US, the industry partner continues stability testing of the drug product, and project 849 supports the overseas human trials activities of the topical cream. FY 2012 Plans: Review evaluations, and human clinical trials of malarial/anti-malarial drugs, vaccines, diagnostics, insect repellents, and grouped infectious disease (Dengue [a severe debilitating disease caused by a virus and transmitted by a mosquito] and Leishmania [a skin-based disease caused by a parasite and transmitted by sand flies]) vaccines, drugs and diagnostics. Will seek industry partner and evaluate and complete down-selection of drug candidates for human trials for prevention or treatment of malaria. Will continue to evaluate the vaccine candidate for dengue with industry partner Sanofi Pasteur. For Topical Antileishmanial Cream,

## C. Other Program Funding Summary (\$ in Millions)

849 supports the overseas human trials activities of the topical cream.

N/A

# D. Acquisition Strategy

Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure and Environmental Protection Agency registration.

### **E. Performance Metrics**

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

**Accomplishments/Planned Programs Subtotals** 

Army Page 4 of 29 R-1 Line Item #71

will continue a human treatment protocol in the US, the industry partner continues stability testing of the drug product, and project

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

808- DOD DRUG & VACC AD

**DATE:** February 2011

| Management Services                                      | (\$ in Millio                | ns)                               |                              | FY 2  | 2011          | FY 2<br>Bas |               | FY 2 |               | FY 2012<br>Total |                     |            |                                |
|--|------------------------------|-----------------------------------|------------------------------|-------|---------------|-------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item                                       | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost        | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1M individually | Various                      | Not Applicable:Not applicable     | 9.316                        | 1.530 |               | 1.250       |               | -    |               | 1.250            | Continuing          | Continuing | Continuin                      |
|  |                              | Subtotal                          | 9.316                        | 1.530 |               | 1.250       |               | -    |               | 1.250            |                     |            |                                |
| Product Development (                                    | \$ in Millio                 | ns)                               |                              | FY 2  | 2011          | FY 2<br>Bas | -             | FY 2 |               | FY 2012<br>Total |                     |            |                                |
| Cost Category Item                                       | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost        | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1M individually | Various                      | Not applicable:Not applicable     | 9.114                        | 1.819 |               | 8.269       |               | -    |               | 8.269            | Continuing          | Continuing | Continuin                      |
|  |                              | Subtotal                          | 9.114                        | 1.819 |               | 8.269       |               | -    |               | 8.269            |                     |            |                                |
| Support (\$ in Millions)                                 |                              |                                   |                              | FY 2  | 2011          | FY 2<br>Bas | -             | FY 2 |               | FY 2012<br>Total |                     |            |                                |
| Cost Category Item                                       | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost        | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1M individually | Various                      | Not Applicable:Not applicable     | 3.820                        | 1.495 |               | 1.250       |               | -    |               | 1.250            | Continuing          | Continuing | Continuin                      |
|  |                              | Subtotal                          | 3.820                        | 1.495 |               | 1.250       |               | -    |               | 1.250            |                     |            |                                |
| Test and Evaluation (\$                                  | in Millions                  | s)                                |                              | FY 2  | 2011          | FY 2<br>Bas |               | FY 2 |               | FY 2012<br>Total |                     |            |                                |
| Cost Category Item                                       | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost        | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1M individually | Various                      | Not applicable:Not applicable     | 38.363                       | 2.381 |               | 0.800       |               | -    |               | 0.800            | Continuing          | Continuing | Continuin                      |
| greater than \$ not mulvidually                          |                              | • •                               |                              |       |               |             |               |      |               |                  |                     |            |                                |

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY
2040: Research, Development, Test & Evaluation, Army
BA 4: Advanced Component Development & Prototypes (ACD&P)

DATE: February 2011

R-1 ITEM NOMENCLATURE
PE 0603807A: Medical Systems - Adv Dev
808: DOD DRUG & VACC AD

| _                   |             |       |     |        |      |      |      |         |          |            |          |
|---------------------|-------------|-------|-----|--------|------|------|------|---------|----------|------------|----------|
| -                   | Total Prior |       |     |        |      |      |      |         |          |            | Target   |
|                     | Years       |       |     | FY 2   | 2012 | FY 2 | 2012 | FY 2012 | Cost To  |            | Value of |
|                     | Cost        | FY 2  | 011 | Ва     | ise  | 00   | o    | Total   | Complete | Total Cost | Contract |
| Project Cost Totals | 60.613      | 7.225 |     | 11.569 |      | -    |      | 11.569  |          |            |          |

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

DATE: February 2011

R-1 ITEM NOMENCLATURE
PE 0603807A: Medical Systems - Adv Dev
808: DOD DRUG & VACC AD

|   |   | FY 2010 |   |   | FY 2011 |   |   |   | FY 2012 |   |   | FY 2013 |   |   | FY 2014 |   |   |   | FY 2015 |   |   |   | FY 2016 |   |   |   |   |   |
|---|---|---------|---|---|---------|---|---|---|---------|---|---|---------|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---|---|
|   | 1 | 2       | 3 | 4 | 1       | 2 | 3 | 4 | 1       | 2 | 3 | 4       | 1 | 2 | 3       | 4 | 1 | 2 | 3       | 4 | 1 | 2 | 3       | 4 | 1 | 2 | 3 | 4 |
| New Standard Military Topical Insect Repellant (MS-B)     |   |         |   |   |         |   |   |   | •       |   |   | ,       |   |   |         |   |   | , |         |   |   |   |         |   |   |   |   |   |
| Anti-Malarial drug candidates Product Design Review (PDR) |   |         |   |   |         |   |   |   |         |   |   |         |   |   |         |   |   |   |         |   |   |   |         |   |   |   |   |   |
| Leishmania Skin Test CDR                                  |   |         |   |   |         |   |   |   |         |   |   |         |   |   |         |   |   |   |         |   |   |   |         |   |   |   |   |   |

Exhibit R-4A, RDT&E Schedule Details: PB 2012 Army

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY R-1 ITEM NOMENCLATURE PROJECT

2040: Research, Development, Test & Evaluation, Army PE 0603807A: Medical Systems - Adv Dev 808: DOD DRUG & VACC AD

BA 4: Advanced Component Development & Prototypes (ACD&P)

# Schedule Details

|   | St      | art  | Eı      | nd   |
|---|---------|------|---------|------|
| Events  | Quarter | Year | Quarter | Year |
| New Standard Military Topical Insect Repellant (MS-B)     | 1       | 2011 | 1       | 2011 |
| Anti-Malarial drug candidates Product Design Review (PDR) | 1       | 2011 | 1       | 2011 |
| Leishmania Skin Test CDR                                  | 2       | 2011 | 2       | 2011 |

Army Page 8 of 29 R-1 Line Item #71

DATE: February 2011

| EXHIBIT IN-ZA, IND TOLE PROJECT 303 | illication. FL   | 2012 711119 |         |            |             |             |             |                  | DATE. 1 ebituary 2011 |            |            |  |  |  |
|-------------------------------------|--|-------------|---------|------------|-------------|-------------|-------------|------------------|-----------------------|------------|------------|--|--|--|
| APPROPRIATION/BUDGET ACTIV          | /ITY   |             |         | R-1 ITEM N | OMENCLA     | TURE        | PROJECT     |                  |                       |            |            |  |  |  |
| 2040: Research, Development, Tes    |  |             |         | PE 060380  | 7A: Medical | Systems - A | 811: MIL HI | IIV VAC&DRUG DEV |                       |            |            |  |  |  |
| BA 4: Advanced Component Develo     | 4: Advanced Component Development & Prototypes (ACD&P) |             |         |            |             |             |             |                  |                       |            |            |  |  |  |
| COST (f in Millians)                |  |             | FY 2012 | FY 2012    | FY 2012     |             |             |                  |                       | Cost To    |            |  |  |  |
| COST (\$ in Millions)               | FY 2010  | FY 2011     | Base    | осо        | Total       | FY 2013     | FY 2014     | FY 2015          | FY 2016               | Complete   | Total Cost |  |  |  |
| 811: MIL HIV VAC&DRUG DEV           | 1.410  | 2.923       | 2.348   | -          | 2.348       | 1.188       | 0.808       | 0.824            | 0.835                 | Continuing | Continuing |  |  |  |
| Quantity of RDT&F Articles          |  |             |         |            |             |             |             |                  |                       |            |            |  |  |  |

## A. Mission Description and Budget Item Justification

Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)

Exhibit R-24 RDT&F Project Justification: PR 2012 Army

This project funds development of militarily relevant human immunodeficiency virus (HIV) medical countermeasures. It provides funding for the planning and conducting of human clinical trials in a group of healthy volunteers to assess the drug/vaccine for safety, tolerability, how the drug/vaccine is distributed, metabolized, and excreted from the body, and to investigate the appropriate dose for therapeutic use. Development efforts are focused on militarily unique needs effecting manning, mobilization, and deployment.

The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)   | FY 2010 | FY 2011 | FY 2012 |
|--|---------|---------|---------|
| Title: Military HIV Vaccine & Drug Development   | 1.410   | 2.923   | 2.348   |
| Articles:  | 0       | 0       |         |
| Description: Funding is provided for the following effort  |         |         |         |
| FY 2010 Accomplishments:   |         |         |         |
| Evaluated and down-select drug/vaccine candidates for preliminary human trials and conduct Design Readiness Review (DRR).  |         |         |         |
| FY 2011 Plans:   |         |         |         |
| Seek new industry partnership for selected candidate(s) drug/vaccine for HIV medical treatment/prevention.   |         |         |         |
| FY 2012 Plans:   |         |         |         |
| Perform three inter-related studies to enhance our understanding of precisely how the vaccine strategy used in the safety/efficacy   |         |         |         |
| trial completed in 2009 caused vaccine recipients to be protected from infection, including intense laboratory studies using   |         |         |         |
| samples from the trial, and commencement of two small clinical vaccine trials to generate data and samples to hopefully define what vaccine responses to try to generate for next increment studies. |         |         |         |
| , , , ,  | 1 110   | 0.000   |         |
| Accomplishments/Planned Programs Subtotals   | 1.410   | 2.923   | 2.348   |

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|  | UNCLASSIFIED   |                       |                                   |
|--|--|-----------------------|-----------------------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army  |  |                       | DATE: February 2011               |
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P) | R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev | PROJECT<br>811: MIL H | IIV VAC&DRUG DEV                  |
| C. Other Program Funding Summary (\$ in Millions)  N/A   |  |                       |                                   |
| D. Acquisition Strategy Test and evaluate commercially developed drug/vaccine candidates   | s in government-managed trials.                              |                       |                                   |
| E. Performance Metrics  Performance metrics used in the preparation of this justification mat  | erial may be found in the FY 2010 Army Performa              | nce Budget Ju         | stification Book, dated May 2010. |
|  |  |                       |                                   |
|  |  |                       |                                   |
|  |  |                       |                                   |
|  |  |                       |                                   |
|  |  |                       |                                   |
|  |  |                       |                                   |
|  |  |                       |                                   |
|  |  |                       |                                   |

**UNCLASSIFIED** 

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army

PE 0603807A: Medical Systems - Adv Dev

811: MIL HIV VAC&DRUG DEV

**DATE:** February 2011

BA 4: Advanced Component Development & Prototypes (ACD&P)

| Management Services (                                     | \$ in Millio                 | ons)                              |                              | FY 2011 |               | FY 2<br>Ba | -             | FY 2 | 2012<br>CO    | FY 2012<br>Total |                     |            |                                |
|---|------------------------------|-----------------------------------|------------------------------|---------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item  | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost    | Award<br>Date | Cost       | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1M individually. | TBD                          | Not Applicable:Not<br>Applicable  | 0.456                        | 0.473   |               | 0.473      |               | -    |               | 0.473            | Continuing          | Continuing | Continuing                     |
|   |                              | Subtotal                          | 0.456                        | 0.473   |               | 0.473      |               | -    |               | 0.473            |                     |            |                                |

### **Remarks**

Not Applicable

| Product Development (                                    | Product Development (\$ in Millions) |                                   |                              |       |               | FY 2<br>Ba | 2012<br>se    |      | 2012<br>CO    | FY 2012<br>Total |                     |            |                                |
|--|--------------------------------------|-----------------------------------|------------------------------|-------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item                                       | Contract<br>Method<br>& Type         | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost       | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1M individually | Various                              | Not applicable:Not applicable     | 1.215                        | 0.746 |               | 0.360      |               | -    |               | 0.360            | Continuing          | Continuing | Continuing                     |
|  |                                      | Subtotal                          | 1.215                        | 0.746 |               | 0.360      |               | -    |               | 0.360            |                     |            |                                |

| Support (\$ in Millions)                                 |                              |                                   |                              | FY 2  | 2011          | FY 2<br>Ba | 2012<br>se    | FY 2012<br>OCO |               | FY 2012<br>Total |                     |            |                                |
|--|------------------------------|-----------------------------------|------------------------------|-------|---------------|------------|---------------|----------------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item                                       | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost       | Award<br>Date | Cost           | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1M individually | TBD                          | Not applicable:Not<br>Applicable  | 1.215                        | 0.597 |               | 0.408      |               | -              |               | 0.408            | Continuing          | Continuing | Continuing                     |
|  |                              | Subtotal                          | 1.215                        | 0.597 |               | 0.408      |               | -              |               | 0.408            |                     |            |                                |

### Remarks

Not Applicable

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

**DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

811: MIL HIV VAC&DRUG DEV

| Test and Evaluation (\$ | in Millions                  | 3)                                |                              | FY 2  | 2011          | FY 2<br>Ba |               | FY 2012<br>OCO |               | FY 2012<br>Total |                     |            |                                |
|-------------------------|------------------------------|-----------------------------------|------------------------------|-------|---------------|------------|---------------|----------------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item      | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost       | Award<br>Date | Cost           | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| Test and Evaluation     | TBD                          | U.S. Component<br>AFRIMS,:Bangkok | 12.200                       | 1.107 |               | 1.107      |               | -              |               | 1.107            | Continuing          | Continuing | Continuing                     |
|                         |                              | Subtotal                          | 12.200                       | 1.107 |               | 1.107      |               | -              |               | 1.107            |                     |            |                                |

### Remarks

Not Applicable

|        | Ye            | al Prior<br>ears<br>Cost | FY 2  | 2011 | FY 2<br>Ba | FY 2 | 2012<br>CO | FY 2012<br>Total | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
|--------|---------------|--------------------------|-------|------|------------|------|------------|------------------|---------------------|------------|--------------------------------|
| Projec | t Cost Totals | 15.086                   | 2.923 |      | 2.348      | -    |            | 2.348            |                     |            |                                |

### Remarks

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army

Exhibit R-4, RDT&E Schedule Profile: PB 2012 Army

PE 0603807A: Medical Systems - Adv Dev

811: MIL HIV VAC&DRUG DEV

| BA 4: Advanced | Component | Development | & Prototypes | (ACD&P) |
|----------------|-----------|-------------|--------------|---------|
|                |           |             |              |         |

|   |   | FY 2010 |   |   |   | FY 2011 |   |   | FY 2012 |   |   |   | FY 2013 |   |   | FY 2014 |   |   |   | FY 2015 |   |   | FY 2016 |   |   |   |   |   |
|---|---|---------|---|---|---|---------|---|---|---------|---|---|---|---------|---|---|---------|---|---|---|---------|---|---|---------|---|---|---|---|---|
|   | 1 | 2       | 3 | 4 | 1 | 2       | 3 | 4 | 1       | 2 | 3 | 4 | 1       | 2 | 3 | 4       | 1 | 2 | 3 | 4       | 1 | 2 | 3       | 4 | 1 | 2 | 3 | 4 |
| HIV Vaccine Design Readiness Review (DRR) |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |   |   |
| RV305 Phase 2 Study of Secondary Boost    |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |   |   |
| RV306 Phase 2 Study                       |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |   |   |
| RV3XX ALVAC vs NYVAC Phase 2 Study        |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |   |   |
| Prime/Boost Phase 3 Study                 |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |         |   |   |   |   |   |

Exhibit R-4A, RDT&E Schedule Details: PB 2012 Army

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY R-1 ITEM NOMENCLATURE PROJECT

2040: Research, Development, Test & Evaluation, Army
BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

811: MIL HIV VAC&DRUG DEV

## Schedule Details

|   | St      | art  | E       | nd   |
|---|---------|------|---------|------|
| Events                                    | Quarter | Year | Quarter | Year |
| HIV Vaccine Design Readiness Review (DRR) | 3       | 2010 | 3       | 2010 |
| RV305 Phase 2 Study of Secondary Boost    | 1       | 2011 | 3       | 2013 |
| RV306 Phase 2 Study                       | 1       | 2011 | 3       | 2013 |
| RV3XX ALVAC vs NYVAC Phase 2 Study        | 4       | 2011 | 3       | 2014 |
| Prime/Boost Phase 3 Study                 | 4       | 2014 | 3       | 2016 |

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DATE. Cabarram, 2014

| EXHIBIT R-2A, RD1&E Project Just   | EXHIBIT R-2A, RDT&E Project Justification: PB 2012 Army |                                 |                 |                              |                                 |         |         |         | DAIE: Febi | uary 2011           |            |
|--|---|---------------------------------|-----------------|------------------------------|---------------------------------|---------|---------|---------|------------|---------------------|------------|
| APPROPRIATION/BUDGET ACTIV<br>2040: Research, Development, Test<br>BA 4: Advanced Component Develo |   | <b>R-1 ITEM N</b><br>PE 0603807 | _               | T <b>URE</b><br>Systems - Ad | Medical Systems Advanced<br>ent |         |         |         |            |                     |            |
| COST (\$ in Millions)  | FY 2010   | FY 2011                         | FY 2012<br>Base | FY 2012<br>OCO               | FY 2012<br>Total                | FY 2013 | FY 2014 | FY 2015 | FY 2016    | Cost To<br>Complete | Total Cost |
| 836: Field Medical Systems<br>Advanced Development   | 20.011  | 17.984                          | 19.465          | -                            | 19.465                          | 11.572  | 8.233   | 8.611   | 8.454      | Continuing          | Continuing |
| Quantity of RDT&E Articles   |   |                                 |                 |                              |                                 |         |         |         |            |                     |            |

#### Note

In FY10 Project 837 Soldier Sys Prot-AD has been consolidated into this Project, 836.

Major contractors/intra-governmental agencies include: IGR Enterprises, Inc.; Army Medical Department Board Test Center; SeQual Technologies, Inc.; Ultrasonic Diagnostics, Inc.; HemCon Medical Technologies, Inc.; Hemerus Medical, LLC.; Fast Track Drugs & Biologics, LLC; Clinical Research Management, and Walter Reed Army Institute of Research (WRAIR) and Institute of Surgical Research (ISR) for user evaluation. Other military agencies include Program Executive Office (PEO) Soldier, PEO Combat Service Support, and Naval Undersea Warfare Center.

### A. Mission Description and Budget Item Justification

Exhibit D 24 DDT9E Ducingt Instification, DD 2042 August

This project funds the demonstration and validation of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project funds human clinical trials to test the safety and effectiveness of biologics (products derived from living organisms) and devices necessary to meet medical requirements. When available, commercial-off-the-shelf (COTS) medical products are also tested and evaluated for transition to system development and demonstration. Consideration is also given to reducing the medical logistics footprint through smaller weight, volume, and equipment independence from supporting materials. All clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)  |           | FY 2010 | FY 2011 | FY 2012 |
|---|-----------|---------|---------|---------|
| Title: Field Medical Systems Advanced Development   |           | 20.011  | 17.984  | -       |
|   | Articles: | 0       | 0       |         |
| Description: Funding is provided for the following effort   |           |         |         |         |
| FY 2010 Accomplishments:  Conducted human trials to assess intranasal ketamine drug effects on a subject's judgment. Antiplaque Gum: trans  |           |         |         |         |
| from project 840 and conducted a small human safety and dose escalation study in health adults. Environmental Spiement of the project 827 and increment 2 from technology development 1 from technology development |           |         |         |         |
| Biomonitor (ESB): transitioned increment 1 from project 837 and increment 2 from technology development project development of increment 2 ESB system for use in conjunction with field water facilities. Field tested one Ceramic  |           |         |         |         |
| Generator system for the Force Provider Early Entry Combat Support Hospital (CSH). Transitioned Ultrasonic brai product to project 832 for Systems Development and Demonstration.   | , 0       |         |         |         |
| FY 2011 Plans:  |           |         |         |         |
|   |           |         |         |         |

Army Page 15 of 29 R-1 Line Item #71

| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army  |  | DATE: F  | ebruary 2011 |         |
|--|--|--|--------------|---------|
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)   | R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev   | PROJECT<br>836: Field Medical S<br>Development                   | ystems Advan | ced     |
| B. Accomplishments/Planned Programs (\$ in Millions, Article Qua   | ntities in Each)   | FY 2010  | FY 2011      | FY 2012 |
| Total Intravenous Anesthesia (TIVA): Perform clinical trials and submit Critical Care System (ACCLS): Conduct validation testing and Army D devices. Urinary Facilitation Device: Testing, reports, and review for FD if preclinical results are favorable, conduct environmental testing and ic fieldable unit. Pursue additional regulatory approvals as needed. Plast environmental testing and identify any needed design modifications to approvals as needed. Hydrosurgery System: Conduct operational and Develop software, conduct testing, and refinement for MOC Sensor Mc Medical Mission Package for Treatment Variants: Tansition to Project 832. Shock and V Air Medical Evacuation Vehicles: Transition to Project 832. Shelter for Variant: Transition to Project 832. Passive Cold Chain Capability for Te 832. The intranasal ketamine drug effects study transition to project 83 | T/OT/AWC. Submit the 510K for FDA review for rDA approval. PEAK Surgical System (Plasma Bladentify any needed design modifications to produce ma Knife: if preclinical results are favorable, condeproduce a fieldable unit. Pursue additional regulation environmental testing. Remote Diagnostic Accessed and Development phase. Treatment Table for Plass. Refrigerator for PM, HBCT for Medical Mission Package for Treatment FDM, HBCT for Medical Mission Package for Treatment Sensitive Medical Materiel: Transition 22 for Systems Development and Demonstration. | modified ide): ce a uct atory s (RDA): M, HBCT on ound and tment |              |         |
| Title: Field Medical Systems Advanced Development - PM Medical De  | evices   | -  | -            | 7.428   |
| <b>Description:</b> Funding is provided for the following effort   |  |  |              |         |
| FY 2012 Plans: Non-invasive Multi-Analyte Monitor submission for RFP in 2QFY12 for concentration in blood. Hydration Meter: will conduct validation testing in PE 832 line. Eye Tracking System for Assessing Concussions is a tr trial to move to FDA submission in 1Q FY. Fibrinogen Bandages will us wound sites from bacterial infection. 2Q FY12 final review of Good Ma forward to FDA submission. Cardiopulmonary Enhancement: conduct relife threatening trauma devices for enhanced treatment.  | in 4Q. Plasma Knife: Will transition product to 6. raumatic brain injury diagnostic tool that begins clisse an antimicrobial irrigation solution to protect blanufacturing Practice (GMP) will be conducted for  | 5 funding<br>nical<br>ast injury<br>movement                     |              |         |
| Title: Field Medical Systems Advanced Development - PM Pharmaceu   | uticals  | -  | -            | 7.759   |
| Description: Funding is provided for the following effort  |  |  |              |         |
| FY 2012 Plans: Cryopreserved Platelets (CPP) (use of cryopreserved platelets for cont evaluations and conduct good manufacturing practices preliminary valid   |  |  |              |         |

**UNCLASSIFIED** 

Army Page 16 of 29 R-1 Line Item #71

| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army   |  |              | DATE: February 2011      |
|---|--|--------------|--------------------------|
| APPROPRIATION/BUDGET ACTIVITY                             | R-1 ITEM NOMENCLATURE                  | PROJECT      |                          |
| 2040: Research, Development, Test & Evaluation, Army      | PE 0603807A: Medical Systems - Adv Dev | 836: Field N | Medical Systems Advanced |
| BA 4: Advanced Component Development & Prototypes (ACD&P) |  | Developme    | nt                       |
|   |  |              |                          |

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)  | FY 2010 | FY 2011 | FY 2012 |
|---|---------|---------|---------|
| (FDP) Program (hemorrhage treatment candidate): Will conduct preliminary clinical evaluations and conduct good manufacturing practices preliminary validation studies.  |         |         |         |
| Title: Field Medical systems Advanced Development - PM Integrated Clinical Systems (ICS)  | -       | -       | 0.888   |
| Description: Funding is provided for the following effort   |         |         |         |
| FY 2012 Plans: Will conduct final testing of Phase IV of the Remote Diagnostic Access (RDA). Will Develop a universal security compliant access portal to serve as a standardized compliance wrapper for all vendors, medical technology, and even IT management products that may traverse between the .com and .mil networks. The Milestone Decision Authority (MDA) is scheduled to review the RDA project in March 2011 for continuation or termination.  |         |         |         |
| Title: Field Medical Systems Advanced Development - PM Medical Support Systems  | -       | -       | 3.390   |
| Description: Funding is provided for the following effort   |         |         |         |
| FY 2012 Plans:  Treatment Table and Blood Refrigerator prototypes for PM HBCT will be finished and prepared for testing. Shock and Vibration Litter Isolation data analysis will be presented to the MDA for decision to transition to 832. New cold chain technologies will be explored for MES set inclusion. Quad fold litter, litter straps, and hands-free litter system from RFIs will continue to be explored and transition to 832. New ISO shelter panels will be tested in FY12 and transitioned back into ISO shelter specification for future shelter buys. Testing of Trauma Tiered Medical Bag will be accomplished and transition to PEP soldier. Soft-walled shelter development will continue to finalize Force Provider modules for use in Combat Support Hospitals. Prototype Water and Waste Water Management system will be developed and transitioned to 832 for testing. |         |         |         |
| Accomplishments/Planned Programs Subtotals  | 20.011  | 17.984  | 19.46   |

## C. Other Program Funding Summary (\$ in Millions)

N/A

# D. Acquisition Strategy

Develop in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.

## E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Army Page 17 of 29 R-1 Line Item #71

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE

PE 0603807A: Medical Systems - Adv Dev

**DATE:** February 2011

836: Field Medical Systems Advanced

Development

| Management Services (                                    | (\$ in Millio                | ens)                              |                              | FY 2  | 2011          |       | 2012<br>se    | FY 2 | 2012<br>CO    | FY 2012<br>Total |                     |            |                                |
|--|------------------------------|-----------------------------------|------------------------------|-------|---------------|-------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item                                       | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost  | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$M individually. | Various                      | Not Applicable:Not applicable     | 33.721                       | 0.944 |               | 2.540 |               | -    |               | 2.540            | Continuing          | Continuing | Continuing                     |
|  |                              | Subtotal                          | 33.721                       | 0.944 |               | 2.540 |               | -    |               | 2.540            |                     |            |                                |

| <b>Product Development</b>                          | (\$ in Millio                | ns)  |                              | FY 2  | 011           | FY 2<br>Ba |               |      | 2012<br>CO    | FY 2012<br>Total |                     |            |                                |
|---|------------------------------|--|------------------------------|-------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item                                  | Contract<br>Method<br>& Type | Performing<br>Activity & Location                        | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost       | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| Product Development                                 | C/FFP                        | Clinical Research<br>Management:Hinckley,<br>Ohio        | -                            | 1.133 |               | -          |               | -    |               | -                | Continuing          | Continuing | Continuing                     |
| Product Development                                 | TBD                          | Allied Technologies<br>& Consulting<br>LLC:Frederick, MD | 3.365                        | 2.000 |               | -          |               | -    |               | -                | Continuing          | Continuing | Continuing                     |
| Product Development                                 | TBD                          | Aquila Alaska<br>Corporation:Aquila<br>Alaska            | 1.200                        | -     |               | -          |               | -    |               | -                | Continuing          | Continuing | Continuing                     |
| Product Development                                 | Various                      | HemCon Medical<br>Technologies:Tigard,<br>Oregon         | -                            | -     |               | 8.000      |               | -    |               | 8.000            | 0.000               | 8.000      | 0.000                          |
| Product Development                                 | Various                      | Not Applicable:Not<br>Applicable                         | 20.618                       | -     |               | -          |               | -    |               | -                | Continuing          | Continuing | Continuing                     |
| Development of Platelet<br>Derived Hemostatic agent | Various                      | Fast Track Drugs &<br>Biologics:Frederick, MD            | -                            | -     |               | 1.500      |               | -    |               | 1.500            | 0.000               | 1.500      | 0.000                          |
| Product Development                                 | Various                      | ALL Product:Various                                      | -                            | -     |               | 1.000      |               | -    |               | 1.000            | 0.000               | 1.000      | 0.000                          |
|   |                              | Subtotal   | 25.183                       | 3.133 |               | 10.500     |               | -    |               | 10.500           |                     |            |                                |

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE

PE 0603807A: Medical Systems - Adv Dev

PROJECT

836: Field Medical Systems Advanced

**DATE:** February 2011

Development

| Support (\$ in Millions)                                 |                              |                                   |                              | FY 2  | 2011          |       | 2012<br>se    |      | 2012<br>CO    | FY 2012<br>Total |                     |            |                                |
|--|------------------------------|-----------------------------------|------------------------------|-------|---------------|-------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item                                       | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost  | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$M individually. | Various                      | Not Applicable:Not applicable     | 33.721                       | 5.253 |               | 0.969 |               | -    |               | 0.969            | Continuing          | Continuing | Continuing                     |
|  |                              | Subtotal                          | 33.721                       | 5.253 |               | 0.969 |               | -    |               | 0.969            |                     |            |                                |

### Remarks

No product/contract costs greater than \$1M individually.

| Test and Evaluation (\$  | in Millions                  | 3)                                |                              | FY 2  | 2011          | FY 2<br>Ba | 2012<br>se    |      | 2012<br>CO    | FY 2012<br>Total |                     |            |                                |
|--|------------------------------|-----------------------------------|------------------------------|-------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item   | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Total Prior<br>Years<br>Cost | Cost  | Award<br>Date | Cost       | Award<br>Date | Cost | Award<br>Date | Cost             | Cost To<br>Complete | Total Cost | Target<br>Value of<br>Contract |
| No product/contract costs greater than \$1 Million individually. | C/UCA                        | Not applicable:Not applicable     | 13.091                       | 8.654 |               | 5.456      |               | -    |               | 5.456            | Continuing          | Continuing | Continuing                     |
|  | •                            | Subtotal                          | 13.091                       | 8.654 |               | 5.456      |               | -    |               | 5.456            |                     |            |                                |

### Remarks

No product/contract costs greater than \$1M individually.

| To                  | Total Prior |         |         |      |     |         |          |                   | Target   |
|---------------------|-------------|---------|---------|------|-----|---------|----------|-------------------|----------|
|                     | Years       |         | FY 2012 | FY 2 | 012 | FY 2012 | Cost To  |                   | Value of |
|                     | Cost        | FY 2011 | Base    | oc   | o   | Total   | Complete | <b>Total Cost</b> | Contract |
| Project Cost Totals | 105.716     | 17.984  | 19.465  | -    |     | 19.465  |          |                   |          |

### Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2012 Army

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE

PE 0603807A: Medical Systems - Adv Dev

PROJECT

836: Field Medical Systems Advanced

Development

|  |   | FY : | 2010 | ) |   | FY | <b>'</b> 20 | 11  |   | ı | FY 2 | 2012 | 2 |   | FY: | 201 | 3 |   | FY | 20° | 14 |   |   | FΥ | 201 | 5 |   | FΥ | 201 | 6 |
|--|---|------|------|---|---|----|-------------|-----|---|---|------|------|---|---|-----|-----|---|---|----|-----|----|---|---|----|-----|---|---|----|-----|---|
|  | 1 | 2    | 3    | 4 | 1 | 2  | 2 3         | 3 4 | 4 | 1 | 2    | 3    | 4 | 1 | 2   | 3   | 4 | 1 | 2  | : 3 | 3  | 4 | 1 | 2  | 3   | 4 | 1 | 2  | 3   | 4 |
| Antiplaque Gum: Safety Study                         |   |      |      |   |   |    |             |     | , |   |      |      |   |   | ,   |     |   |   | ,  |     |    |   |   | ,  |     |   | , |    |     | , |
| Total intravenous Anesthesia (TIVA): Clinical Trials |   |      |      |   |   |    |             |     |   |   |      |      |   |   |     |     |   |   |    |     |    |   |   |    |     |   |   |    |     |   |
| Fibrinogen Bandages                                  |   |      |      |   |   |    |             |     |   |   |      |      |   |   |     |     |   |   |    |     |    |   |   |    |     |   |   |    |     |   |
| Cryopreserved Platelets Critical Design Review MS-B  |   |      |      |   |   |    |             |     |   |   |      |      |   |   |     |     |   |   |    |     |    |   |   |    |     |   |   |    |     |   |
| Freeze-Dried Plasma MS-B                             |   |      |      |   |   |    |             |     |   |   |      |      |   |   |     |     |   |   |    |     |    |   |   |    |     |   |   |    |     |   |
| Non-invasive Multi-Analyte Monitor                   |   |      |      |   |   |    |             |     |   |   |      |      |   |   |     |     |   |   |    |     |    |   |   |    |     |   |   |    |     |   |
| Hydration Meter                                      |   |      |      |   |   |    |             |     |   |   |      |      |   |   |     |     |   |   |    |     |    |   |   |    |     |   |   |    |     |   |
| Eye Tracking System for Assessment of Concussions    |   |      |      |   |   |    |             |     |   |   |      |      |   |   |     |     |   |   |    |     |    |   |   |    |     |   |   |    |     |   |

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Exhibit R-4A, RDT&E Schedule Details: PB 2012 Army

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY R-1 ITEM NOMENCLATURE PROJECT

2040: Research, Development, Test & Evaluation, Army PE 0603807A: Medical Systems - Adv Dev 836: Field Medical Systems Advanced

BA 4: Advanced Component Development & Prototypes (ACD&P)

Development

## Schedule Details

|  | St      | art  | E       | nd   |
|--|---------|------|---------|------|
| Events   | Quarter | Year | Quarter | Year |
| Antiplaque Gum: Safety Study                         | 3       | 2010 | 4       | 2010 |
| Total intravenous Anesthesia (TIVA): Clinical Trials | 3       | 2011 | 3       | 2011 |
| Fibrinogen Bandages                                  | 3       | 2012 | 3       | 2012 |
| Cryopreserved Platelets Critical Design Review MS-B  | 3       | 2011 | 4       | 2011 |
| Freeze-Dried Plasma MS-B                             | 1       | 2012 | 1       | 2012 |
| Non-invasive Multi-Analyte Monitor                   | 1       | 2012 | 1       | 2012 |
| Hydration Meter                                      | 3       | 2012 | 3       | 2012 |
| Eye Tracking System for Assessment of Concussions    | 4       | 2011 | 4       | 2011 |

R-1 ITEM NOMENCI ATURE

**DATE:** February 2011

PROJECT

| ALL KOLKIATION/DODGET ACTIV                      | V              |             |                 | 1 Z= 1   1   E   M   1 | CIVILITOEA       | IOIL        |         | INCOLO     |           |                     |            |
|--|----------------|-------------|-----------------|------------------------|------------------|-------------|---------|------------|-----------|---------------------|------------|
| 2040: Research, Development, Tes                 | t & Evaluation | n, Army     |                 | PE 060380              | 7A: Medical      | Systems - A | dv Dev  | CS4: MEDI  | CAL SYSTE | MS ADV DE           | īV         |
| BA 4: Advanced Component Devel                   | opment & Pro   | totypes (AC | D&P)            |                        |                  |             |         | INITIATIVE | S (CA)    |                     |            |
| COST (\$ in Millions)                            | FY 2010        | FY 2011     | FY 2012<br>Base | FY 2012<br>OCO         | FY 2012<br>Total | FY 2013     | FY 2014 | FY 2015    | FY 2016   | Cost To<br>Complete | Total Cost |
| CS4: MEDICAL SYSTEMS ADV<br>DEV INITIATIVES (CA) | 4.775          | -           | -               | -                      | -                | -           | -       | -          | -         | Continuing          | Continuing |
| Quantity of RDT&E Articles                       |                |             |                 |                        |                  |             |         |            |           |                     |            |

# A. Mission Description and Budget Item Justification

Exhibit R-2A, RDT&E Project Justification: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

Congressional Interest Item funding for medical systems advanced development initiatives.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)                     | FY 2010       | FY 2011 | FY 2012 |
|--|---------------|---------|---------|
| Title: Wireless Medical Monitoring System  | 2.400         | -       | -       |
| Articles   | <i>:</i> 0    |         |         |
| Description: This is a Congressional Interest Item.  |               |         |         |
| FY 2010 Accomplishments:   |               |         |         |
| Conducted advanced development research in Wireless Medical Monitoring System                        |               |         |         |
| Title: Quality Systems Program for FDA Regulation Activities   | 1.175         | -       | -       |
| Articles   | <i>:</i> 0    |         |         |
| Description: This is a Congressional Interest Item.  |               |         |         |
| FY 2010 Accomplishments:   |               |         |         |
| Conducted advanced development research of a Quality Systems Program for FDA Regulation Activities   |               |         |         |
| Title: Model for Green Laboratories and Clean Rooms  | 1.200         | -       | -       |
| Articles   | <i>:</i> 0    |         |         |
| Description: This is a Congressional Interest Item.  |               |         |         |
| FY 2010 Accomplishments:   |               |         |         |
| Conducted advanced development research and study for a Model for Green Laboratories and Clean Rooms |               |         |         |
| Accomplishments/Planned Programs Subtotal  | <b>4</b> .775 | -       | -       |

|  | 0.1102/10011 122   |   |
|--|--|---|
| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army  |  | DATE: February 2011                                   |
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P) | R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev | PROJECT CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA) |
| C. Other Program Funding Summary (\$ in Millions) N/A  |  |   |
| D. Acquisition Strategy N/A  |  |   |
| E. Performance Metrics   |  |   |
| Performance metrics used in the preparation of this justification mat  | terial may be found in the FY 2010 Army Performa             | nce Budget Justification Book, dated May 2010.        |
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| Exhibit R-2A, RDT&E Project Just  | tification: PE | 3 2012 Army | 1               |                |                         |         |         |                                 | <b>DATE:</b> Feb | ruary 2011          |             |
|---|----------------|-------------|-----------------|----------------|-------------------------|---------|---------|---------------------------------|------------------|---------------------|-------------|
| APPROPRIATION/BUDGET ACTIV<br>2040: Research, Development, Tes<br>BA 4: Advanced Component Develo | t & Evaluatio  |             | D&P)            |                | IOMENCLA<br>7A: Medical |         | dv Dev  | PROJECT<br>VS7: MEDE<br>PACKAGE |                  | ON EQUIPM<br>V DEV  | <i>IENT</i> |
| COST (\$ in Millions)   | FY 2010        | FY 2011     | FY 2012<br>Base | FY 2012<br>OCO | FY 2012<br>Total        | FY 2013 | FY 2014 | FY 2015                         | FY 2016          | Cost To<br>Complete | Total Cost  |
| VS7: MEDEVAC MISSION<br>EQUIPMENT PACKAGE (MEP) -<br>ADV DEV                                      | -              | -           | 1.615           | -              | 1.615                   | 1.177   | 0.455   | -                               | -                | 0.000               | 3.247       |
| Quantity of RDT&E Articles  |                |             |                 |                |                         |         |         |                                 |                  |                     |             |

## A. Mission Description and Budget Item Justification

Original models of Army Black Hawk MEDEVAC helicopters continue to play a major role in maintaining high US troop survival rates in Iraq and Afghanistan by evacuating wounded troops in less than one-hour. In 2009 a VCSA-approved force design update increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operational needs. In 2010, the AMEDD accepted life-cycle management of the MEDEVAC MEP from PEO Aviation. In order to achieve required operational capability and enhance commonality across the MEDEVAC fleet, the MEDEVAC MEP program upgrades, retrofits, trains, and sustains the 256 MEDEVAC legacy helicopters to achieve the medical capability provided by the HH-60M, which is factory built for the MEDEVAC mission.

| B. Accomplishments/Planned Programs (\$ in Millions)   | FY 2010 | FY 2011 | FY 2012 |
|--|---------|---------|---------|
| Title: MEDEVAC Mission Sensor Foward Looking Infrared (FLIR)   | -       | -       | 0.575   |
| Description: Funding is provided for the following effort  |         |         |         |
| FY 2012 Plans:  MEDEVAC Mission Sensor (MMS) FLIR for UH-60 aircraft. One of the requirements for the UH-60A/L MEDEVAC is a sensor system that will assist the pilots in locating patient pick-up points and assist them in maintaining situational awareness in night and adverse weather conditions. The MMS is currently being qualified for use on the HH-60M aircraft. This system will be installed on UH-60 aircraft using the proven Sponson-Mount FLIR system, which is currently being used in OEF for the MEDEVAC mission. The funds will develop and test a Medical Mission Sensor FLIR prototype on the UH-60A/L. |         |         |         |
| Title: Environmental Control System for MEDEVAC aircraft   | -       | -       | 0.509   |
| Description: Funding is provided for the following effort  |         |         |         |
| FY 2012 Plans: The HH-60A/L/M has an environmental control system to assist in regulating the cabin temperature. This system will help prevent injury and loss of life to patients due to heat stress or hypothermia during transport. The system will also provide improved crew comfort in extreme environmental conditions, particularly high temperatures. The system will utilize the component-qualified 2-Pallet ECS developed for the HH-60M and develop and test a prototype installation for the UH-60A/L.   |         |         |         |
| Title: Telemedicine for MEDEVAC aircraft   | -       | -       | 0.531   |

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| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army   |  |                | <b>DATE:</b> February 2011 |
|---|--|----------------|----------------------------|
| APPROPRIATION/BUDGET ACTIVITY                             | R-1 ITEM NOMENCLATURE                  | <b>PROJECT</b> |                            |
| 2040: Research, Development, Test & Evaluation, Army      | PE 0603807A: Medical Systems - Adv Dev | VS7: MEDE      | EVAC MISSION EQUIPMENT     |
| BA 4: Advanced Component Development & Prototypes (ACD&P) |  | PACKAGE (      | (MEP) - ADV DEV            |
|   |  |                |                            |

| B. Accomplishments/Planned Programs (\$ in Millions)   | FY 2010 | FY 2011 | FY 2012 |
|--|---------|---------|---------|
| Description: Funding is provided for the following effort  |         |         |         |
| FY 2012 Plans: Telemedicine is an on going requirement for US Army MEDEVAC, to allow the patient care-giver at point of injury or during transport to access the knowledge and expertise of a more qualified care-giver at a remote location, and to provide patient data to the receiving facility prior to patient arrival, allowing the facility more time to prepare for intensive care patients. The program will develop, install, and test a telemedicine system for the UH-60A/L family of aircraft. |         |         |         |
| Accomplishments/Planned Programs Subtotals   | -       | -       | 1.615   |

# C. Other Program Funding Summary (\$ in Millions)

N/A

## D. Acquisition Strategy

Develop in-house or industrial prototypes in government-managed programs to meet military MEDEVAC and regulatory requirements for production and fielding.

## E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

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UNCLASSIFIED Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army DATE: February 2011 APPROPRIATION/BUDGET ACTIVITY **R-1 ITEM NOMENCLATURE PROJECT** 2040: Research, Development, Test & Evaluation, Army PE 0603807A: Medical Systems - Adv Dev **VS7: MEDEVAC MISSION EQUIPMENT** BA 4: Advanced Component Development & Prototypes (ACD&P) PACKAGE (MEP) - ADV DEV FY 2012 FY 2012 FY 2012 Management Services (\$ in Millions) FY 2011 oco Base Total **Total Prior** Target Contract Method Performing Years Award Award Award Cost To Value of **Cost Category Item Activity & Location** Cost Cost Date Cost Date Cost Date Complete **Total Cost** Contract & Type Cost No product/contract costs APM MEDEVAC greater than \$1 Million **TBD** PFO 0.176 0.176 0.000 0.176 0.000 individually Aviation: Huntsville, AL 0.176 0.176 0.000 0.176 0.000 Subtotal FY 2012 FY 2012 FY 2012 **Product Development (\$ in Millions)** FY 2011 oco Total Base Contract **Total Prior Target** Method Performing Years Award Award Award Cost To Value of Cost Cost **Cost Category Item** & Type **Activity & Location** Cost Cost Date Date Date Cost Complete **Total Cost** Contract No product/contract costs APM MEDEVAC PEO greater than \$1Million Various 1.140 1.140 0.000 1.140 0.000 Aviation: Huntsville, AL individually Subtotal 1.140 \_ 1.140 0.000 1.140 0.000 FY 2012 FY 2012 FY 2012 Support (\$ in Millions) FY 2011 oco Base Total Contract **Total Prior Target** Method Performing Cost To Value of Years Award Award Award **Cost Category Item** & Type **Activity & Location** Cost Cost Date Cost Date Cost Date Cost Complete **Total Cost** Contract APM MEDEVAC No product/contract costs TBD PFO 0.100 0 100 0.000 0.100 0.000 greater than \$1M individually Aviation:Huntsville Al Subtotal 0.100 \_ 0.100 0.000 0.100 0.000 FY 2012 FY 2012 FY 2012 Test and Evaluation (\$ in Millions) **FY 2011** Base oco Total Contract **Total Prior** Target Method Value of Performing Years Award Award Award Cost To **Cost Category Item** & Type **Activity & Location** Cost Cost Date Cost Date Cost Date Complete **Total Cost** Contract Cost No product/contract costs APM MEDEVAC **TBD PEO** 0.199 0.199 greater than \$1Million 0.000 0.199 0.000 individually Aviation: Huntsville, AL

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Subtotal

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0.199

0.000

0.199

0.000

0.199

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army
BA 4: Advanced Component Development & Prototypes (ACD&P)

PROJECT
VS7: MEDEVAC MISSION EQUIPMENT
PACKAGE (MEP) - ADV DEV

| Total Pr            | or |      |         |     |      |         |          |                   | Target   |
|---------------------|----|------|---------|-----|------|---------|----------|-------------------|----------|
| Years               |    |      | FY 2012 | FY: | 2012 | FY 2012 | Cost To  |                   | Value of |
| Cost                | FY | 2011 | Base    | 0   | co   | Total   | Complete | <b>Total Cost</b> | Contract |
| Project Cost Totals |    |      | 1.615   | -   |      | 1.615   | 0.000    | 1.615             | 0.000    |

Remarks

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

Exhibit R-4, RDT&E Schedule Profile: PB 2012 Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE PROJECT

PE 0603807A: Medical Systems - Adv Dev VS7: MEDEVAC MISSION EQUIPMENT

PACKAGE (MEP) - ADV DEV

|                                   |   | FY 2010 |   | FY 2011 |   |   |   | FY 2012 |   |   | FY 2013 |   |   | 3 | FY 2014 |   |   |   | FY 2015 |   |   |   | FY 2016 |   |   |   |   |   |
|-----------------------------------|---|---------|---|---------|---|---|---|---------|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---|---|
|                                   | 1 | 2       | 3 | 4       | 1 | 2 | 3 | 4       | 1 | 2 | 3       | 4 | 1 | 2 | 3       | 4 | 1 | 2 | 3       | 4 | 1 | 2 | 3       | 4 | 1 | 2 | 3 | 4 |
| MEDEVAC Mission Sensor (MMS) FLIR |   |         |   | •       |   |   |   |         |   |   | •       |   |   |   |         | • |   |   |         |   |   |   |         | • |   |   |   |   |
| Environmental Control System      |   |         |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |   |   |
| Telemedicine                      |   |         |   |         |   |   |   |         |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |   |   |

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Exhibit R-4A, RDT&E Schedule Details: PB 2012 Army **DATE:** February 2011 PROJECT

APPROPRIATION/BUDGET ACTIVITY R-1 ITEM NOMENCLATURE

2040: Research, Development, Test & Evaluation, Army VS7: MEDEVAC MISSION EQUIPMENT PE 0603807A: Medical Systems - Adv Dev

BA 4: Advanced Component Development & Prototypes (ACD&P) PACKAGE (MEP) - ADV DEV

# Schedule Details

|                                   | St      | art  | E       | nd   |
|-----------------------------------|---------|------|---------|------|
| Events                            | Quarter | Year | Quarter | Year |
| MEDEVAC Mission Sensor (MMS) FLIR | 4       | 2011 | 4       | 2011 |
| Environmental Control System      | 4       | 2011 | 4       | 2011 |
| Telemedicine                      | 4       | 2011 | 1       | 2012 |

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