In recent testimony before the House Armed Services Committee’s military personnel subcommittee, the Surgeon General of the U.S. Army, LTG Patricia D. Horoho, noted:

“More than a decade of war has led to tremendous advances in knowledge and care of combat-related wounds, both physical and mental.” She credited U.S. Army Medical Research and Materiel Command (MRMC) for “leading Army Medicine in scientific research [with] ongoing [efforts] focused on establishing more effective methods for diagnosis, treatment and long-term management of the health-related consequences of war, including TBI [traumatic brain injury], behavioral health care, PTSD [post-traumatic stress disorder], burn and other disfiguring injuries, chronic pain, and limb loss.”
One of several MRMC subordinate organizations that is contributing to this process of protecting and preserving the lives of warfighters is the U.S. Army’s Medical Materiel Development Activity (USAMMDA), headquartered at Fort Detrick, Md. Among its primary roles, USAMMDA guides promising products and technologies developed at MRMC laboratories through advanced development and regulatory processes. Upon certification by the Food and Drug Administration (FDA), USAMMDA works with the U.S. Army Medical Materiel Agency to develop plans for fielding the new medical materiel.

“USAMMDA is made up of a team of dedicated professionals—military, government civilians and contractors—whose No. 1 priority is to develop and deliver medical solutions to protect, treat and sustain the health of our servicemembers,” said COL Stephen J. Dalal, USAMMDA commander. “We are focused on the development of pharmaceutical drugs, vaccines and medical devices that are safe, effective and FDA approved. Areas of focus include TBI and PTSD; antiparasitic therapies against malaria, dengue and leishmaniasis; combat casualty care products such as blood products, hemorrhage control and resuscitation products; and anti-infectives such as the hanta virus vaccine and meningococcal vaccine. Our organization has recently developed a new project management office charged with the advanced development of treatments for neurotrauma and psychological health disorders. This team will be conducting clinical trials to establish the efficacy of treatments for signature injuries from our recent conflicts, such as TBI and PTSD. The team has initiated collaboration with the Department of Veterans Affairs in order to conduct their initial trials. Through this office, our organization will be a key partner in the MRMC’s efforts to improve behavioral health outcomes for warfighters and their family members. As the needs of the warfighter evolve, rest assured that USAMMDA is poised and ready to meet the challenges of developing medical solutions to meet those needs.”

Other subordinate USAMMDA project management offices include medical support systems, pharmaceutical systems, the Armed Forces Institute of Regenerative Medicine, and force health protection. Some of the recent representative programs undertaken by USAMMDA’s medical support systems project management office address a new ground ambulance kit, litter loading system and litter standardization.

The ground ambulance kit, formerly known as the MRAP casualty evacuation kit, is described as a lightweight, low-cost kit that helps servicemembers quickly and efficiently evacuate casualties from the battlefield. More than 1,700 were fielded in support of Operation Enduring Freedom through the end of fiscal year (FY) 2012. FY 2013 quantities are pending.

Program representatives also point to the advanced development of a litter loading system for the retrofit of the MRAP MaxxPro Plus vehicle into an ambulance configuration. They note that the current MaxxPro Dash ambulance
kit is too small, with the litters holding only wounded soldiers up to 5 feet 11 inches tall and limited space for equipment and medics. In response to this challenge, prototypes using the MaxxPro Dash litter loading system are being developed for two MaxxPro Plus vehicles—one by Navistar and one by the government. In addition to greater space, the design will shorten time requirements for casualty loading in hostile settings. Testing and evaluation of the prototypes should be complete by the fourth quarter of FY 2014.

Other efforts include advanced development of a standardized NATO 7309 litter. The standardized design addresses the current situation of several litter types and sizes, with not all evacuation vehicles able to accommodate litters. The NATO 7309 litter will work on MRAP vehicles as well as rotary- and fixed-wing aircraft to benefit all services. User testing is under way.

Other representative project office efforts range from development of a new medic bag to an insecticide-impregnated bed net to protect against biting flies.

The pharmaceutical systems project management office manages DoD resources applied to the advanced development of pharmaceutical products—drugs, vaccines, biologicals, diagnostics, hemorrhage control and resuscitation products—for use by the U.S. military to prevent, diagnose, or treat infectious diseases and combat casualties.

Some of the representative efforts undertaken by this office include continuing work to combat the infectious disease threat of cutaneous leishmaniasis (CL), which is also known by a range of common terms like “Baghdad boil,” administering the adenovirus vaccine and enhancing red blood cell extended life capabilities.

According to COL Dalal, CL is a parasitic disease transmitted by sand flies that is endemic in nearly 100 countries, including those in the Middle East and North Africa, Central and South America, and some regions of Europe and the United States. CL is diagnosed in millions of people every year worldwide and has been diagnosed in more than 3,000 U.S. servicemembers since 2003. The disease causes ulcers in the skin that can lead to disfiguring scars, social stigma and lifelong psychological impacts. There is currently no FDA-approved diagnostic test or treatment for CL in the United States. The treatments that are available often are toxic, require administration in a hospital setting, and are quite expensive. The cost for a servicemember’s hospitalization, treatment and 60–90 days of lost duty time is about $35,000. To diagnose CL in a deployed servicemember, samples have to be shipped to a laboratory in the United States, and it can take weeks to get a definitive result.

Two of USAMMMA’s efforts to combat CL—a rapid diagnostic detection device and a topical paromomycin treatment drug—are currently in final clinical trials throughout the world to support FDA approval. The CL Detect Rapid Test is being developed in conjunction with InBios International, Inc., and will allow medical providers to determine within minutes whether a servicemember in a deployed setting has CL. The test provides a handheld, disposable, point-of-care way to rapidly detect the presence of leish-
mania parasites found in samples of lesions from patients displaying symptoms of CL. Topical paromomycin is an antileishmanial cream made from two aminoglycoside antibiotics, paromomycin (15%) and gentamicin (0.5%), formulated in an aquaphilic base.

USAMMDA also manages the acquisition and distribution of the adenovirus vaccine, which has been administered to the enlisted recruits of all the military services during basic training since October 2011. Administered orally in the form of tablets, the vaccine prevents febrile respiratory illness (FRI) caused by adenovirus types 4 and 7, which caused about 15,000 cases of FRI each year between 1999 and 2010.

Project office representatives also refer to a USAMMDA partnership with Hemerus Medical LLC (recently acquired by Haemonetics Corp.) that received FDA approval of the new drug application for its SOLX System in April. The SOLX System is a whole blood collection system that produces leukoreduced red blood cells and plasma. FDA approval allows for six weeks’ red blood cell storage. Other trials show it can store red blood cells for at least two weeks longer. This could potentially save DoD millions of dollars per year in transportation costs and decreased product loss due to outdated during military deployments.

USAMMDA’s Armed Forces Institute of Regenerative Medicine (AFIRM) oversees a broad spectrum of government-academia-industry partnerships to develop novel strategies for healing servicemembers with severe combat wounds. Two representative sectors of the portfolio include skin products for treating severe burns as well as hand and face transplants.

One skin product now in pivotal trial in the United States is the ReCell device. Approved in Australia and the European Union, it uses a skin biopsy the size of a postage stamp to treat areas of burns roughly 300 times larger. Another effort that USAMMDA credits with positive preliminary results is Stratagraft tissue, a skin substitute that uses allogeneic tissue, which does not come from the patient, for treating burns.

AFIRM also oversees all hand and face transplant programs currently funded by DoD. To date, four face transplants and 10 hand transplants have been performed using funds managed by this office.

AFIRM representatives note that recipients have done well, recovering motion and sensation as expected. Rejection episodes have been limited and quickly controlled. Recipients consider the transplants to have improved the quality of their lives.

USAMMDA’s force health protection (FHP) division portfolio consists of medical countermeasures to prevent or mitigate the effects of botulism, malaria, smallpox, leishmaniasis, multidrug-resistant bacteria and several hemorrhagic fevers. Recent representative FHP activities have involved arbekacin, ribavirin, ST-246 and rBV. In June, FHP received protocol approval to provide investigational arbekacin, an aminoglycoside from Japan, to treat infections caused by multidrug-resistant bacteria when other antibiotics cannot be used due to unavailability, intolerance, contraindications (when using them could harm the patient) or a lack of response to treatment. Ribavirin is an antiviral used under an investigational new drug protocol to treat viral hemorrhagic fevers such as hemorrhagic fever with renal syndrome or Crimean-Congo hemorrhagic fever. ST-246 tecovirimat is an oral antiviral product currently under development by SIGA Technologies, Inc., for the treatment of smallpox. Recombinant botulinum A/B vaccine (rBV A/B) is intended to protect warfighters against exposure to botulinum toxin types A and B. The rBV A/B vaccine is being developed by Dyn Port Vaccine, a CSC Company.

While praising the broad spectrum of accomplishments and achievements across USAMMDA, COL Dalal acknowledged a special sense of organizational pride in programs like the development of new therapies against parasitic threats—like CL and malaria—and the development of a new whole blood pathogen reduction device (WBPRD).

The World Health Organization estimated that 219 million cases of malaria in 2010 caused roughly 600,000 deaths, COL Dalal said.

“Within the United States, there are an average of 1,500 cases per year, of which approximately 150 will be severe and life threatening,” he said. “In 2007, the FDA and CDC
[Centers for Disease Control and Prevention] approved a treatment IND [investigational new drug] with a primary purpose of making USAMMDA-provided intravenous artesunate available for treatment of severe malaria in U.S. hospitals for cases when the only other intravenous treatment option was contraindicated or unavailable. As of January 2012, 154 people—including three servicemembers—had received this lifesaving product under the program. In addition, USAMMDA has an agreement with the Canadian Malaria Network to supply clinical intravenous artesunate for the treatment of severe or complicated malaria in Canada. Through February 2012, 143 doses were administered to 42 patients through that protocol.

“With our industry partner, Terumo BCT, we recently began a clinical trial to validate the safety and efficacy of the WBPRD,” he added. “After FDA approval, the WBPRD will be used in the combat theater to treat whole blood collected for emergency transfusions to wounded military personnel.”

Noting that “advances in protective equipment have resulted in higher survival rates among wounded servicemembers,” but that they had “also resulted in soldiers surviving devastating injuries that are very difficult to treat,” COL Dalal said the efforts of USAMMDA’s AFIRM program office also provide a special sense of pride across the organization.

“AFIRM started out as a five-year program with the goal of having one clinical trial for one treatment at the end of the five years,” he said. “Instead, it has produced more than 20 clinical trials and more than a dozen products in advanced development. This was possible because DoD invested in high-risk regenerative technologies, which allowed it to leverage private sector investments that would not have happened without assuming that risk early on. This is clearly a beneficial unanticipated outcome and one than can be repeated with future efforts.”

When asked how he sees the organization evolving over the next five years, COL Dalal said, “Many of our current focus areas will remain a priority over the next five years, such as antiparasitic, combat casualty care, restorative and regenerative medicine, TBI and PTSD. The field of regenerative medicine has grown dramatically in the last few years and has seen amazing advances. Having positioned itself as a leader in this space, USAMMDA will have the opportunity to shape research and clinical priorities for regenerative medicine in a way that will benefit warfighters for years to come.”

Left, soldiers evacuate a casualty using the ground ambulance kit. It is a light-weight, low-cost kit that includes spine boards, a spine board restraint system and litter straps. Below, helicopter medical evacuation is central to battlefield care. MRMC is responsible for the addition of several components that will increase the capability of the helicopter, such as one that transforms high pressure air generated by the engine into medical-grade oxygen.