Over the past 15 years, we have seen the increased threat of chemical, biological, radiological, and nuclear attacks on US and allied troops. Terrorists, state and non-state actors are now able to weaponise and deliver chemical and biological weapons, increasingly putting US troops in harm’s way. Chemical weapons have already been used in Iraq, Syria and the UK. There is also an increased threat from emerging and re-emerging infectious diseases as we have seen with the recent outbreaks of Ebola and plague. All these threats affect civilian and military populations alike.

The Department of Defense (DoD) is facing the unparalleled challenge of protecting and treating troops against all these agents and ensuring they can effectively complete their missions. As part of this effort, the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) and the Joint Project Management Office for Medical Countermeasure Systems (MCS) are working closely with the Food and Drug Administration (FDA) to develop and field medical countermeasures that support US service members around the world. MCS is a Joint Project Management Office located at Fort Detrick in Frederick, Maryland, and facilitates the advanced development and fielding of medical countermeasures against these threats.

As defined by the FDA, medical countermeasures are FDA regulated products that may be used in the event of a potential public health emergency stemming from a terrorist attack with CBRN material or naturally occurring emerging diseases. Medical countermeasures include vaccines, diagnostics, and therapeutics. They are a critical component of a multilayered defense strategy to protect troops, accurately diagnose exposure or illness, and provide post exposure treatments that save lives of US and allied service members. In order to streamline the medical countermeasure development process, JPEO-CBRND and MCS are employing a new agile medical paradigm. This paradigm is a strategic framework aimed at accelerating the delivery of medical countermeasures by addressing policy and technology issues. Part of this framework is readjusting our policies to better align with available regulatory mechanisms to expedite development and availability of medical countermeasures.

Congress has codified this engagement between the FDA and DoD in Public Law 115-92. Specific provisions in this law allow the DoD to
License to cure

request, and the FDA to provide, enhanced assistance in expediting medical countermeasure development. This law also expanded the emergency use authorisation provision (section 564 of the Federal Food, Drug, and Cosmetics Act) to medical products for threat agents associated with an imminently life threatening and specific risk to military forces. The enhanced engagements provision in the new law will strengthen existing relationships and foster new ones between the chem/bio defence programme and the FDA. The objective is to get critical, safe and effective medical countermeasures into the warfighters’ hands faster.

“We look forward to expanding our relationships with the FDA in expediting development and approval for critical medical countermeasures in the CBRN space,” said Carmen Maher, senior director of medical regulatory affairs for JPEO-CBRND, the Defense Threat Reduction Agency (DTRA) Joint Science and Technology Office and MCS. “This legal framework strengthens our existing collaborations with the FDA and enhances it to meet the needs of our service members protecting our nation.”

In a January 2018 release, FDA commissioner Dr Scott Gottlieb is quoted as saying: “The FDA is fully committed to working closely with the DoD to expedite the availability of medical products essential to the health and safety of US service members”. The FDA hopes to address the DoD’s immediate product priorities by working closely with the DoD to make these medical products available in a more expeditious manner.

As part of this effort, leaders from the FDA, DoD’s Office of Health Affairs, the US army Medical Research and Materiel Command, and JPEO-CBRND now meet on a semi-annual basis to work on prioritising and expediting the medical products needed on the battlefield. The most recent meeting occurred on 5 April 2018. For the CBRN community in particular, current priorities are for accelerated development of vaccines against plague and botulinum toxin, as well as products to mitigate the effects of seizures caused by nerve agent exposure. Vaccines to protect against plague and botulinum toxin, as well as products to mitigate the effects of seizures caused by nerve agent exposure, are currently in advanced development at MCS. The product for mitigating seizures is also a collaborative effort involving other offices of the Department of Health and Human Services, mainly the biomedical advanced research and development authority [see Interview pp.8 Ed.].

There is also a notable military need for a rescue therapy against synthetic opioids. For instance, the national guard supports law enforcement agencies by assisting in anti drug activities such as the seizure of large quantities of illicit drugs, including opioids. There is the potential for accidental or intentional exposure to opioids during these activities. Spearheaded by the Chemical Defense Pharmaceuticals Joint Product Management Office within MCS, in collaboration with the DTRA, the rapid opioid countermeasure system programme is actively working to acquire a medical product that can be used as a rescue therapy against accidental or intentional opioid exposure. There is currently no FDA approved product that could be utilised efficiently based on the operational concerns and scenarios that US troops are placed in. Public Law 115-92 has enabled the DoD to put an opioid countermeasure near the top of the priority list in order to expedite FDA approval and rapidly field an opioid rescue therapy to US service members in harm’s way. It is envisioned that law enforcement and civilian first responders could also utilise the rescue therapy under development in MCS, thus providing a whole of government capability.

“With the increased threat of CBRN attacks, it is paramount that our troops have the tools and resources at their disposal to complete their missions,” said Douglas Bryce, joint programme executive officer for CBRN defence. “This partnership with the FDA will enable us to get critical medical products sooner into the warfighters’ hands.”

In all, these enhanced collaborations between the FDA and DoD are just the starting point in equipping US service members with the best possible military medical support against CBRN threats. As this relationship continues to grow and expand, it is crucial for the two agencies to continue to work together in support of the troops working to protect our nation.
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