



# 59th Medical Wing



## Establishing a Military Medical Product Commercialization Partnership Intermediary

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**PEOPLE**

**MISSION**

**INNOVATION**



# Disclaimer



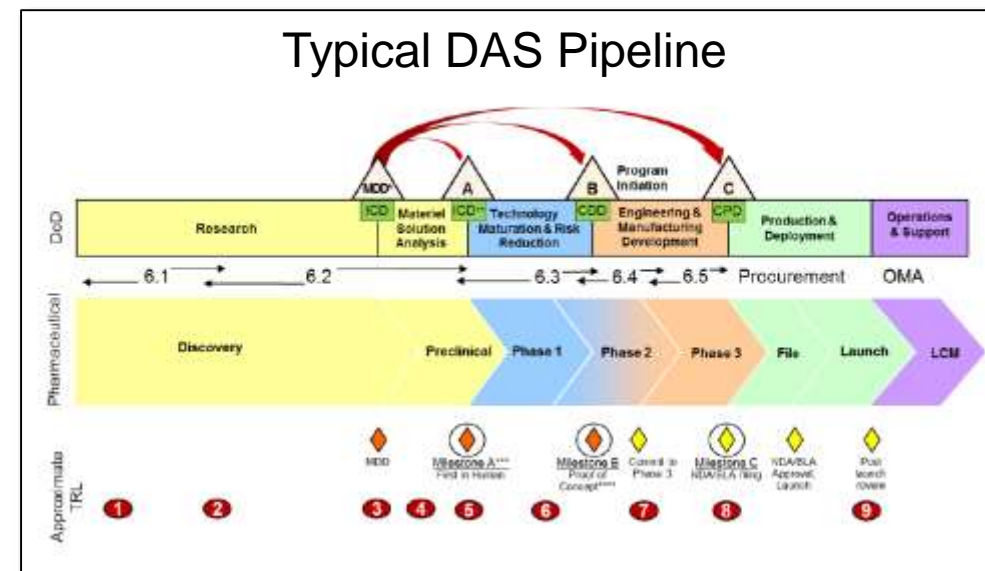
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# Define Problem



- Significant delays and costs to field new medical products and capabilities; considerable funding wasted on unrealized projects
- Some stem from using Defense Acquisition System (DAS, DoDI 5000.02) to manage medical product development
- DAS is designed to develop low-volume, highly specialized, cutting-edge, and uniquely military products (Kendell, 2017)
- Most military medical products are high volume, highly generalized/ universal, and not military unique, as 95% have commercial applications (Ludwig & Rosarius, 2013 )
- DAS unnecessarily duplicates industry and FDA processes, adds costs and delays
- JCIDS often cannot keep pace with new commercial development, especially medical
- Very difficult to coordinate procurement & fielding of medical products for all services
- Difficult to maintain acquisition trained/experienced workforce in DoD medical R&D







# Define Potential Solution



- Need a new method to develop medical products urgently needed by the DoD using commercial approaches that:
  - Leverages industry and academia involvement to rapidly commercially develop most effective, affordable, medical products for the DoD
  - Influences industry to invest their modernization funding to reduce DoD costs & risks
  - Enables commixing of funding and resources from venture capitalists, angel investors, foundations, and other government organizations
- Focus on affordability, as most military medical products must be commercially viable
- Would emulate rapid development and fielding processes already used by SOF & MCSC, as well as Other Transaction Authorities (OTA) & flexible contracting strategies
- Need to operate outside the complexities of the Federal Acquisition Regulations (FAR)
- Applicable to less complex medical products needed for battlefield survivability (Class I or II products requiring FDA clearance)
- Not applicable to programs to develop vaccines, drugs, and complex medical systems typically requiring tens of millions, large clinical trials, and 5 – 7 years to develop (Class III products requiring FDA approval)



# What about Partnership Intermediaries?



- Contract, agreement, or memorandum of understanding with non-profit partnership intermediary to engage academia and industry on behalf of the government to accelerate tech transfer and licensing
- Supported by 15 U.S. Code § 3715, established through a Partnership Intermediary Agreement (PIA) issued by a contract officer, enables Directors of Federal laboratories to engage partnership intermediary to perform services on behalf of the Federal lab
- Partnership Intermediaries can function as objective third-party brokers between government and industry to increase opportunity for commercialization of new products
- Operate outside the FAR to accomplish tasks the government would struggle to work
- Enables Government to pay for services to support technology transfer and transition
- Partnership intermediaries can engage in proactive marketing of lab technologies to industry to enable tech transition/tech insertion
- Used by government labs to facilitate technology transfer to private sector and increase likelihood of success with fielding capabilities/products



# How Military Medical Product Commercialization Partnership Intermediary would work



- MMPC Partnership Intermediary formed with \$2M first year of funding, \$1M per year for operating costs, period of performance 3 – 5 years for pilot study
- DHA assign a contracting officer (KO) and organization to support establishing a PIA
- 59 MDW with USAISR & NAMRU-SA oversee launch of MMPC Partnership Intermediary *as a pilot study of the concept*
  - Provide feedback, guidance, help establish networking
- DHA establishes a DoD board: joint service, DHA, and COCOM medical readiness user representatives to 1) prioritize medical products to be developed, 2) select COAs for medical product development, provide end user representatives for each product development (to provide feedback), and 4) keep medical logistics informed of medical products that are being developed and when they will be available on the market
- DHA assigns a Program Manager (PM) to oversee MMPC Partnership Intermediary operations
- MMPC Partnership Intermediary establish organization, hire personnel, establish processes, hold first meeting with DoD Board members within first 6 months



# How Military Medical Product Commercialization Partnership Intermediary Would Work



- DoD Board provides three “approved requirements” for desired medical products in accordance with Section 804 of Public Law 114-92, paragraph (b)(2) for pilot study
  - May be a Capability Development Document (CDD) or other user-defined set of performance metrics developed from streamlined processes
  - DHA assigned PM authorized to make trade-off decisions IAW paragraph (c)(4)(E)
- Initial scope of commercial medical products needs to be limited to developing commercially-available medical products that preserve life and limb in austere locations, including the following medical capabilities:
  - Combat Casualty Care/care under fire/duress
  - Pre-hospital medical treatment/Point Of Injury (POI) care
  - Tactical Combat Casualty Care (TCCC)
  - Austere clinical operations (ROC I, II, and II enhanced)
- MMPC Partnership Intermediary assesses commercial market, queries federal labs, market, conducts business case analyses, and develops acquisitions strategies
  - Can transition medical products from any federal lab (USU, 59 MDW, USAISR, NAMRU-SA, etc...) or best available commercial/non-developmental item





# How Military Medical Product Commercialization Partnership Intermediary Would Work



- MMPC Partnership Intermediary briefs acquisition strategies with cost, schedule, performance, and risk assessment to DHA-led board for selection; may lead to decision, request for revision, or elimination of product item from request list
- For each COA to be developed, DHA provides RDT&E funding to MMPC Partnership Intermediary to develop medical products for **commercial market** and **military** use
- DHA-led oversight board assigns a medical readiness user representative to each product development initiative
- MMPC Partnership Intermediary begins develop of medical product for commercial market and for military use using agile project management, involving the assigned medical readiness user representative in development team
- MMPC Partnership Intermediary fosters interest by commercial developers to bring forward commercially viable and available solutions
- Emulates processes for rapid development of critically needed medical products for SOF and MCSC, or when conventional forces engaged in active combat





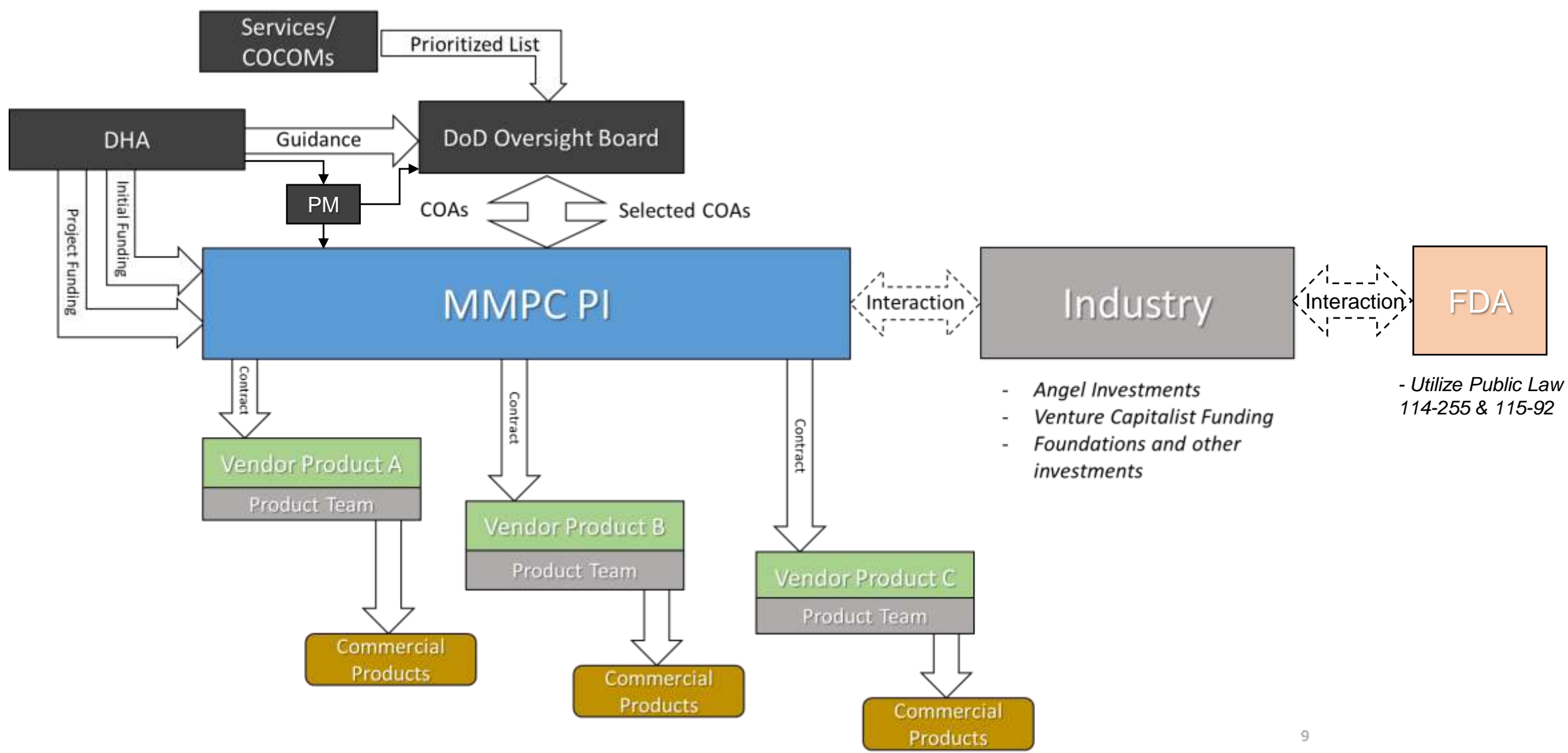
# How Military Medical Product Commercialization Partnership Intermediary Would Work



- The MMPC Partnership Intermediary creates and awards business to business contracts with vendors for selected COAs
- The MMPC Partnership Intermediary works with oversight board of DoD medical leaders to populate development teams with end-user service representatives, manages project team of vendors and end user service representatives
- End user service representatives determine the DoD-unique test and evaluation standards that the product must meet (i.e.: ruggedization, MIL-STD-810G, etc..), coordinate operational user evaluations of prototypes to provide feedback, and involve medical logisticians as product reaches maturity to address sustainment & maintenance
- The MMPC Partnership Intermediary assists with entering items into Electronic Catalog (ECAT), assigning NSNs, facilitating other avenues for procurement
- Medical products are available for military to procure off the market at a discount
- Also provides method for fielding viable medical products from DoD funded projects that the services are unwilling or unable to support (non-operational based, in-garrison care, training, maturing phase II SBIRs, etc..)



# MMPC Model for DoD





# Military Medical Product Commercialization Partnership Fits Within DAS



- The MMPC Partnership Intermediary mirrors tailoring of project management to the product being developed per Frank Kendall (Jan 2015) & DoDI 5000.02
- The MMPC Partnership Intermediary aligns with Section 804 of Public Law 114-92 and draft of DoD 5000.02 *Operation of the Adaptive Acquisition Framework*:
  - Delegated decision authority to Program Managers (PMs) enables broad authority to plan and manage their programs with consistent sound business practices
  - PMs develop acquisition strategies for commercializing medical products and leverage a combination of acquisition pathways to provide value, capabilities, and products
  - Follows one of two proposed pathways for developing commercial medical products: Quick Reaction Capabilities Acquisition (<2 years) or Middle Tier Acquisition (<5 years)
- Quick Reaction Capabilities Acquisition and Middle Tier Acquisition activities will not be subject to the Joint Capabilities Integration and Development System (JCIDS)
- DoD reduces risk and costs while maximizing benefits by using commercial-off-the-shelf practices & products that are successfully demonstrated in the commercial marketplace
- Larger, more complex medical acquisition programs still follow ACAT III or IV pathways



# Military Medical Product Commercialization Partnership Supported By DoD



- DoD Instruction 1100.22 (12 April 2010) directs components to use the manpower mix criteria outlined in the instruction to identify inherently governmental and commercial activities and conduct a cost comparison of personnel when considering outsourcing
- The DOD's National Defense Business Operations Plan for FY18-22 states that workforce rationalization strategies include identifying functions and positions **that are commercial in nature** that may be appropriately or efficiently delivered via private sector support
  - Supports Strategic Goal 3: Reform the Department's Business Practices for Greater Performance and Affordability
- GAO Report 19-102 Defense Health Care *Additional Assessments Needed to Better Ensure an Efficient Total Workforce* stipulates the DOD **employ a strategic approach** to determine the most appropriate and cost-effective mix of personnel to perform its mission
  - Cited significant challenges with the federal civilian hiring process and challenges with the contracting process for maintaining skilled medical workforce
- Supports statutory requirement of FAR Part 12 to seek commercial solutions first when addressing government needs, gaps, and requirements







# Deliverables for Pilot Military Medical Product Commercialization (MMPC) Partnership Intermediary



- The rapid development of three medical products that address the DoD's top priorities for fielding, are available to be procured commercially, and are suitable for military use (i.e.: meet applicable testing standards, especially ruggedization)
- Development, demonstration, and analyses of pilot process for utilizing industry best methods and processes to rapidly develop and field medical products
- Final report will include lessons-learned for improving/optimizing the process and (if successful) plans to scale up the process for other medical products
  - If MMPC Partnership Intermediary is continued/expanded, the PIA would be re-established with DHA
- Establishment of business processes for soliciting, obtaining, and applying investments from non-DoD entities, to include angel investors, venture capitalists, foundations, and other governmental and non-governmental sources
  - Use of matching funds sought whenever possible to facilitate and encourage outside investments, reduce costs, manage risks



# Additional Benefits of Privatization



- Civilian organizations have more stable workforce with experience, education, and knowledge of commercialization, manufacturing, and venture capitalist investment
- Civilian organizations have more flexibility with hiring/releasing employees and more able to adjust workforce as needed to funding and workload fluctuations
- Civilian organizations are able to seek and entice outside (matching) investments from venture capitalists, angel investors, corporate investments
- Not limited to operating within Defense Acquisition System (DAS) for commercial medical product development
- More able to align development with procurement from multiple services by making medical products commercially available via ECAT (ease of ordering)
  - Includes small initial procurement to start the production line; provided to interested services; DoD can purchase medical items at costs below retail market
  - Eliminates funding/schedule (commitment) gaps between development and procurement decisions
- Eliminates personality-driven medical development via DoD senior medical team oversight; unifies military medical RDA approach for commercial development



# Recommendations



- Fund pilot study to establish a medical product commercialization partnership that will create a plan for developing three prioritized medical products for commercialization and fielding over 3 – 5 year period
- Endorse the 59 MDW to launch a medical product commercialization PIA
  - Can include NAMRU-SA and USAISR
- Establish DoD oversight board of DHA J-4, DHA J-9, Office of the Joint Staff Surgeon (OJSS), COCOMs, and representatives from each service
- Assign a DHA-appointed PM to manage the MMPC pilot project when operational
- Request In-Q-Tel provide mentorship for new commercial-development organization
- Provide medical RDT&E to fund each of the COAs that are selected by the DoD panel/board
- Periodically review status and brief DHA CAE to determine if the pilot program should be discontinued, continued, modified, or scaled up for developing additional medical products