Chemical Biological Defense Acquisition Initiatives Forum (CBDAIF)

MEDICAL COUNTERMEASURES (MCM) SECTOR REPORT

23 May 2019

Presented by Sector Representative, Pam Duchars

Companies in Sector

- Big Pharma
  - Examples are Janssen, Sanofi, GSK, Merck, and Pfizer
- Specialty Pharma
  - Examples are Emergent Biosolutions, Bavarian Nordic and Ology
- Small Companies
  - Examples are Profectus, Kineta, AktiVax and Mapp Pharmaceuticals
- CMOs
  - Examples are ABL and Fujifilm Pharmaceuticals,
- CROs
  - PPD, IITRI, SRI
- Non-profits
  - Examples are Battelle, MRI Global, SwRI, and CUBRC
- Consultants
  - Examples are Latham, Tiber Creek, and SMI

- There are 184 members in the MCDC Consortium at this point in time, 86% NTD and 14% Traditional. This is a decrease from last year's membership of 191 members.
- There have been 21 awards made and almost $132M of funding awarded.

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MCM Sector Health

- **Current Health**
  - Medical Countermeasure Sector capability to support DoD and others remains better in areas where there is a synergistic commercial need like infectious disease and weaker in other areas such as chemical and radiological. Of note, there has been a **continued weakening of the infectious disease capabilities in the pharma market due to market forces, and a potential strengthening in the diagnostic device market due to positive shift in FDA regulation**
- **Future Health**
  - Medical Countermeasure Sector capabilities remain threatened due to lack of clarity on future business opportunities, lack of clarity on funding, **unexpected shifting of funds**, lack of coordination between agencies, lack of granularity on procurement volumes, **low margins on small procurement volumes and the lack of other incentives beyond low sales**
- **Notable**
  - ***Bad News: Infectious Disease market is suffering***
    - ***Pew and other reports on the antibiotic market show that there will likely need to be economic incentives to prop up the market***
      - ***https://www.pewtrusts.org/en/about/events/2019/fixing-the-broken-antibiotic-market***
    - ***Market projections for the infectious disease market are lower than a few years back***
  - ***Good News: Diagnostics is Growing***
    - ***Multiple reports indicate that the global in vitro diagnostics market was valued at $60 million in 2017, and is estimated to reach over $90 million by 2025***

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Major Sector Concerns

- Length of time to get from proposal to contract continues to be longer and negotiations more difficult than expected
- No award due to lack of funding after intense year long back and forth negotiations
  - Huge cost impact to industry to support the legal and other fees for the negotiation
  - Loss of confidence in JPEO CBD will impact industry participation
- Medical sector concern for the DOD on the medical side due to shifting funds at JPEO CBD and other recent shifts at DHA and MRMC
- Feeling of unfair advantage in areas where Ology Primes and is also expected to be a sub, example recent PRISM award
- Feeling that some of the RPPs are wired and should not be competed if there is a known candidate of choice, making industry feel like column fodder
- Confusion over what is happening to PRISM with the organization changes
- Lack of feedback on responses from certain RPPs of concern to team members
- Request more time on extended white paper response in order to build teams
- For DTRA JSTO announcements, not enough notice or time to respond is provided

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Other Sector Issues

- Unfair deadlines, over holidays and other times that were not respectful to industry
- Interest in having MCDC pair organizations technology the way that MTEC does, ie you can submit a partial proposal for a component and don't have to have the team to do the whole scope.
- Better updates on the basket, if your proposal has been placed in the basket
- Lack of ability to participate by foreign entities in MCDC
- Better definition of priorities
- Request updated plans to industry on where JPEO is now going (i.e. revision of 5 yr plan)
- Small companies are still finding the volume and amount of time to given to write and submit proposals to be difficult to manage
- Desire for more combined funding and communication amongst the agencies for similar or same products

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Positive Feedback

- Positive feedback on the changes to the MCDC website, including award announcements, other information, and the teaming platform
- Open dialogue within the MCDC Consortium has been welcomed and received positive accolades throughout the White paper and RPP process
- Priority review vouchers continue to be well received but are concerned that they are sunsetting and would like other incentive mechanisms to also be considered
- Non-profits are appreciative of the changes to the OTA and continue to participate more widely

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