Maximizing Government Opportunities for Growth

MHSRS
Military Health System Research Symposium

Presented by Liz Powell & Greg Kapcar

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G2G's Background

Team:

- Bipartisan
- 70 years experience working in and with government
- Raised over $160M for clients since 2007
- Secured CMS reimbursement rates, shaped regulations, and drafted and enacted policies

Niche:

- Biosciences and high-tech innovation

Locations & Affiliations:

- Offices:
    - Capitol Hill, Washington, D.C.
    - Arlington & Fairfax, VA
    - Cleveland & Columbus, Ohio
- Affiliations:
    - BioOhio & BioEnterprise, Ohio
    - VaBio
    - MichBio
    - MdBio/Tech Council of Maryland
    - NDIA Health Affairs Division and Women in Defense, D.C.

Government Funding

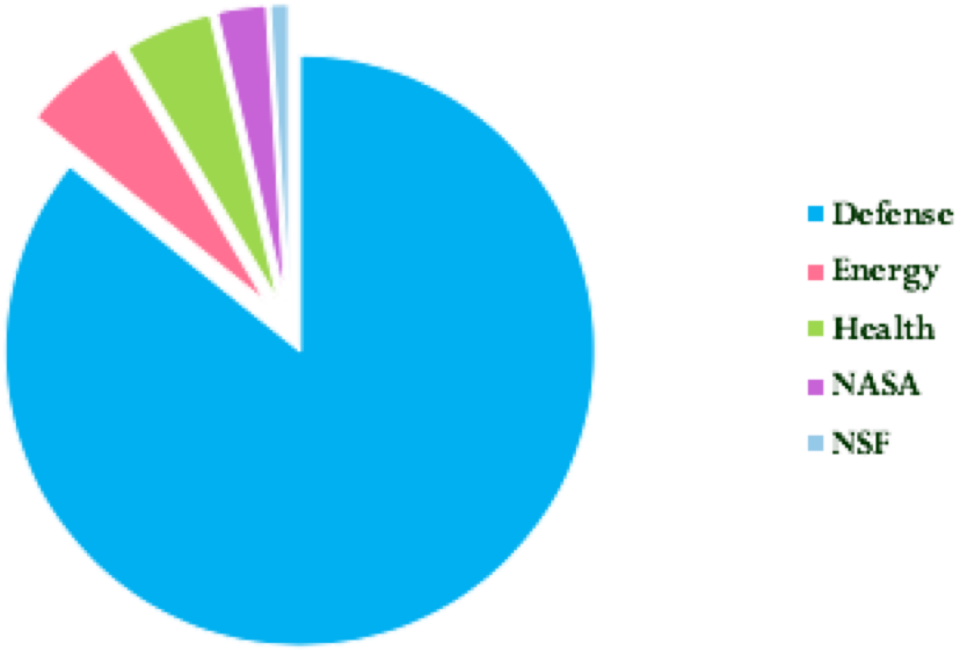
Categories:

Legislation

Grants

Discretionary

Procurement



FY18 Omnibus Spending:

$654.6B Defense

$43.2B Energy

$78B (NIH $37B) Health

$20.7B NASA

$7.8B NSF

What's Happening Concerning Biosciences

- FY19 Funding –12 appropriations bill and mini-bus legislation
  - NIH gets a boost – Senate proposes $2B increase, House proposes $1.3B increase – $711M of NIH's appropriation is from set-asides in 21st Century Cures Act, including: Cancer Moonshot, BRAIN Initiative, and "All of Us" Precision Medicine Initiative
  - Defense exceeds budget caps – House proposes $717B (passed House 359-54), Senate about to pass this week
  - Minibus exceeds budget by $70M – House passed Energy & Water, Legislative Branch and MilCon-VA package by 235-179 and Senate by 86-5; House passed Financial Services and Interior-Environment by 217-199; Senate to pass Financial Services, Interior-Environment, Transportation-HUD, and Agriculture-FDA package
- Medical Device Tax Repeal – H.R. 184 passed the House 283-132; effort in Senate to put House-passed bill straight to the floor, bypassing Finance Committee
- Ensuring Patient Access to Critical Breakthrough Products Act – Ensures CMS coverage for breakthrough innovations, still pending in Congress
- Tax Reform 2.0 – W&M working on bill to encourage innovation, help new businesses write off more of their initial start-up costs, and remove barriers to growth
- National Defense Authorization Act – Passed House and Senate and agreed to in Conference; Relevant changes for tech-based economic development: SBIR/STTR pilot reauthorization, New SBIR Pilots, Advanced Manufacturing Demonstration, Support for Co-ops, and DIUx is continued

MHSRS System

Military Health System:

- 9.4 million beneficiaries:
  - 19,700 inpatient per week and 1,031,000 in year
  - 1,417,000 outpatient per week and 74,000,000 in year
- 55 military hospitals
- 373 military medical clinics
- $48 billion budget – 10% of entire DoD budget

Veterans Affairs:

- 23 VISNs, 152 medical centers, 800 community-based outpatient clinics, 126 nursing home care units, and 35 domiciliaries
- $176 billion budget

Key Areas of Interest:

- DoD – Wound healing, regenerative medicine, sensors, traumatic brain injury, and PTSD; Prolonged Field Care is prioritized
- VA – rehabilitation, chronic conditions, health IT, and hospital care
- Cost-savings is valued nearly as much as the improvement of care

DoD Conferences & Events

- January – Extremity War Injuries Conference in D.C. by AAOS
- March – MHSRS abstract submission
- March/April – NDIA Medical Research, Development & Acquisition Conference in MD
- May – SOMSA Conference in NC and SBIR/STTR Innovation Summit in D.C.
- August – MHSRS in FL
- October – Defense Innovation Technology Acceleration Challenges Conference in FL and BARDA Industry Days Conference in D.C.
- Workshops throughout the year – Health and Medicine Division within National Academies of Sciences, Engineering, and Medicine (formerly Institute of Medicine), FDA, etc.
- Vendor Days – USAMRMC hosts exhibiting opportunities each month

MHSRS Conference

MHSRS Details

- Date: Monday, August 20th – Thursday, August 23rd
- Location: Gaylord Palms Resort & Convention Center in Kissimmee, Florida
- Registration: https://mhsrs.amedd.army.mil/SitePages/Home.aspx
- Hotels: Filling up quickly!
  - Gaylord Hotel
  - Radisson Resort Orlando-Celebration
  - Sheraton Lake Buena Vista
  - Meliá Orlando Suite Hotel at Celebration

MHSRS Day 1 - Monday

- 8am-12pm – Plenary Session and Keynote Remarks
- 1:30-6pm – Breakout Sessions:
  - Emerging Trends in AI for Healthcare
  - Alternative, Non-pharmacological Management of TBI
  - Extremity and Craniomaxillofacial Regeneration
  - Telehealth/Virtual Health/Remote Monitoring in the MHS
  - Wounds, Skin & Soft Tissue Infections
  - Psychological Health & Resilience
  - Enroute Care
  - Advancements in Operational/Clinical Hearing Protection/Tx
- 7pm – Reception

MHSRS Day 2 - Tuesday

- 8am-10am – Plenary Session and Opening Remarks
- 10am-5:30pm – Breakout Sessions:
  - Regenerative Rehabilitation
  - Neurotrauma
  - Hemorrhage Control & Resuscitation
  - Limb Trauma & Amputation
  - TBI Research into Clinical Practice
  - Wound Infections Blast-related Injuries
  - Healthcare Informatics for Agility/Medical Artificial Intelligence
- 5:30pm – Dinner on own

MHSRS Day 3 - Wednesday

- 8am-5:30pm – Breakout Sessions:
  - Mobile Health in Medical Theater of Operation
  - PTSD
  - Blood Products & Military Blood Banking
  - Treatment for Acute Radiation Syndrome
  - Precision Medicine – Physical/Mental Conditioning of Warfighter
  - Ocular Trauma
  - Other Transaction Agreements
  - Infectious Disease
- 5:30pm – Dinner on own

MHSRS Day 4 - Thursday

- 8am-9am – Plenary Session and Keynote Remarks
- 9am-12pm – Breakout Sessions:
  - Prolonged Field Care & Pre-Hospital Tactical Combat Casualty Care
  - Medical Simulation
  - Skin Regeneration & Scar Mitigation
  - Military Women's Health
  - Regulatory Session with FDA & DoD
- 1pm – Conference ends

DoD Research Areas

- Blood/Blood Products
- Burn & Intensive Care
- Cognitive Performance Optimization & Cognitive Burden
- Combat Casualty Simulation, Training & Informatics
- Craniofacial Trauma & Face Regenerative Research
- Enroute Care
- Environmental/Occupational Health Hazards
- Expeditionary & Sea Based Care
- Extremity Trauma & Limb Regenerative Research
- Genitourinary Injury Research
- Global Crisis Response: From Force Health Protection to Security Cooperation
- Hemorrhage Control & Resuscitation
- State of the Science on Wounds/Skin/Soft Tissue Infections & Diagnostics
- Research & Diarrheal Diseases

Research Areas continued

- Malaria Vaccine & Drug Update
- Update on Naturally Occurring Infectious Diseases
- Focus on Hot Topics Identified by Global Emerging Infections Surveillance
- Military Medical Skills Acquisition & Sustainment
- Musculoskeletal Injury Prevention
- Neurotrauma/Brain Injury
- Pain Management
- Physiological Monitoring
- Pre-hospital & Tactical Combat Casualty Care
- Prosthetics &Rehabilitation
- Psychological Health/Post Traumatic Stress Disorder
- Psychological Health/Resilience
- Sensory Issues/Vision, Hearing & Balance
- Systems Biology for Human Performance Optimization

Related Opportunities

- DoD Broad Agency Announcements
- DoD Program Announcements
- Ft. Detrick Vendor Days
- CDMRP Grants
- DARPA Grants and Contracts
- BARDA Contracts
- NIH Grants
- MTEC grants
- ARMI/BioFabUSE
- TATRC Science and Innovation Sessions
- Intramural Funding Opportunities

Grant Tracking

GOVERNMENT BIOSCIENCE GRANTS

http://www.G2Gconsulting.com/bioscience-corner

Comprehensive coverage of all federal funding opportunities released in the previous 30 days summarized and categorized by research area

Examples:

- Extramural Medical Research Broad Agency Announcement (USAMRMC) – Open for 5 years; Letter of Intent and Full Proposal Required
- DARPA Disruptive Capabilities for Future Warfare Broad Agency Announcement – submissions accepted through 6/11/19
- Hearing Restoration Research Program – 2 funding opportunities – Letter of intent due: 7/17/18 and Full Proposal due: 11/8/18
- Peer Reviewed Orthopaedic Research Program – 3 funding opportunities – Pre-proposal due: 7/30/18, Full proposal by invitation only due 10/24/18
- FDA Innovation Challenge to Spur Development of Medical Devices Including Digital Health and Diagnostics that Target Pain, Addiction and Diversion – Proposal due: 9/30/18
- EDA's Public Works and Economic Adjustment Assistance Program – Proposals accepted on rolling basis
- BARDA Broad Agency Announcement – open through 2019, Proposals accepted 7/31, 10/31, 1/31, 4/30

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Case Studies

Never reinvent the wheel

Case Study: MHSRS → Relationship Building

- **Goal:** Obtain federal funding for cellular therapy research to accelerate wound healing.

- **Results:**

- Developed a multi-state strategy for working with DoD and Congress and tied medical R&D to job growth in each state
- Provided introduction to the DoD, developed relationships and garnered funds from several program managers
- Leveraged TATRC relationships to access DARPA contract and insert language in NDAA
- Organized tours, demonstrations and media events with Members of Congress
- Attended MHSRS year after year, building more relationships and research partners
- $11.3 Million in FY2008-10
- $3 Million in FY2012 in NDAA
- $23 Million BARDA grant in FY2013 – up to $100 Million if hit all benchmarks over 5 years

Case Study: MHSRS → Funding

- **Goal:** Target the Program Manager for resuscitation device, explain capabilities and change his mind on how device can help him achieve his goals.

- **Results:**

- Wrote and disseminated 1-page white paper to align with DoD focus areas prior to MHSRS, had made introductions and tried to work with the Program Manager but he was not interested because working with another company
- Maintained communications in 5 months leading up to MHSRS, researched the other company and its capabilities, then arranged to meet Program Manager at MHSRS
- Gave tailored, thorough explanation of how device aligns with other company he was working with and of how can fund both
- Made submission for funding
- $300,000 allocated from USAMRMC in FY2013

Case Study: Grant Award

- **Goal:** Pursue funding and relationships within the DoD to conduct research on hemorrhage control.

- **Results:**

- Crafted a Strategic Roadmap on key targets within DoD as well as collaborators outside DoD with good connections and record of working with the DoD on R&D initiatives
- Wrote and disseminated 1-page white paper that addressed military requirements for battlefield hemorrhage control to targets
- Met with the key targets at Fort Detrick and at the annual MHSRS
- Secured poster presentation at MHSRS to build support and relationships within DoD
- Organized key collaborators within and outside of the military to jointly pursue funding, and continued dialogue to ensure company remained on radar and the company's application aligned with their top priorities
- $1 Million

Case Study: MHSRS → CRADA

- **Goal:** Meet with the Program Manager for infectious disease, explain early stage research, and find collaborative partners within DoD.

- **Results:**

- Wrote and disseminated 1-page white paper to align with DoD focus areas prior to MHSRS
- Met with Program Manager and explained how innovation could resolve his #1 problem in theater
- Program Manager connected company to WRAIR NMRC Wound Infections Department to collaborate on research
- NMRC/WRAIR issued a CRADA to the company to conduct research together
- With results of study will jointly apply for grants

Takeaways

G2G has raised $160M since 2007 by following these basic principles:

- Despite changing Administrations and Members of Congress, the process is fairly consistent
- Be methodical: research funding needs, create descriptions for each initiative tailored for each government target, build relationships and partnerships within DoD/DARPA/NIH/BARDA, etc., then make strong submissions that align with their priorities and intel shared with you
- Show your innovation is novel and will address gaps/requirements
- Pay attention to timing and criteria
- Remember your goal: build relationships long-term

Never give up!

www.G2Gconsulting.com

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