Preparedness, Pandemics, and Program Management: Embracing Serendipity in a Scientific Career

Matthew Lawlor, PhD
Director, RSV Program Management, Novavax Inc.
Agenda

- Three career experiences
  - Science policy
  - Contract management
  - Program management

- For each career
  - My experience
  - Sample work product
  - Opportunities
Science Policy

My Start

- Began researching science policy opportunities about halfway through graduate school
  - Lots of dead-ends

- Two years before graduation, applied to three different fellowship programs
  - No awards

- Prior to graduating, re-applied to all three programs
  - Awarded Presidential Management Fellowship
Science Policy

My Experience

- Presidential Management Fellow for 2 years at the US Department of Health and Human Services in the Office of the Assistant Secretary for Preparedness and Response

- Establishing medical countermeasure requirements and policies to prepare for intentional biological threats [anthrax, smallpox, etc.]

- Detailed to CDC to work on first National Biosurveillance Strategy for Human Health

- Positions: PMF; Program Analyst; Biological Threats Branch Chief
HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

- Decision-making body to coordinate investments and activities across multiple departments and agencies
- Top-level body includes CDC Director, NIH Director and ASPR
- Next-level group is comprised of Deputy Directors
- Working groups include subject matter experts to review scientific data and make recommendations
  - e.g., optimal vaccine characteristics
Science Policy

Sample Work Product

How much anthrax vaccine should we stockpile?

- Define the threat
  - Material threat determination by the Department of Homeland Security
  - Medical consequence modeling to determine potential number of illnesses and deaths during an event

- Evaluate the product landscape
  - Current products, manufacturing capacity, and shelf life
  - Next generation products and development timeline

- Prioritize across biodefense portfolio
HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats (April 2007)

- Result of months of deliberations and negotiations
- First time that the federal government communicated priorities for CBRN medical countermeasures
- Downstream impacts on priorities for federal agencies and product developers

<table>
<thead>
<tr>
<th>BIOLOGICAL THREATS</th>
<th>Near-Term (FY 2007-08)</th>
<th>Mid-Term (FY 2009-13)</th>
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<tbody>
<tr>
<td>Diagnostics</td>
<td>DSNS</td>
<td>SRF</td>
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<tr>
<td>Broad spectrum antibiotic(s)</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Anthrax antitoxin(s)</td>
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<td>DSNS, SRF</td>
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<td>Anthrax vaccine(s)</td>
<td>SRF</td>
<td>XX</td>
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<tr>
<td>Medical Countermeasure(s) for Filoviruses</td>
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<td>SRF, XX</td>
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<td>Smallpox antiviral(s)</td>
<td>SRF</td>
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<tr>
<td>Smallpox vaccine</td>
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<tr>
<th>RADIOLOGICAL and NUCLEAR THREATS</th>
<th>Near-Term (FY 2007-08)</th>
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<tbody>
<tr>
<td>Medical Countermeasure(s) for ARS/DEARE</td>
<td>SRF</td>
<td>XX</td>
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<tr>
<td>Biodosimetry, Bioassay</td>
<td>SRF†</td>
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<tr>
<td>Radionuclide-specific agent(s)</td>
<td>SRF</td>
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<tr>
<th>CHEMICAL THREATS</th>
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<tr>
<td>Enterprise CHEMPACKs</td>
<td>DSNS</td>
<td>XX</td>
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## Science Policy Opportunities

<table>
<thead>
<tr>
<th>Program</th>
<th>Pros</th>
<th>Cons</th>
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<tbody>
<tr>
<td>National Academies: Christine Mirzayan</td>
<td>Good crash course</td>
<td>~3 months</td>
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<tr>
<td>Science &amp; Technology Policy Graduate</td>
<td>Connection to National Academies</td>
<td>No connection to future employment</td>
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<tr>
<td>Fellowship Program</td>
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<tr>
<td>AAAS: Science &amp; Technology Policy</td>
<td>Prestigious</td>
<td>No connection to future employment</td>
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<tr>
<td>Fellowships</td>
<td>Executive branch and Congressional committee positions</td>
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<tr>
<td></td>
<td>Excellent network</td>
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<td></td>
<td>1 year with option for a second</td>
<td></td>
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<tr>
<td>Presidential Management Fellowships</td>
<td>Strong reputation</td>
<td>Mostly non-science positions</td>
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<td></td>
<td>Wide variety of executive branch positions</td>
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<td></td>
<td>Good network</td>
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<td></td>
<td>Includes one rotation</td>
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<td></td>
<td>2 years</td>
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<td></td>
<td>Converts into permanent federal position</td>
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<tr>
<td>Non-profits and advocacy organizations</td>
<td>Less competitive than fellowship programs</td>
<td>Opportunities are difficult to find, and</td>
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After 4 years in policy, interested more in “science” than “policy”

Biomedical Advanced Research and Development Authority (BARDA)
- Responsible for developing vaccines, therapeutics, and diagnostics from Phase 2 clinical trials through licensure and acquisition
- Targeted pathogens include CBRN threats, pandemic influenza, and emerging infectious diseases

Position: Project Officer, Influenza and Emerging Diseases Division
- Oversaw $179M development contract for recombinant influenza vaccine
- Project Officer on first Broad Agency Announcement for Influenza Medical Countermeasures
- Served on biosurveillance task force during 2009 H1N1 pandemic
Project Officer
A Brief Definition

- Once contract is awarded, provides technical oversight of contractor progress towards all deliverables
- Partners with Contracting Officer
  - Responsible for oversight of all financial aspects of the contract
- Serves as lead for team of subject-matter experts reviewing progress
- Reviews monthly technical reports and chairs quarterly site visits

BARDA Subject-Matter Experts
- Manufacturing
- Process and Analytical
- Preclinical
- Clinical
- Regulatory
- Quality
Should we proceed to GMP manufacturing with our current vaccine candidate?

Liu et al., Vaccine (2012) 30:6833
Should we proceed to GMP manufacturing with our current vaccine candidate?

- Review all available data
  - Mouse immunogenicity and ferret challenge studies
  - Status of all release and stability assays
  - Characterization data on lab-scale material
- Evaluate future plans (i.e., understand the program and ask the hard questions)
  - Are timelines reasonable?
  - Do they sufficiently understand their product to scale up manufacturing?
  - Do they have the right internal resources and external partners?
  - What does the rest of your team think?
- Approve path forward
- Monitor monthly invoices and technical reports to ensure the program stays on track
After 3 years managing development programs at BARDA, wanted to get first-hand experience in developing products

Advice from industry veterans: "This is a good experience, but it's only a window into the product development process."

**Novavax, Inc.**

- Small biotech developing recombinant vaccines using insect cell/baculovirus platform
- Portfolio includes vaccines for influenza, respiratory syncytial virus, Ebola virus, along with a novel saponin-based adjuvant
- Positions: Senior Program Manager; Associate Director; Director
Program Management
A Brief Definition

- Develop a plan in partnership with every department
- Reach consensus on the plan
- Monitor progress on a frequent basis
- Review any changes
- Identify key risks and track resolution
- Modify plan as necessary without putting corporate objectives at risk
- Communicate with all levels of the organization
Program Management
Sample Work Product

- **October 2013**
  - Plan for Phase 2 trial in pregnant women to begin fall 2014

- **Early 2014**
  - Increasing corporate interest in pediatric Phase 1 trial

- **Spring 2014**
  - One year data from Phase 1 trial in older adult subjects shows promise for an annual seasonal RSV vaccine

- **Fall 2014**
  - Initiated three RSV clinical trials
Contract and Program Management

Opportunities

- **Government agencies**
  - NIH
  - BARDA
  - DOD/DTRA, DARPA

- **Non-profits**
  - Gates Foundation
  - PATH
  - Malaria Vaccine Initiative
  - Henry M. Jackson Foundation
Closing Thoughts

- **Begin your next step today**
  - Science policy: Read up on current issues; follow Congressional hearings
  - Contract management: Read funding solicitations and agency strategic plans (grants.gov)
  - Program management: Project Management Institute; online trainings

- **Be flexible**
  - Unexpected opportunities can be the most rewarding

- **Be humble**
  - You will be starting at the bottom

- **Be confident in your abilities**

- **Best advice: “You are in charge of your career.”**