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DoD Acquisition of Vaccine Production

Report to the Deputy Secretary of Defense by the Independent Panel of Experts

November 29, 2000
Panel

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  MedImmune, Inc.

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  Senior Director, Viral Vaccine Manufacturing
  Merck & Co., Inc.

- William H. Habig, Ph.D.
  Director, R&D Quality Assurance
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- Gerald V. Quinnan, Jr., M.D.
  Professor, Preventive Medicine, Medicine and Microbiology
  Uniformed Services University of the Health Sciences

- Rita L. Wells, Ph.D.
  Deputy Executive Director
  Committee for Purchase from People Who are Blind or Severely Disabled
The Deputy Secretary of Defense requested that the study by the independent panel of experts focus on the following areas:

- Vaccines to protect Service members against biological warfare threats as well as infectious diseases.
- A comparison of current Department efforts with best business practices in the biologics industry, and if/how the Department can leverage the best aspects of the private sector programs from industry.
- A determination of whether the DoD program requires acquisition processes unique from normal departmental acquisition procedures.
- The development of recommendations for how the Department should best develop and oversee a vaccine acquisition production program.
Facts Bearing on the Problem

- BW and endemic diseases are proven, high consequence threats to military operational effectiveness
- Vaccines are lowest risk, most effective protection
  - Better than antibiotics or other treatments
  - Enable force projection
- Current approach is insufficient and will fail
- **A NEW APPROACH CAN MAKE THIS PROGRAM WORK**
Why Will Current Program Fail?

- Approach is contrary to business success model
  - No one in charge
  - Diffuse management
  - Fragmented program
- Lack of integration from discovery through licensure
- Lack of essential scientific oversight and talent
- Insufficient capture of industrial base
- Goals and dollars do not match
Industry Best Practices
Successful Vaccine Acquisition

Industry Best Practices effectively integrate:

- Policy
- Product life cycle
  - Research
  - Development
  - Production
  - Licensure
  - Sustainment
- Resources
- Management
Resources
Industry Benchmark

• Funding stability
• Up-front multiyear commitment
• Flexible “reprogramming” authority ($ and type)
• Product focus, not budget focus

Baseline Schedule Fully Funded
- R&D $300M - $400M/product
- Facility capital investment estimate
  - Production, labs, and support - $75M - $115M/product
- Operations and Maintenance Estimate
  - Manufacturing $30M - $35M/product/year

DoD Products Underresourced
Human Investment
Industry Benchmark at 8 Product Scale

- 2,500 people
- Exceptional and specialized skills
- Scarce national pool
- Competitive compensation
- Special HR programs necessary
  - Recruit, train, and retain

*People + Process → Vaccines*
Management
Industry Benchmark

- Goal is quality product
- Scientific expertise at every level
- Problem focus for continuing improvement
  - Rapid assessment and decisions
  - Mitigate risk at every stage
- Empowered and accountable management teams
DoD Practices
## Industry Best Practices

<table>
<thead>
<tr>
<th>Industry Best Practices</th>
<th>Assessment of DoD</th>
<th>Rationale for Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated Discovery</td>
<td>R</td>
<td>Piecemeal process</td>
</tr>
<tr>
<td>Through Licensure</td>
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<tr>
<td>Scientific Talent</td>
<td>Y</td>
<td>Good S&amp;T, inadequate development and production</td>
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<tr>
<td>Technical Qualifications of Management</td>
<td>RY</td>
<td>Vaccine Acquisition ≠ Weapons System Acquisition</td>
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<tr>
<td>Management Focus and Accountability</td>
<td>RY</td>
<td>Fragmented and Multilayered below DEPSECDEF</td>
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<tr>
<td>Funding Stability</td>
<td>R</td>
<td>Annual allocation and frequent decrement drills</td>
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<td>Funding Commitment</td>
<td>R</td>
<td>Development/Acquisition not funded following discovery</td>
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<tr>
<td>Flexible Reprogramming</td>
<td>RY</td>
<td>Limited by Congress</td>
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<tr>
<td>Focus on Product Quality</td>
<td>Y</td>
<td>Goal Y; Execution R</td>
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- G = Full Compliance
- Y = Moderate Compliance
- RY = Low Compliance
- R = No Compliance (High Risk)
Strategic Options

- Industry
- Government
- Combined integrated approach
Industry Option: Impediments

- Size & scope of program
- Industrial base at full capacity
- Idle manufacturing
- Risk to industry
  - Efficacy risk
  - Program stability
  - Perceptions
  - Political
- Defense procurement practices
Government Option: Impediments

- Size - 2,500 personnel
- Lack of personnel experienced in vaccine development processes
- Noncompetitive recruitment
Preferred Option: Integrated Approach

- Combines:
  - Management/development skills of industry
  - Acquisition skills of DoD
  - Scientists from Federal, academic/industry labs
  - Exploit industry development/manufacture where possible
  - GOCO for development/manufacture of remaining products

Incentivize Industry
Proposed Management Organization

Strategic Board

VARC — VAE — DMRC

Technical Board

PEO

PM PM PM
• Shell/buildout to process and manufacturing scale
• Expandable
• 3 to 4 product/process capacity
• Pilot production(scale-up
  – 2 products at one time
• Inherent clinical, regulatory, QC & QA elements,
  applied research lab capability
• University/industry corridor location is essential--Northeast coast lowest risk
Resource Estimates
(8 Vaccines*)

- R&D Funds -- $3.2B
- Initial Capital Funding ≥ $370M
  - $75M - $115M for each additional vaccine after first 4
  - 5% - 10% infrastructure improvement/year
- Operations and Maintenance ~ $300M/year
- 2,500 people

* BD and MIDRP require >8 vaccines total; study scale was 8 vaccines
Industry Incentives

- Overture to industry
- Encourage industry development of vaccines
  - Longest multiyear contracts possible
  - Incentive-based contracts
  - Government-provided facility
Findings and Recommendations

1. Vaccines to protect Service members against biological warfare threats as well as infectious diseases.
   - Combine programs from discovery to production
2. A comparison of current Department efforts with best business practices in the biologics industry, and if/how the Department can leverage the best aspects of the private sector programs from industry. 

a. Current Department efforts do not meet industry best practices:
   - Diffuse management and fragmented lines of responsibility
   - Inadequate scientific oversight
   - Inadequate program integration from discovery through licensure
   - Inadequate resources to meet goals

b. Adopt integrated approach utilizing:
   - Management/development skills of industry
   - Accountable, lean DoD management structure
   - Strong technical guidance and personnel
   - GOCO
Findings and Recommendations (cont.)

3. A determination of whether the DoD program requires acquisition processes unique from normal departmental acquisition procedures.

- Yes, vaccine acquisition is different from weapons acquisition and success requires different procedures
  - Strong technical input imperative
    - Workforce
    - Management
  - Stable, long-range funding for vaccine life cycle
  - Reprogramming authority
Findings and Recommendations (cont.)

4. The development of recommendations for how the Department should best develop and oversee a vaccine acquisition production program.
   a. Combined, integrated model
   b. Focused and streamlined organization
   c. Segregated, OSD-sponsored funding
   d. Incentivized industry involvement (with GOCO)
   e. DoD, Executive Branch, and Congressional support to remove impediments and provide necessary incentives
Backup Slides
**Product Life Cycle Integration**

<table>
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<tr>
<th>Component</th>
<th>Example</th>
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<tr>
<td>Research</td>
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<tr>
<td>Development</td>
<td>Optimal shot regimen</td>
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<tr>
<td>Production</td>
<td>Validated process</td>
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<tr>
<td>Licensure</td>
<td>FDA compliance</td>
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<tr>
<td>Sustainment</td>
<td>Reliable supply</td>
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</table>
Success

- Scientifically competent, empowered management
- Must integrate
  - Science & technology
    - Discovery
    - Applied activities
  - Product development
  - Manufacturing
  - Product licensure
  - Postlicensure sustainment
Proposed Management Structure

- Tailored Acquisition Model
  - OSD Vaccine Acquisition Executive (VAE)
  - Oversight (ACAT I)--technically qualified
  - Strategic Board advises VAE

- Vaccine Acquisition Review Council (VARC) and Defense Medical Requirements Council (DMRC)
Proposed Management Structure

- Joint Program Executive Officer (PEO)
  - VAE and PEO with scientific and acquisition skills
- Scientific & technical advisors on tactical operations to PEO
  - Periodic (scheduled) review
- PEO responsible for sponsoring ($$) S&T/relevant infrastructure and exploits DoD lab capability
- No dual hats
Resource Estimates

- **R&D Funds -- $3.2B**
  - ~ 8 successful vaccines (7-12 years each)*
  - ~ $300 - $400M/product R&D to licensure
    - ~ 2 products/year to start
    - ~ 4 products/year at year 4
    - ~ 8 products/year when mature

* BD and MIDRP require >8 vaccines total; study scale was 8 vaccines
Resource Estimates (cont.)

- Capital funds ≥$370M
  - $300M construction for manufacturing
  - $70M construction for labs
  - $75-$115M for each additional vaccine after the initial 4
  - 5%-10% infrastructure improvements/year at year 8

- Operations and Maintenance funds
  - $300M/year for 8 vaccines
Human Investment Estimate

- 2,500 people—exceptional and specialized skills
  - Scarce national pool
- Competitive compensation
- Special programs necessary
  - Train to expand the pool
  - Recruit
  - Retain
  - Compensate

People + Process → Vaccine
Vaccine Study Panel
Panel Sponsors

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  Director, Defense Research and Engineering

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  Deputy Assistant to the Secretary of Defense (Chemical/Biological Defense)
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  Director, Pharmaceuticals Group, Defense Supply Center, Philadelphia

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  William H. Bancroft, M.D.  Mark. R. Brunswick, Ph.D.
  Donna. L. Bareis, Ph.D.  James M. Miller, Esq.
  Thurman D. Gardner, C.C.E/A.  Joseph F. Soukup, Ph.D.
• Hicks Associates, Inc.
  George T. Singley, III
Briefings

• DATSD(CBD): Background and Related Issues
• SAIC: U.S. and International Vaccine Industrial Base
• SAIC: Vaccine Manufacturing Industry Best Practices
• SAIC: Food and Drug Administration Considerations
• SAIC: Overview of DoD Requirements Related to Vaccine Production
• SAIC: Selected Examples of DoD Experience with Acquisition of Licensed Vaccines
• DIA: Worldwide Biological Warfare Threat
• DSMC: Requirements Generation Process and Acquisition Life Cycle
• DSMC: Defense Acquisition Process Milestones and Phases: A Summary of the Revised 5000 Series
Briefings (cont.)

- SAIC: Defense Acquisition Workforce
- Joint Vaccine Acquisition Program: Acquisition of Biological Defense Vaccines
- U.S. Army Medical Research and Materiel Command: Vaccine Development and Production Process & Issues
- Defense Supply Center Philadelphia: Vaccine Management
- Defense Advanced Research Projects Agency: Vaccine Program Overview
- Headquarters, U.S. Navy: Review of DoD Acquisition and Production of Vaccines
Interviews

- Lieutenant General Paul Kern, USA, Military Deputy to the Assistant Secretary of the Army (AL&T) and Director, Acquisition Career Management
- Major General Timothy Malishenko, USAF, Director, Defense Contract Management Agency
- Mr. Robert Scott, Senior Principal, American Management Systems
- Major General John Parker, M.D., USA, Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC)
- Mrs. Vicky Armbruster, Joint Program Manager for Biological Defense
- Colonel David Danley, Ph.D., USA, Project Manager, Joint Vaccine Acquisition Program
- Colonel Charles Hoke, M.D., USA, Director, Military Infectious Diseases Research Program, HQ, USAMRMC
Acronyms

ACAT  Acquisition Category
AAE  Army Acquisition Executive
AMEDD C&S  Army Medical Department Center and School
AMP  Army Modernization Plan
ASA(ALT)  Assistant Secretary of the Army for Acquisition, Logistics and Technology
ASA(M&RA)  Assistant Secretary of the Army for Manpower and Reserve Affairs
ASARC  Army Systems Acquisition Review Council
ASD(HA)  Assistant Secretary Defense for Health Affairs
ASTMP  Army Science and Technology Master Plan
ATSD(NCB)  Assistant to the Secretary of Defense (Nuclear, Chemical, Biological)
BD  Biological Defense
BES  Budget Estimate Submission
BW  Biological Warfare
CG  Commanding General
CINC  Commander in Chief
CJCS  Chairman, Joint Chiefs of Staff
CSA  Chief of Staff, Army
DAB  Defense Acquisition Board
DAE  Defense Acquisition Executive
DATSD(CBD)  Deputy Assistant to the Secretary of Defense (Chemical/Biological Defense)
DCSOPS  Deputy Chief of Staff for Operations (U.S. Army)
DDR&E  Director, Defense Research and Engineering
DEPSECDEF  Deputy Secretary of Defense
DIA  Defense Intelligence Agency
DMRC  Defense Medical Requirements Council
DoD  Department of Defense
DTAP  Defense Technology Area Plan
DTRA  Defense Threat Reduction Agency
DUSD(S&T)  Deputy Under Secretary of Defense (Science and Technology)
FDA  Food and Drug Administration
GOCO  Government-Owned, Contractor-Operated
Acronyms (cont.)

JNBC  Joint Nuclear, Biological, Chemical
JNBCDB Joint Nuclear, Biological, and Chemical Defense Board
JROCC Joint Requirements Oversight Council
JSIG Joint Services Integration Group
JSMG Joint Services Materiel Group
JTCG Joint Technology Coordinating Group
JWSTP Joint Warfighting Science and Technology Plan
MAISRC Major Automated Information System Review Council
MAMP Mission Area Materiel Plan
MARP Management Assessment Review Plan
MDA Milestone Decision Authority
MIDRP Military Infectious Diseases Research Program
MIPR Military Interagency Purchase Request
MRSP Medical Readiness Strategic Plan
OSD Office of Secretary of Defense
PB President's Budget
PBAS Program Budget Accounting System
PEO Program Executive Officer
PM Program Manager
QA Quality Assurance
QC Quality Control
R&D Research and Development
RDA Research, Development, and Acquisition
S&T Science & Technology
SAIC Science Applications International Corporation
SECDEF Secretary of Defense
TFSC Theater Functional Steering Committee
TRADOC Training and Doctrine Command
TSG The Surgeon General
USAMRMC U.S. Army Medical Research and Materiel Command
USD(AT&L) Under Secretary of Defense for Acquisition, Technology and Logistics
USD(PR) Under Secretary of Defense for Personnel and Readiness
VAE Vaccine Acquisition Executive
VARC Vaccine Acquisition Review Council
## APPENDIX E

### Acronyms

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<tr>
<th>Acronym</th>
<th>Description</th>
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<td>Acquisition Category</td>
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<tr>
<td>AAE</td>
<td>Army Acquisition Executive</td>
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<td>ACIP</td>
<td>Advisory Committee on Immunization Practices</td>
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<td>AMAISRC</td>
<td>Army Major Automated Information System Review Council</td>
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<tr>
<td>AMEDD C&amp;S</td>
<td>Army Medical Department Center and School</td>
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<td>ASBREM</td>
<td>Armed Services Biomedical Research Evaluation and Management (Committee)</td>
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<td>ASD(HA)</td>
<td>Assistant Secretary Defense for Health Affairs</td>
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<td>ASTMP</td>
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<td>ATSD(NCB)</td>
<td>Assistant to the Secretary of Defense (Nuclear, Chemical, Biological)</td>
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<td>AVA</td>
<td>Anthrax Vaccine, Adsorbed</td>
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<td>AVP</td>
<td>Acquisition of Vaccine Production</td>
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<td>BDP</td>
<td>Biological Defense Program</td>
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<td>BES</td>
<td>Budget Estimate Submission</td>
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<td>BW</td>
<td>Biological Warfare</td>
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<td>CBER</td>
<td>Center for Biologics Evaluation and Research</td>
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<td>CG</td>
<td>Commanding General</td>
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<td>CINC</td>
<td>Commander in Chief</td>
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<td>CJCS</td>
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<td>DNA</td>
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<td>DoD</td>
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<td>DTAP</td>
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<td>Acronym</td>
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<td>DTRA</td>
<td>Defense Threat Reduction Agency</td>
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APPENDIX C

Surgeon General’s Letter to the Secretary of Defense
The Honorable Donald H. Rumsfeld
Secretary of Defense
Washington, D.C. 20301

Dear Mr. Secretary:

In fulfillment of the requirement in Section 218 of the National Defense Authorization Act for FY 2001, I am pleased to offer the following observations regarding the utility for the civilian sector of a government-owned, contractor-operated (GOCO) vaccine production facility, particularly for vaccines relevant to defense against the release of biological warfare agents.

Biological agents, even if adversaries intend them solely for use against military targets, could have the potential for causing severe, primary or collateral civilian casualties. Therefore, HHS has a substantial interest in the availability of vaccines that can be used, in sufficient quantity, to offer protection for civilian populations. For many reasons, a GOCO vaccine production facility, under the proper conditions, could assure the availability of these vaccines for military, as well as eventual civilian use should the need arise. Therefore, we want to encourage DOD to proceed with plans to develop a GOCO vaccine production capability and offer our technical assistance within the resources available to HHS. We believe that civilian participation can strengthen GOCO's operation and contribute to its success. Joint planning could avoid the eventual consideration of separate government-owned production of orphan and other vaccine products required mainly by the civilian population.

Should civilian use of the products of a GOCO be incorporated into your plans, we would welcome the opportunity to discuss means to participate in facility design and eventual product planning and production financing. The list of biological weapon threats facing civilian populations is very similar to that under consideration in DOD's initial planning, but the total production requirements may be substantially different. In addition, there may eventually be vaccines that need to be produced in a GOCO facility for which civilian needs dominate total demand (e.g., malaria, viral hemorrhagic fevers) but for which there is also a substantial requirement for force protection, even though the diseases against which they are protective are not considered bio-weapons.

In designing a GOCO and determining its requirements, we hope that product and production flexibility would be an important consideration. In the projected eight years to completion of the facility, disease and other threat profiles may evolve with a commensurate change in production needs. The introduction of West Nile encephalitis to the United States is just one example of how rapidly threats from infectious agents may change without warning, producing new challenges for protection of our armed forces as well as of our civilian population. New
production technologies are also on the horizon, and what now may be considered an "orphan" vaccine may take on new significance in the future.

We believe that a GOCO vaccine production facility can yield many benefits for meeting defense as well as civilian vaccine needs. We look forward to working with you in addressing such questions as how joint investment and production management might be achieved, how vaccine requirements for extended age groups might be accommodated, and how a variety of legal questions such as vaccine licensing and liability might be addressed.

I look forward to our continued discussions about this important step in further assuring the protection of our country from the effects of the unleashing of biological agents against our armed forces and civilian population.

Sincerely yours,

David Satcher, M.D., Ph.D.
Surgeon General, USPHS

cc: Dr. Anna Johnson-Winegar