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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

20040517 013

Panel

- **Franklin H. Top, Jr., M.D. – Chair**
Executive Vice President and Medical Director
MedImmune, Inc.
- **John J. Dingerdissen**
Senior Director, Viral Vaccine Manufacturing
Merck & Co., Inc.
- **William H. Habig, Ph.D.**
Director, R&D Quality Assurance
Centocor, Inc.
- **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

Terms of Reference

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

Resources (cont.)

Industry Benchmark

- 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

Best Business Assessment

| Industry Best Practices | Assessment of DoD | Rationale for Assessment |
|---|-------------------|--|
| Integrated Discovery Through Licensure | Ⓡ | Piecemeal process |
| Scientific Talent | Y | Good S&T, inadequate development and production |
| Technical Qualifications of Management | ⓇY | Vaccine Acquisition ≠ Weapons System Acquisition |
| Management Focus and Accountability | ⓇY | Fragmented and Multilayered below DEPSECDEF |
| Funding Stability | Ⓡ | Annual allocation and frequent decrement drills |
| Funding Commitment | Ⓡ | Development/Acquisition not funded following discovery |
| Flexible Reprogramming | ⓇY | Limited by Congress |
| Focus on Product Quality | Y | Goal Ⓢ; Execution Ⓡ |

- Ⓢ = Full Compliance
- Y = Moderate Compliance
- ⓇY = Low Compliance
- Ⓡ = 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

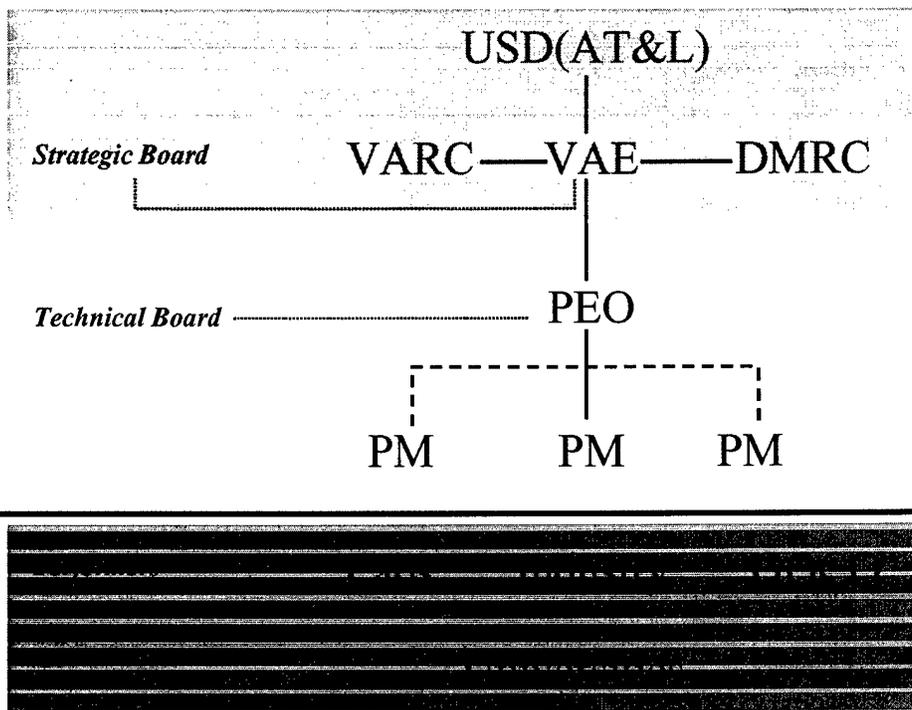
- Size - 2,500 personnel
- Lack of personnel experienced in vaccine development processes
- Noncompetitive recruitment

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



GOCO Facilities

- 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 \geq \$370M
 - \$75M - \$115M for each additional vaccine after first 4
 - 5% - 10% infrastructure improvement/year
- Operations and Maintenance \sim \$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

Findings and Recommendations (cont.)

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

Component

Research

Development

Production

Licensure

Sustainment

Example

Follow-on candidates

Optimal shot regimen

Validated process

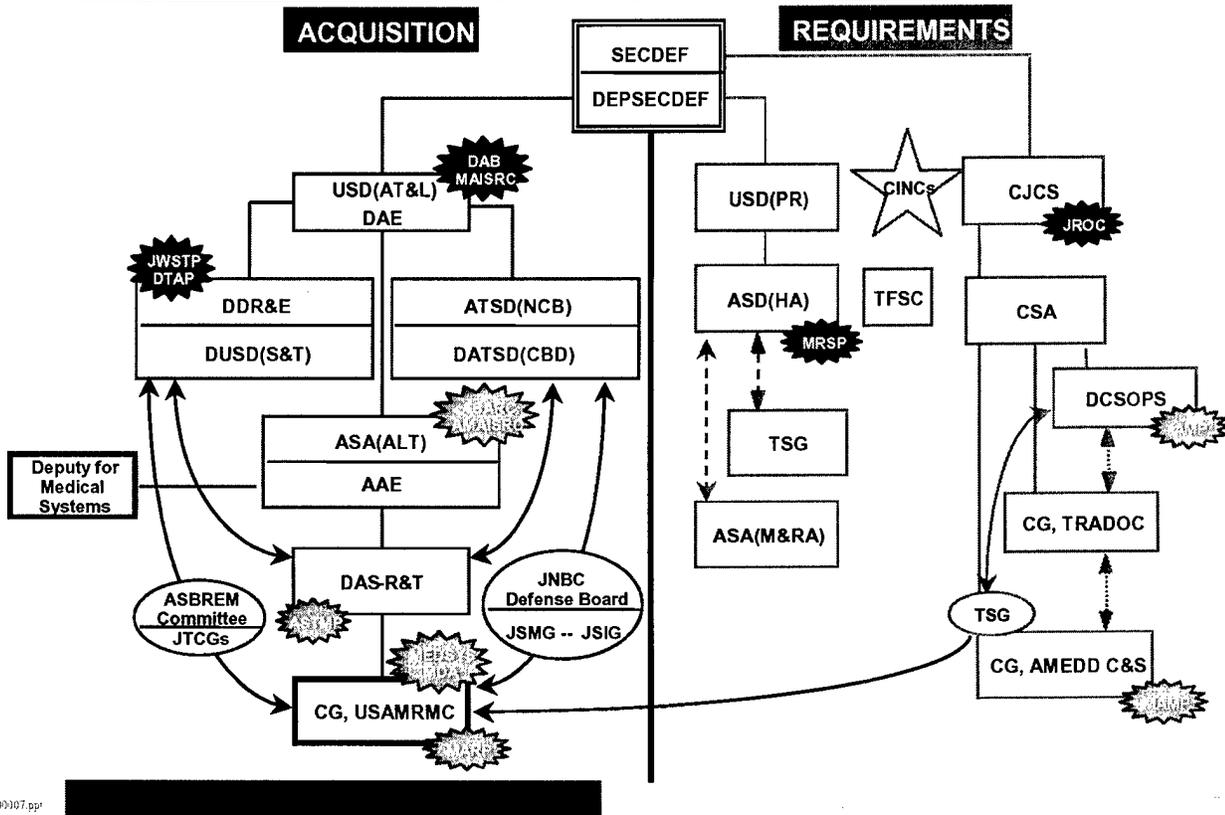
FDA compliance

Reliable supply

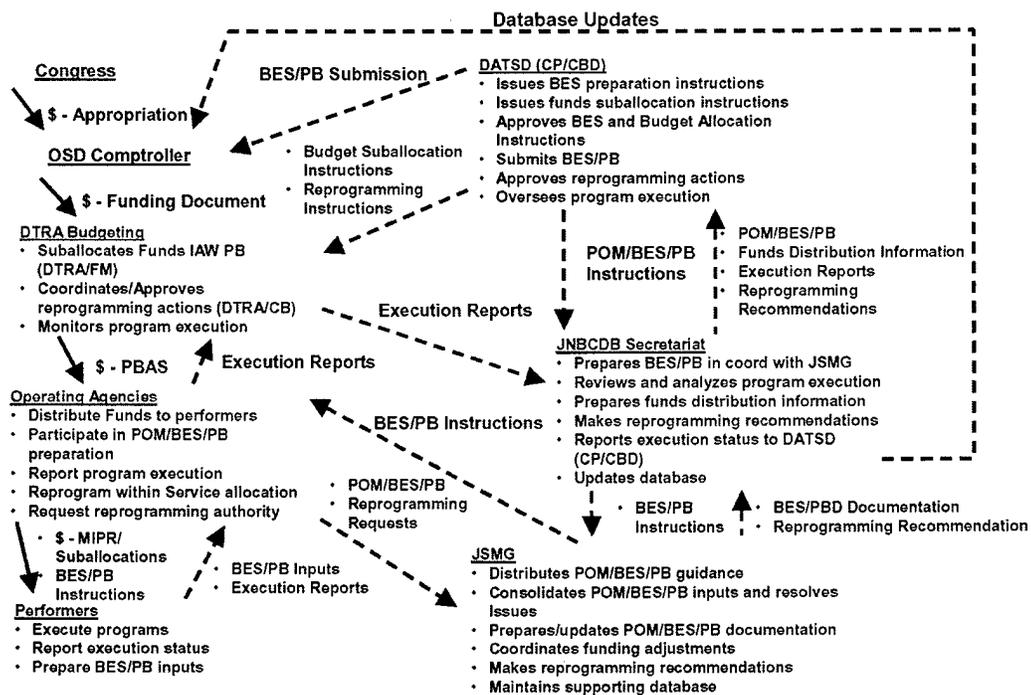
Success

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

Management Organization



Chemical and Biological Defense Program Funds Management Process



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 \geq \$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

- Hans Mark, Ph.D.
Director, Defense Research and Engineering
- J. Jarrett Clinton, M.D., M.P.H.
Acting Assistant Secretary of Defense (Health Affairs)

Panel Support

Department of Defense

- **Anna Johnson-Winegar, Ph.D.**
Deputy Assistant to the Secretary of Defense (Chemical/Biological Defense)
- **Robert E. Foster, Ph.D.**
Director, Bio Systems, Office of the Deputy Under Secretary of Defense (S&T)
- **Steve McManus**
Director, Pharmaceuticals Group, Defense Supply Center, Philadelphia

Contract

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

Acronyms (cont.)

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

APPENDIX E**Acronyms**

| | |
|----------------------|--|
| ACAT | Acquisition Category |
| AAE | Army Acquisition Executive |
| ACIP | Advisory Committee on Immunization Practices |
| AMAIIRC | Army Major Automated Information System Review Council |
| 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 |
| ASBREM | Armed Services Biomedical Research Evaluation and Management (Committee) |
| 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) |
| AVA | Anthrax Vaccine, Adsorbed |
| AVP | Acquisition of Vaccine Production |
| BDP | Biological Defense Program |
| BES | Budget Estimate Submission |
| BW | Biological Warfare |
| CBER | Center for Biologics Evaluation and Research |
| 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 |
| DAS-R&T | Deputy Assistant Secretary of the Army for Research and Technology |
| 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 |
| DLA | Defense Logistics Agency |
| DMRC | Defense Medical Requirements Council |
| DNA | Deoxyribonucleic Acid |
| 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) |
| EEE | Eastern Equine Encephalitis |
| FDA | Food and Drug Administration |
| FTE | Full-time Equivalent |
| GOCO | Government-Owned, Contractor-Operated |
| HIV | Human Immunodeficiency Virus |
| IAW | In Accordance With |
| IDP | Infectious Disease Program |
| IND | Investigational New Drug |
| IOM | Institute of Medicine |
| JNBC | Joint Nuclear, Biological, Chemical |
| JNBCDB | Joint Nuclear, Biological, and Chemical Defense Board |
| JPO BD | Joint Program Office for Biological Defense |
| JROC | Joint Requirements Oversight Council |
| JSIG | Joint Services Integration Group |
| JSMG | Joint Services Materiel Group |
| JTCG | Joint Technology Coordinating Group |
| JVAP | Joint Vaccine Acquisition Program |
| JVAP PMO | Joint Vaccine Acquisition Program, Project Management Office |
| JWSTP | Joint Warfighting Science and Technology Plan |
| MACOMs | Major Commands |
| 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 |
| NCI | National Cancer Institute |
| NEPA | National Environmental Policy Act |
| NIAID | National Institute of Allergy and Infectious Diseases |
| O&M | Operations and Maintenance |
| ODDR&E | Office of the Director, Defense Research and Engineering |
| OMA | Operations and Maintenance, Army |
| OSD | Office of Secretary of Defense |
| OTA | Other Transaction Authority |
| PB | President's Budget |
| PBAS | Program Budget Accounting System |
| PBD | Program Budget Decision |
| PEO | Program Executive Officer |

| | |
|----------------------|--|
| PMs | Program Managers |
| PPB | Planning, Programming, and Budgeting |
| PSC | Prime Systems Contractor |
| QA | Quality Assurance |
| QC | Quality Control |
| R&D | Research and Development |
| RDA | Research, Development, and Acquisition |
| RDT&E | Research, Development, Test, and Evaluation |
| RFPs | Request for Proposals |
| S&E | Scientists & Engineers |
| S&T | Science & Technology |
| SAIC | Science Applications International Corporation |
| SEB | Staphylococcal Enterotoxin B |
| SECDEF | Secretary of Defense |
| TFSC | Theater Functional Steering Committee |
| TRADOC | Training and Doctrine Command |
| TSG | The Surgeon General |
| UNICEF | United Nations International Children's Emergency Fund |
| USAMRIID | U.S. Army Medical Research Institute of Infectious Diseases |
| 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 |
| VEE | Venezuelan Equine Encephalitis |
| WEE | Western Equine Encephalitis |
| WMA | Worldwide Marketing Assessment |
| WRAIR | Walter Reed Army Institute of Research |

APPENDIX C

**Surgeon General's Letter
to the
Secretary of Defense**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Assistant Secretary for Health
Surgeon General
Washington, D.C. 20201

JAN 31 2001

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

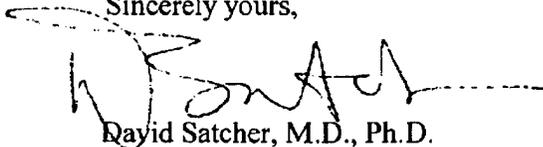
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production technologies are also on the horizon, and what now may be considered an Aorphan® vaccine may take on new significance in the future.

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,

A handwritten signature in black ink, appearing to read "D. Satcher", with a horizontal line extending to the right.

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

cc: Dr. Anna Johnson-Winegar ✓