DoD Acquisition of Vaccine Production

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

November 29, 2000

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	R	Piecemeal process
Scientific Talent	Y	Good S&T, inadequate development and production
Technical Qualifications of Management	R/Y	Vaccine Acquisition ≠ Weapons System Acquisition
Management Focus and Accountability	R/Y	Fragmented and Multilayered below DEPSECDEF
Funding Stability	R	Annual allocation and frequent decrement drills
Funding Commitment	R	Development/Acquisition not funded following discovery
Flexible Reprogramming	R/Y	Limited by Congress
Focus on Product Quality	Y	Goal G; Execution R

G = Full Compliance

Y = Moderate Compliance

R/Y = 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

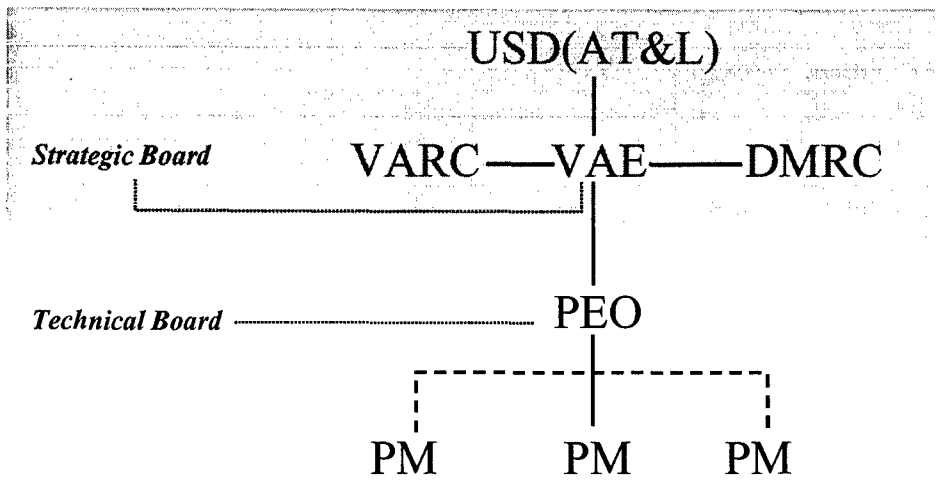
- Size - 2,500 personnel
- Lack of personnel experienced in vaccine development processes
- Noncompetitive recruitment

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



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 ≥ $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

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

[redacted]

Backup Slides

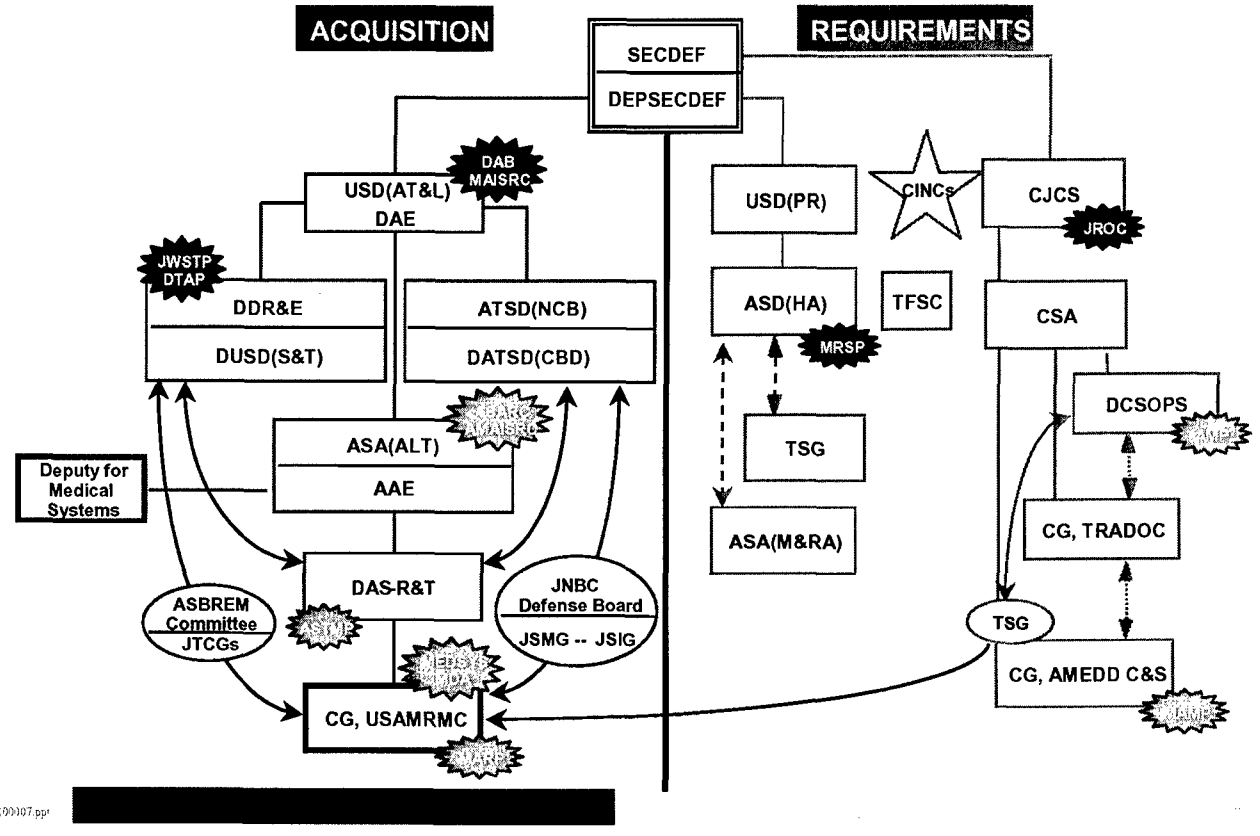
Product Life Cycle Integration

Component	Example
Research	Follow-on candidates
Development	Optimal shot regimen
Production	Validated process
Licensure	FDA compliance
Sustainment	Reliable supply

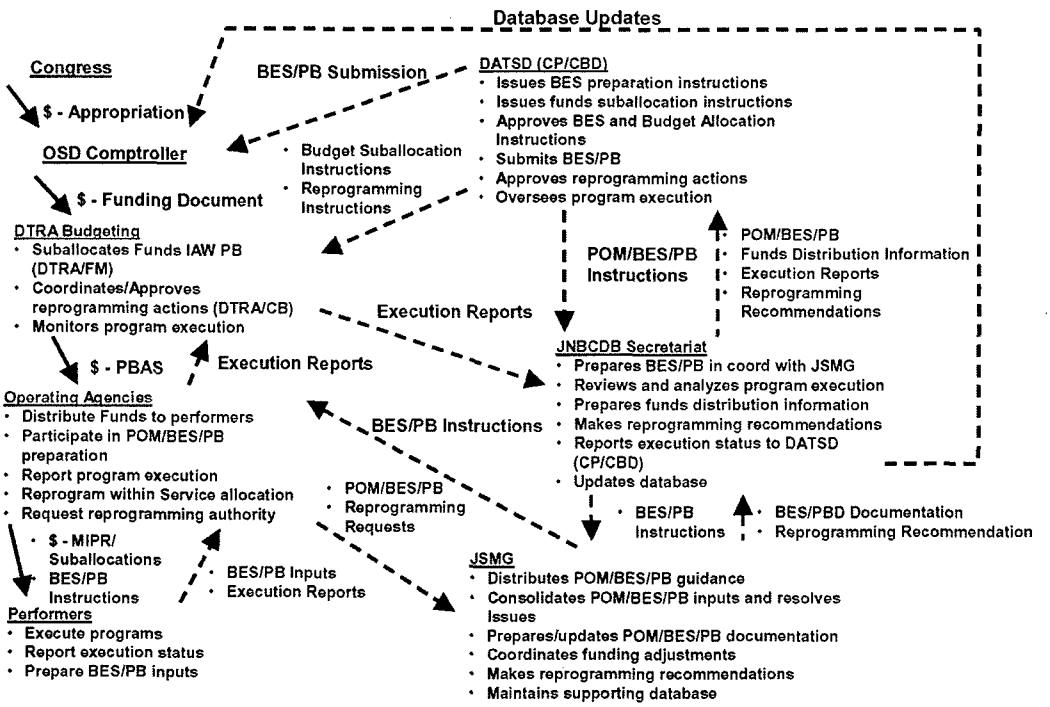
Success

- 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



JSMG Hand Book of Standard Operating Procedures, Fig IV-I, Page 19

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

- 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

  Daniel L. Rickett, Ph.D.
  William H. Bancroft, M.D.
  Donna. L. Bareis, Ph.D.
  Thurman D. Gardner, C.C.E/A.
  Joseph C. Denniston, V.M.D., Ph.D.
  Mark. R. Brunswick, Ph.D.
  James M. Miller, Esq.
  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
JROC	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

ACAT	Acquisition Category
AAE	Army Acquisition Executive
ACIP	Advisory Committee on Immunization Practices
AMAISRC	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

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,

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

cc: Dr. Anna Johnson-Winegar