



***Executive
Overview Briefing
to the
U.S. Air Force
Reserve***

**Anthrax Vaccine Immunization Program
and
Smallpox Vaccination Program**

28 January 2003



Why all the controversy?



From the package insert...

“Occasional fever may result. A nodule may be palpable at the injection site for a few weeks. Sterile abscesses and SC atrophy may occur [10 cases/million doses]. Other adverse reactions include erythema, boggy edema, pruritis, lymphadenopathy and induration surrounding the injection site, pain and tenderness. Malaise, generalized aches and pains, headaches, flushing, pruritis, tachycardia, hypotension, anaphylaxis, and neurological complications can result. Arthus-type hypersensitivity reactions may result in some people.”



Carcinogenesis, Mutagenesis, Impairment of Fertility?

From the package insert...

“[The vaccine] has not been evaluated for its carcinogenic potential, mutagenic potential or potential for impairment of fertility.

Animal reproduction studies have not been conducted with [the vaccine]. It is also not known whether [the vaccine] can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. [The vaccine] should be given to a pregnant woman only if clearly needed.”



In the newspaper...

“In trying to enforce the medical fetish of vaccination on an unwilling public, it seems to me that the germ-huns owe it to the public to give a definition of what vaccination really is...

No doctor knows the composition of the vaccine...

No doctor knows what the effect is on the blood...

No doctor can guarantee his vaccinated victim against [the disease]...

No doctor can say how long the supposed protection will last...”



From the package insert...of the Tetanus Toxoid Vaccine

“Occasional fever may result. A nodule may be palpable at the injection site for a few weeks. Sterile abscesses and SC atrophy may occur [10 cases/million doses]. Other adverse reactions include erythema, boggy edema, pruritis, lymphadenopathy and induration surrounding the injection site, pain and tenderness. Malaise, generalized aches and pains, headaches, flushing, pruritis, tachycardia, hypotension, anaphylaxis, and neurological complications can result. Arthus-type hypersensitivity reactions may result in some people.”



Carcinogenesis, Mutagenesis, Impairment of Fertility?

From the package insert...of Hepatitis A Vaccine

“*Havrix* has not been evaluated for its carcinogenic potential, mutagenic potential or potential for impairment of fertility.

Animal reproduction studies have not been conducted with *Havrix*. It is also not known whether *Havrix* can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. *Havrix* should be given to a pregnant woman only if clearly needed.”



In the newspaper...March 22, 1919...smallpox vaccine

“In trying to enforce the medical fetish of vaccination on an unwilling public, it seems to me that the germ-huns owe it to the public to give a definition of what vaccination really is...

No doctor knows the composition of the vaccine...

No doctor knows the effect is on the blood...

No doctor can guarantee his vaccinated victim against *smallpox*

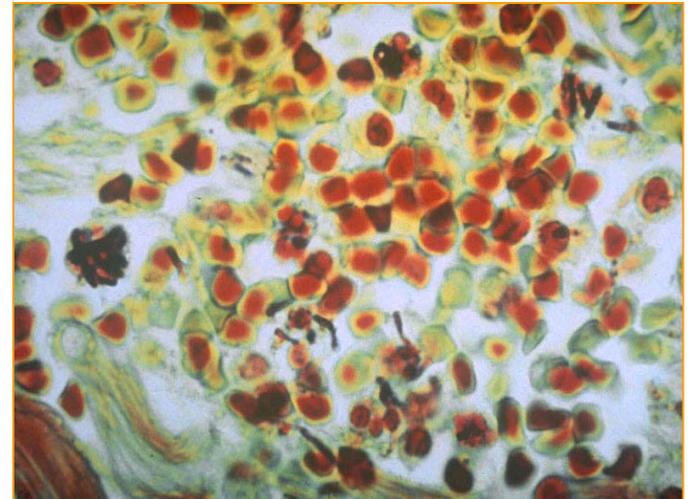
No doctor can say how long the supposed protection will last...”

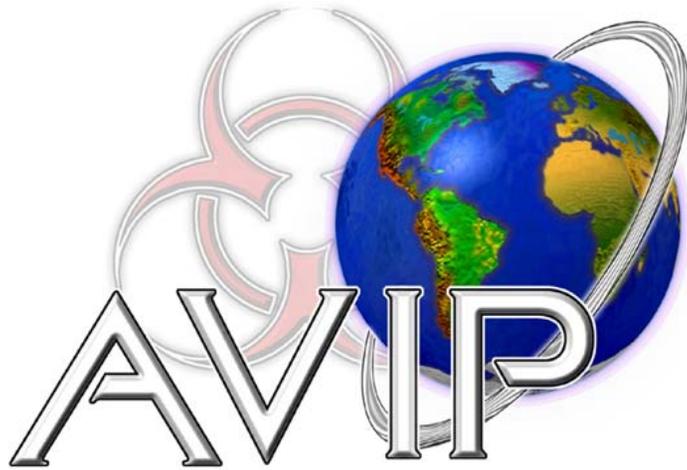


- **Anthrax - an offensive BW agent**

- ◆ Highly lethal
- ◆ Easy to develop and weaponize
- ◆ Remains viable for long periods
- ◆ Colorless, odorless, difficult to detect
- ◆ **At least seven potential adversaries suspected of researching, developing, and/or weaponizing anthrax**

- **Rapidly progressing infection, caused by spore-forming bacteria called *Bacillus anthracis***
- **Spores hardy...difficult to kill...survive decades**
- **Most common in grazing animals—can also infect people**
- **Several dozen human outbreaks of anthrax occur naturally around the world each year**
- **If antibiotic treatment begins immediately after exposure, death rate can be reduced from over 80% to near zero.**
- **Three types—Cutaneous, Gastrointestinal, Inhalational**



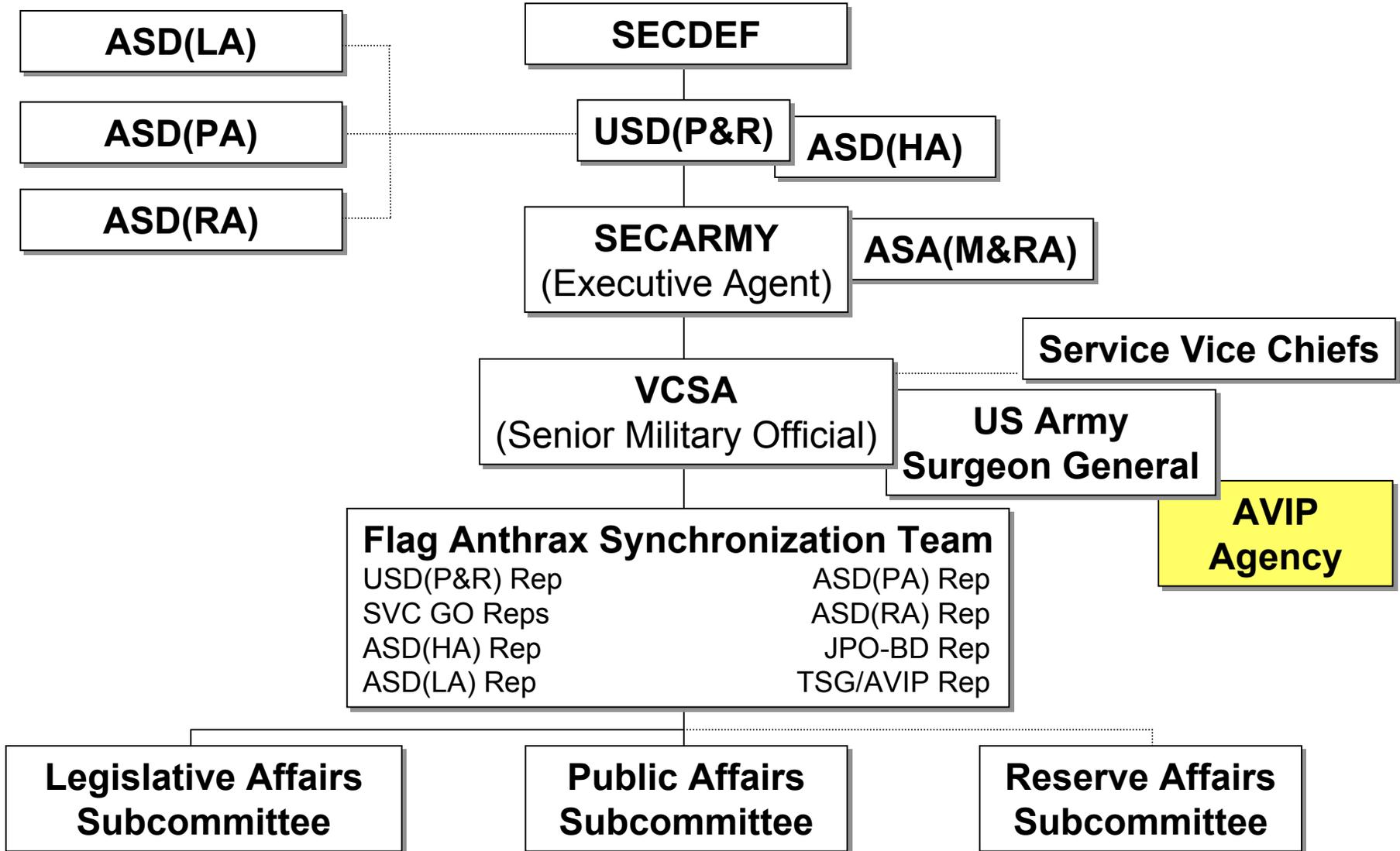


*Department of Defense
Anthrax Vaccine
Immunization Program*

AVIP History



DoD AVIP Organization



*18 May 1998 SECDEF Memo Provides Overarching Guidance



DoD AVIP (MIL VAX) Agency Organization

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Deputy Director
Operations/Army AVIP
MAJ Eric Sones

Deputy Director
Clinical Operations
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Management Analyst
Scott Engel
Webmaster
Andrew Brown

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Operations Center
Chief
CPT Brandon Pretlow
Current Operations Mgr
Bonnie Pereschuk

INS, INC.
Future Operations Mgr
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Division

Communication
Division

Regional Liaison
Analysts

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Tampa, FL
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Camp Pendleton, CA
Vacant

Norfolk, VA
Vacant

Colorado Springs, CO
Vacant

STRENGTH:

Military - 4
Civilian - 3
Contractor - 29

Eagle 23
INS 4
ASM 2

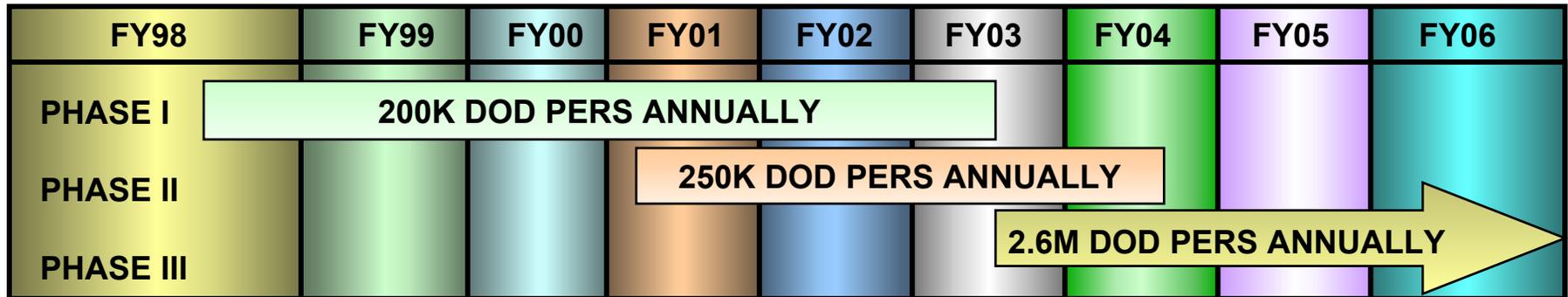
As of 8 Oct 02



AVIP Concept of Execution (Original Plan)

Phased Execution for the Total Force

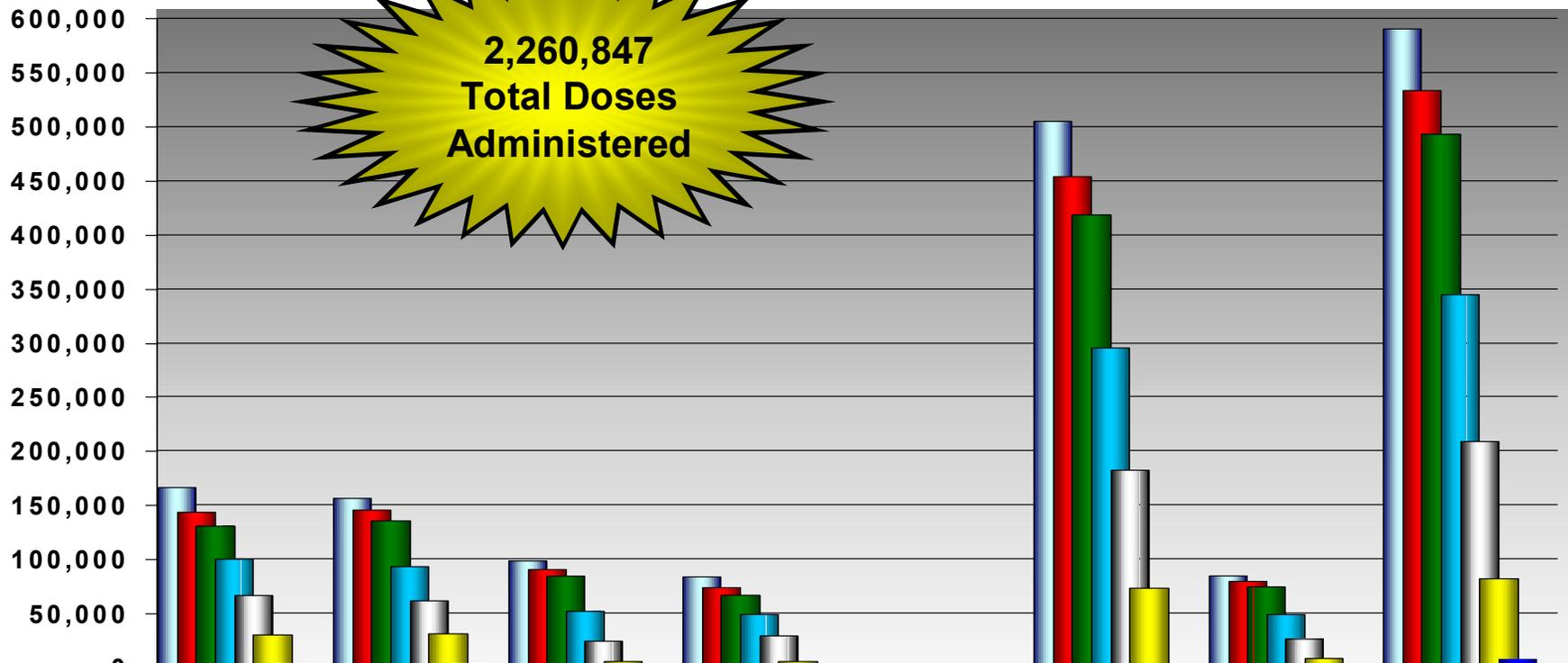
- **PHASE I:** DoD vaccinates only forces assigned or rotating to High Threat Areas (HTA) of Southwest Asia (SWA) and Korea
- **PHASE II:** Starts only after “assured production” of vaccine is guaranteed by BioPort/FDA approval. DoD will vaccinate early-deploying forces (C to C+35) into HTAs of SWA and Korea
- **PHASE III:** Remainder of Total Force, accessions, and sustainment





Total Force Anthrax Immunization Status

**2,260,847
Total Doses
Administered**

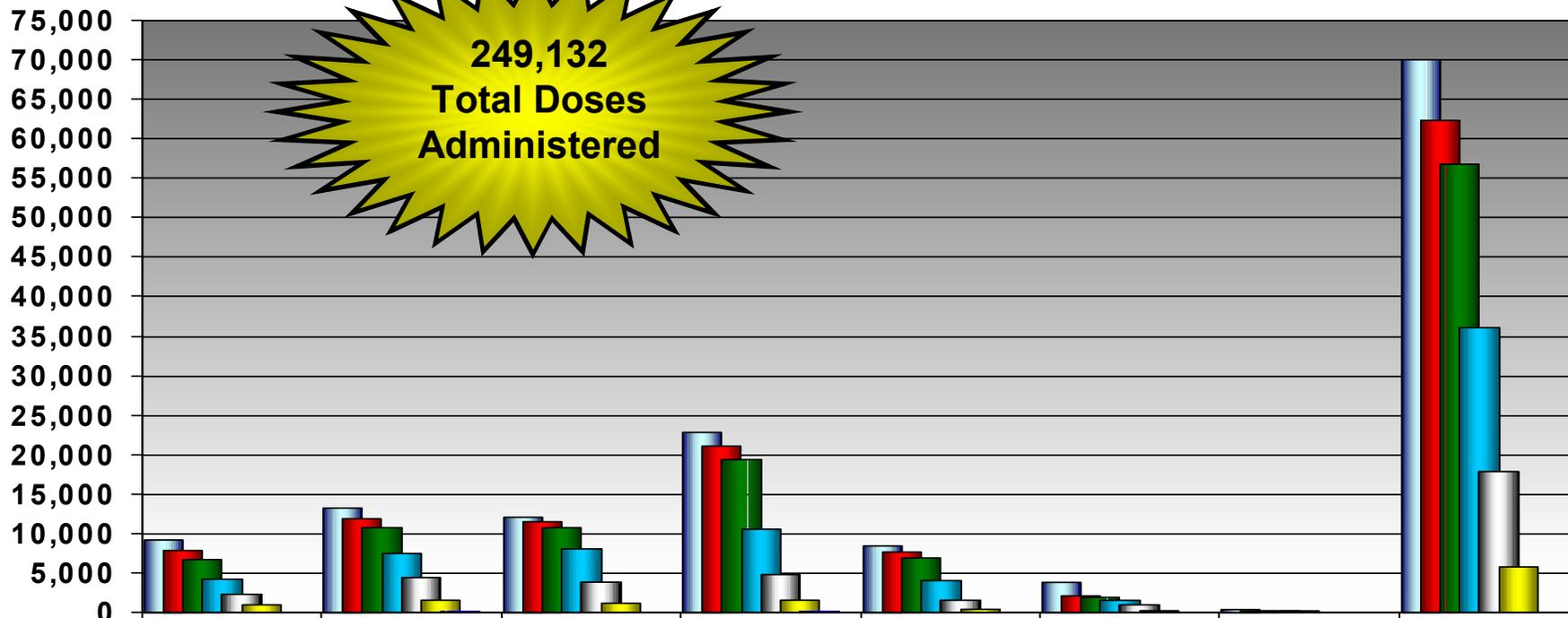


	ARMY	AIR FORCE	NAVY	MARINES	COAST GUARD	TOTAL (current program)	ARCHIVED IMMUNIZATIONS	TOTAL IMMUNIZATIONS
DOSE #1	166,309	156,203	97,858	83,752	1,020	505,142	84,830	589,972
DOSE #2	143,754	145,425	90,522	73,308	812	453,821	79,371	533,192
DOSE #3	130,989	135,505	84,360	66,716	728	418,298	74,283	492,581
DOSE #4	100,595	93,475	51,986	49,416	508	295,980	48,915	344,895
DOSE #5	66,767	61,995	24,409	29,331	222	182,724	26,502	209,226
DOSE #6	30,073	30,993	6,351	6,255	45	73,717	8,935	82,652
BOOSTER	3,888	4,123	22	14	0	8,047	282	8,329
TOTAL	642,375	627,719	355,508	308,792	3,335	1,937,729	323,118	2,260,847



Reserve Components Immunization Status

249,132
Total Doses
Administered

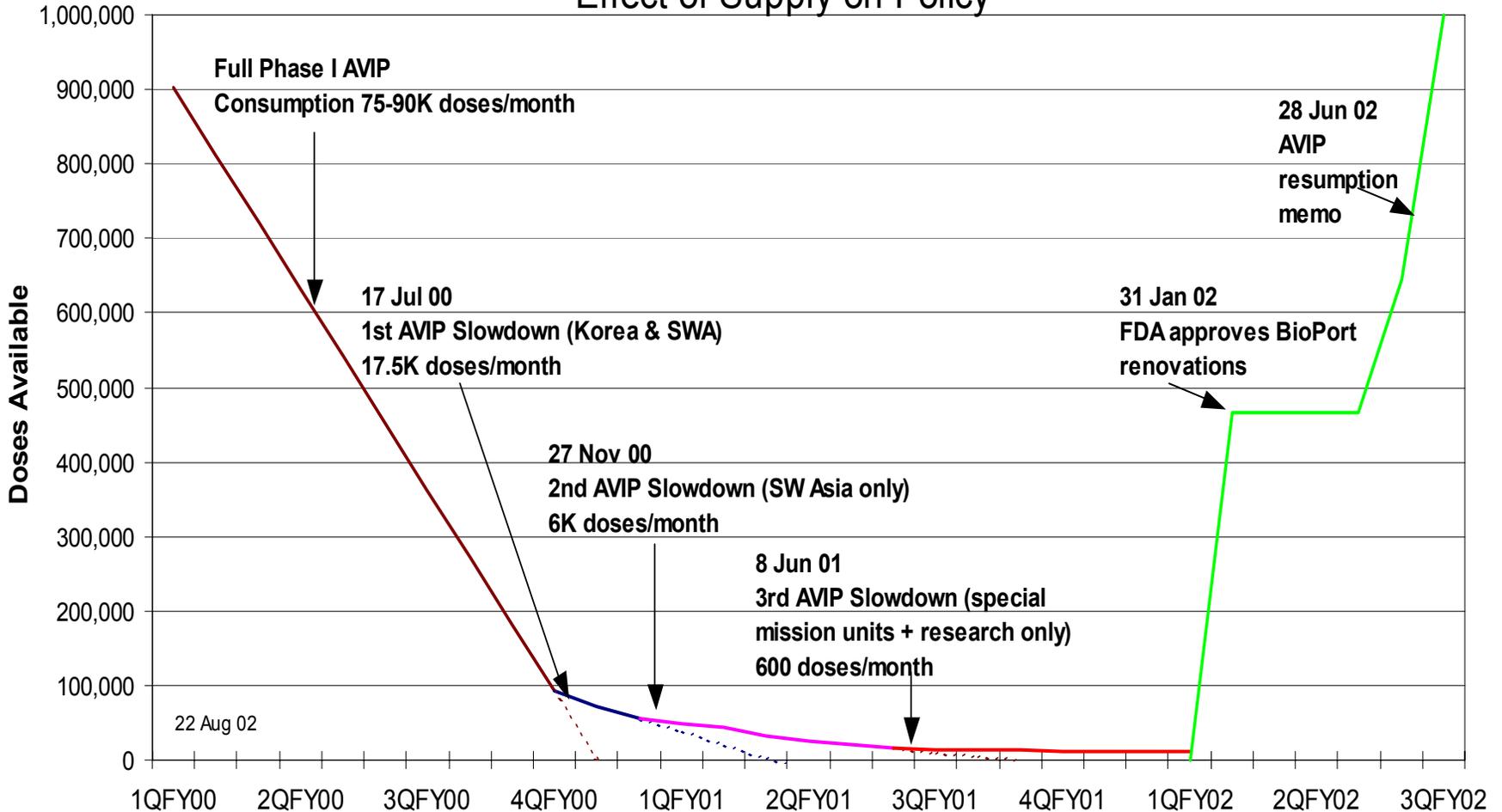


	USAR	ARNG	USAFR	ANG	NAVRES	MARFORRES	USCGR	TOTAL
DOSE #1	9,284	13,276	12,085	22,888	8,411	3,766	313	70,023
DOSE #2	7,829	11,936	11,443	21,015	7,721	2,121	225	62,290
DOSE #3	6,711	10,777	10,764	19,450	6,976	1,992	189	56,859
DOSE #4	4,161	7,528	8,098	10,459	4,097	1,518	106	35,967
DOSE #5	2,354	4,350	3,932	4,719	1,605	903	15	17,878
DOSE #6	911	1,509	1,121	1,536	318	273	2	5,670
BOOSTER	67	96	93	186	3	0	0	445
TOTAL	31,317	49,472	47,536	80,253	29,131	10,573	850	249,132



AVIP Vaccine Stockpile and Slowdowns

Anthrax Vaccine Immunization Program: Effect of Supply on Policy





- **BioPort purchased Michigan Biologic Products Institute Sep 98**
 - ◆ Inherited older state-run, undercapitalized facility during renovation
 - ◆ Inherited legacy of negative FDA inspection results and bad press
 - ◆ New company with “growing pains” and new management team
 - ◆ AVIP used older, FDA-released vaccine lots, but nearly ran out

- **No new vaccine available from BioPort’s renovated anthrax vaccine (AVA) production suite until FDA approved BioPort’s Biologic License Application (BLA) supplement. Approval of BLA was iterative and complicated—FDA considered both:**
 - ◆ Renovation of anthrax vaccine production suite
 - ◆ Validation of vaccine production process
 - ◆ Other vaccine manufacturers dropping out because so difficult and costly (causing both US flu and tetanus vaccine shortages)

- **FDA took final action approving BioPort’s BLA supplement and releasing newly-produced vaccine 31 Jan 02**



*Department of Defense
Anthrax Vaccine
Immunization Program*

The Vaccine



Anthrax Vaccine, Adsorbed

- **Manufactured by BioPort Corp., Lansing, Michigan**
- **FDA-licensed product since 1970; NOT an investigational new drug (IND)**
- **Dosing schedule, 6 doses over 18 mos: 0, 2, 4 weeks; 6, 12, 18 mos; annual booster thereafter**
- **Inactivated, cell-free, made from anthrax strain that does not cause the disease**
- **Basic component is Protective Antigen, common to all naturally occurring strains of *Bacillus anthracis***



- **Human clinical field trial, Brachman et al, 1950s: 92.5% effective in preventing anthrax, jointly cutaneous and inhaled (5 inhaled cases among unvaccinated; 0 cases among vaccinated)**
- **Unethical to conduct further human research; must rely on animal data: 95% of vaccinated rhesus monkeys and 98% of rabbits survive lethal inhalation challenge--unvaccinated animals uniformly die**
- **Protective value of U.S. anthrax vaccine based on human data, animal data, and understanding of immunology**



- **Side-effect profile similar to other vaccines**
- **Inactivated vaccines do not affect fertility or pregnancy**
- **No known long-term health effects based on numerous studies over last 50 years**
- **Anthrax vaccine studied longer than hepatitis A, Lyme disease and chicken-pox vaccines**
- **Vaccine Adverse Event Reporting System (VAERS) monitoring: Unprecedented review by independent civilian panel--no unexpected patterns of adverse events**
- **DHHS' Anthrax Vaccine Expert Committee—unprecedented VAERS review, vaccine surveillance by nationally renowned civilian medical experts**



- **“The committee finds that the available evidence from studies with humans and animals, coupled with reasonable assumptions of analogy, show that AVA as licensed is an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *B. anthracis*.”**
- **“The committee found no evidence that people face an increased risk of experiencing life-threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population. Nor did it find any convincing evidence that people face elevated risk of developing adverse health effects over the longer term, although data are limited in this regard (as they are for all vaccines).”**



*Department of Defense
Anthrax Vaccine
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AVIP Future



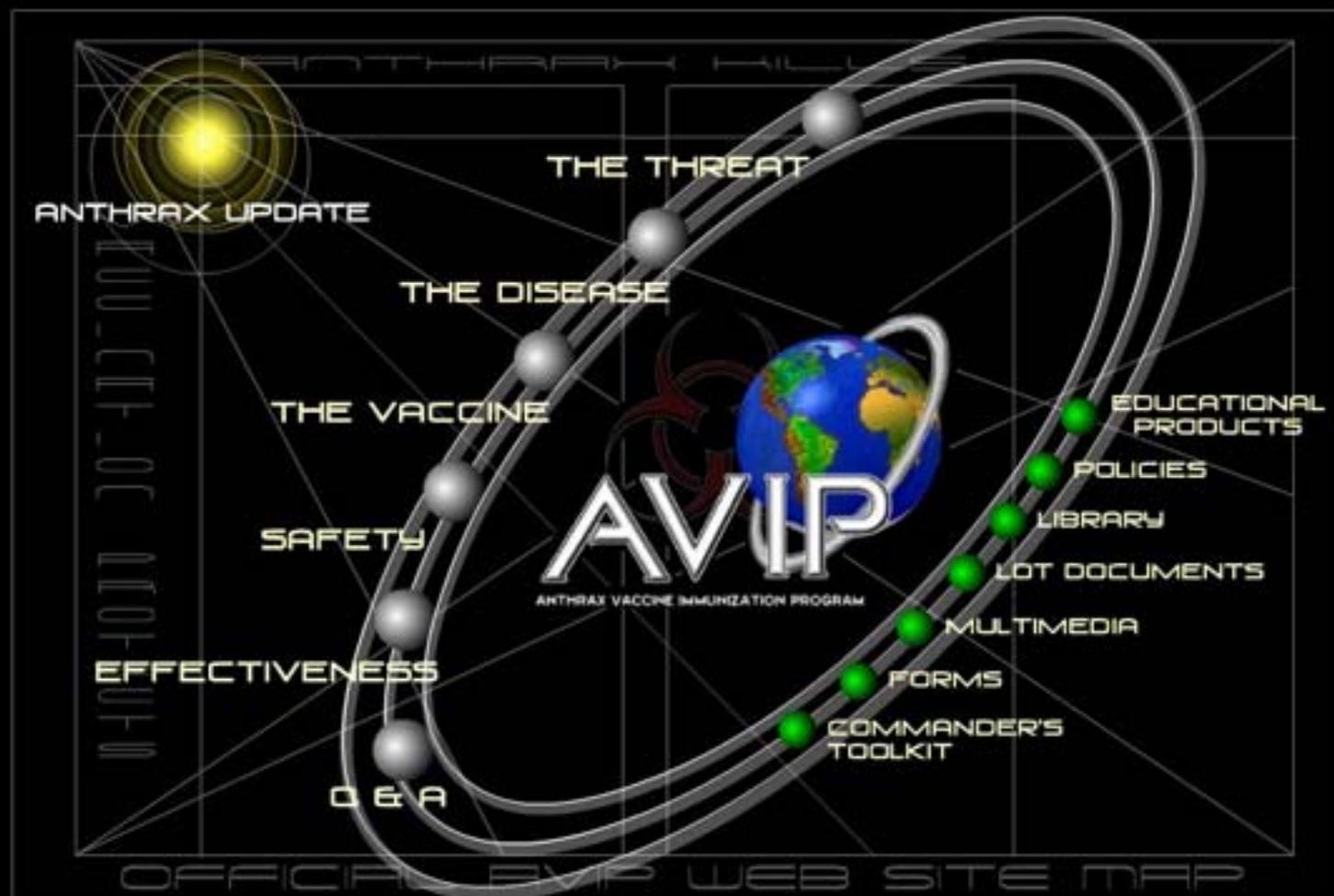
- **DEPSECDF 28 Jun 02 AVIP Resumption Policy:**
 - **Continues vaccinations to Priority 1 Special Mission units, researching all manufacturers.**
 - **Vaccinates military personnel, emergency essential DoD civilians and contractors deploying for greater than 15 consecutive days to High Threat Areas.**
 - **Services and combatant commanders can nominate other personnel at risk for exposure to *Bacillus anthracis* due to duty positions**



- We must ensure a continuous supply of vaccine
- We must educate all customers early: patients, family members, health-care professionals, general public
- Our patients perceive the risk-benefit ratio for BW vaccines differently than other “routine” vaccines
- A strong foundation of research-based, third-party endorsed, published science is critical to credibility
- Command/leader involvement is key to local success



- **DoD AVIP Internet Web site: www.anthrax.mil**
- **Toll-free information line: [1-877-GETVACC](tel:1-877-GETVACC)**
 - ◆ 10-hour daily operation; answering service after hours; flexible contract facilitates expanded hours, if needed
 - ◆ Quick replies; links to subject-matter experts
- **Reader e-mail: avip@otsg.amedd.army.mil**
- **Distributive training products**
 - ◆ New trifold on web site 15 Sep 02
 - ◆ Program-overview videotape, Oct 02
 - ◆ Silent training aids, Oct 02
 - ◆ Interactive multimedia CD-ROM, Oct 02



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anthrax vaccine immunization program

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Your health and safety are our #1 concerns.

The anthrax vaccine is safe and effective.

The threat from anthrax is deadly and real.

Vaccination offers a layer of protection in addition to antibiotics and other measures that is needed for certain members of the Armed Forces.

[Institute of Medicine Releases Report on Anthrax Vaccine Safety and Effectiveness](#)

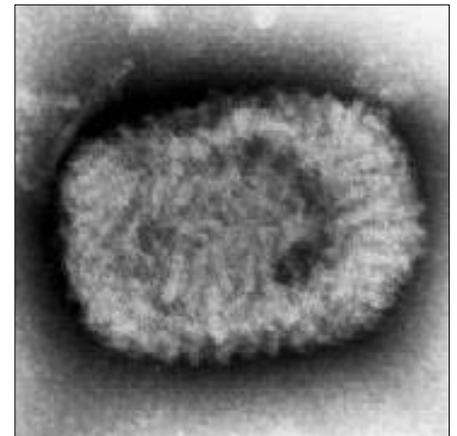
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Internet

Important Information About Smallpox and the Smallpox Vaccine



- **Caused by the the variola virus.**
- **Killed 500 million people in the 20th century.**
- **Killed 2 million people in 1967 alone.**
- **Known since ancient times.**
- **Natural disease has been eradicated.**
 - Last U.S. case 1949
 - Last international case 1978
 - Declared eradicated 1980





Bioweapon Potential—Threat to Fighting Forces

- **Features making smallpox a lethal agent:**
 - Can be produced in large quantities
 - Known to produce a stable aerosol
 - Highly contagious—high mortality, 30% average
 - Most people have little or no immunity
- **Released as a weapon, smallpox virus would significantly degrade mission capability, because most troops are susceptible.**
- **Outbreak could restrict movement of troops, aircraft, ships.**
- **Smallpox would stress medical operations.**
- **Former Soviet capabilities confirmed—stocks, and weaponization. In others' hands now?**



■ **Incubation period.**

- Asymptomatic from infection to onset of prodrome
- Range 7-17 days, typical 12-14 days

■ **Prodromal period.**

- Nonspecific febrile illness, flu-like
- Contagious, day or two before rash

■ **Eruptive period.**

- Characteristic rash—deep, tense blisters by Day 2 of rash
- Turns to round, deep pustules that dry to scab by Day 9
- Scabs separate, leaving permanent scars

■ **Mortality.**

- 25-30% overall in unvaccinated population
- Infants, elderly, immunocompromised higher (>40%)
- Variations: hemorrhagic 100%; Flat (Malignant) >90%





Prevention - Smallpox Vaccination History

■ Variolation

- Antiquated inoculation with infectious smallpox 1% to 2% mortality
- Eastern countries ancient times; U.S. by Rev. Cotton Mather 1721
- George Washington ordered variolation of Continental Army

■ Vaccination introduced by Edward Jenner in 1796

- Inoculated boy with pustular fluid from cowpox
- 1st immunization using virus of similar disease; not lifetime immunity

■ War Dept orders Jennerian vaccine/method in 1812

■ 1919 - Citizens outraged that Woodrow Wilson permits smallpox vaccination of troops

■ 1980 - WHO declares Earth free of of naturally occurring smallpox

■ 1990 - DoD suspends vaccinations

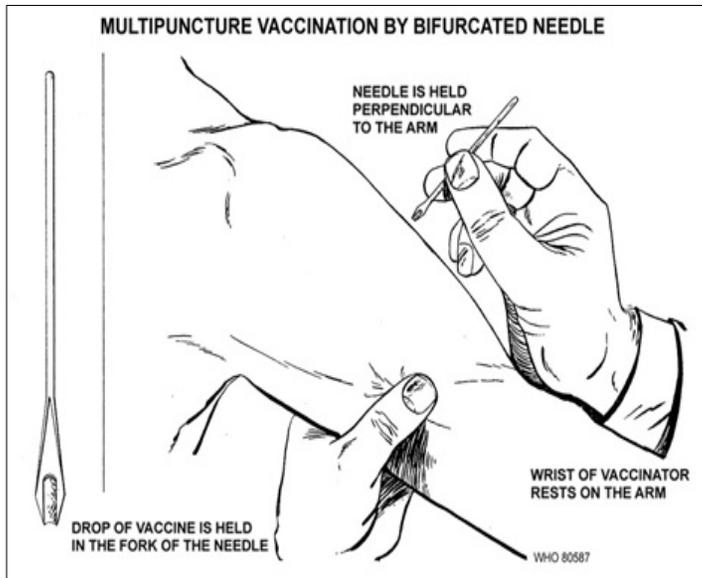


■ Vaccinia virus cross-protects to smallpox

- Related to cowpox and variola
- Source: calf lymph
- Now cell-culture methods available

■ Smallpox vaccine with diluent and bifurcated needles

- Training needed scarification technique with bifurcated needles





Smallpox Vaccine - Modern Times

- **Powder for reconstitution, refrigerate, 100-dose vials with bifurcated needles, scarification**
- **Smallpox vaccine protects within ~10 days, >95% effective with one dose**
Vaccination up to 4 days after face-to-face exposure prevents death
Protection wanes over decades
- **Side effects:** fever, swelling, pustule, muscle ache, malaise
- **Serious events:** Cause-and-effect relationship, serious, but rare
Encephalitis: ~5 to 12 per million adult vaccinees
Severe skin reactions: ~12 to 32 per million adult vaccinees
Death: 1 to 2 per 1,000,000 adult-primaries, 1 per 4,000,000 revaxtns
- **Serious events more common if immunocompromised, eczema, etc.**
- **Vaccinia virus present at vaccination site:**
25 to 606 accidental infections per 1,000,000 vaccinations
Spread to others by touch contamination
8 serious reactions per 1,000,000 vaccinations (e.g., eye, genitals)



Smallpox Vaccine - Supply Issues

Product	Source	Doses	License Status	Comment
<i>Dryvax</i> vaccine	Wyeth	~14M, dilutable ~70M	License 25Oct02	DHHS commits 1M doses to DoD (net ~80%)
vaccine	Aventis Pasteur	~85M, dilutable 425M	IND	Relicensing unlikely
vaccine	Acambis	209M contract, ~150M in bulk, ~10M bottled	IND	License estimated 2003
vaccine	Dynport, Bio-Reliance	~16,000	IND	License est 2003-04
Vaccinia immune globulin (VIG)	IM – Hyland IV – DVC	For ~10M vaccinations	IND	~4M more to DoD Dec 02; CDC contract for ~300M by Jan 04



DoD Smallpox Response Plan

Process - 430-page plan for DoD's global duties, developed using 10 teams of subject-matter experts.

Purpose - To prepare for and respond to smallpox outbreak, regardless of magnitude or location. Plan provides for both ring vaccination and wide-area vaccination.

Scope - Smallpox outbreaks on military installations or during contingency operations around the world, as well as military support to civil authorities.

Status - Pending DEPSECDEF approval.



DoD Smallpox Response Plan

DoD Smallpox Response Plan, version 3.1, 29 Sep 02, 430 pages:

Basic Plan

Annex A. Surveillance, Contact Tracing, & Epidemiological Investigation

Annex B. Vaccination Guidelines

Annex C. Isolation & Quarantine Guidelines

Annex D. Specimen Collection Guidelines

Annex E. Communications Plans & Activities

Annex F. Decontamination Guidelines

Annex G. Medical Care Of Smallpox Patients (Variola Infection)

Annex H. Medical Care Of Adverse Events After Smallpox Vaccination

Annex I. Medical Logistics & Product Distribution

Annex J. Resources

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- **Services form response teams and medical teams. Train and vaccinate team members. Exercise teams.**
- **Installations develop local supporting plans (e.g., identify needed facilities).**
- **Services begin to train health-care providers to recognize smallpox and implement surveillance for defined fever-rash illnesses.**
- **Training issues:**
 - How to use bifurcated needle.
 - Bandaging, isolation, duty limitations after smallpox vaccination.
 - How to document IND drug administration.



Why Military Vaccines Are Important

- **Boer War, 1899, British develop typhoid vaccine**
 - ◆ **Opposition to vaccine grows**
 - ◆ **Opposition boards transport ship, throws typhoid vaccine into Southampton harbor**
 - ◆ **British military makes typhoid vaccine optional**
 - 14,000 soldiers take it, with 2% infection rate
 - Among unvaccinated, 14% infected:
 - ⇒ 58,000 contract typhoid fever
 - ⇒ 9,000 needlessly die of typhoid fever
- **1914: 97% of British troops accept typhoid vaccine**
- **We don't want the last chapter on AVIP to be the Boer War, revisited.**

Source: Parish, 1965; Benenson, 1984; Plotkin, 1999



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