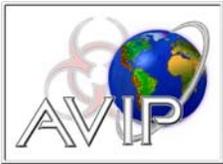




*Department of Defense
Anthrax Vaccine
Immunization Program*

Executive Update Briefing

26 April 2001

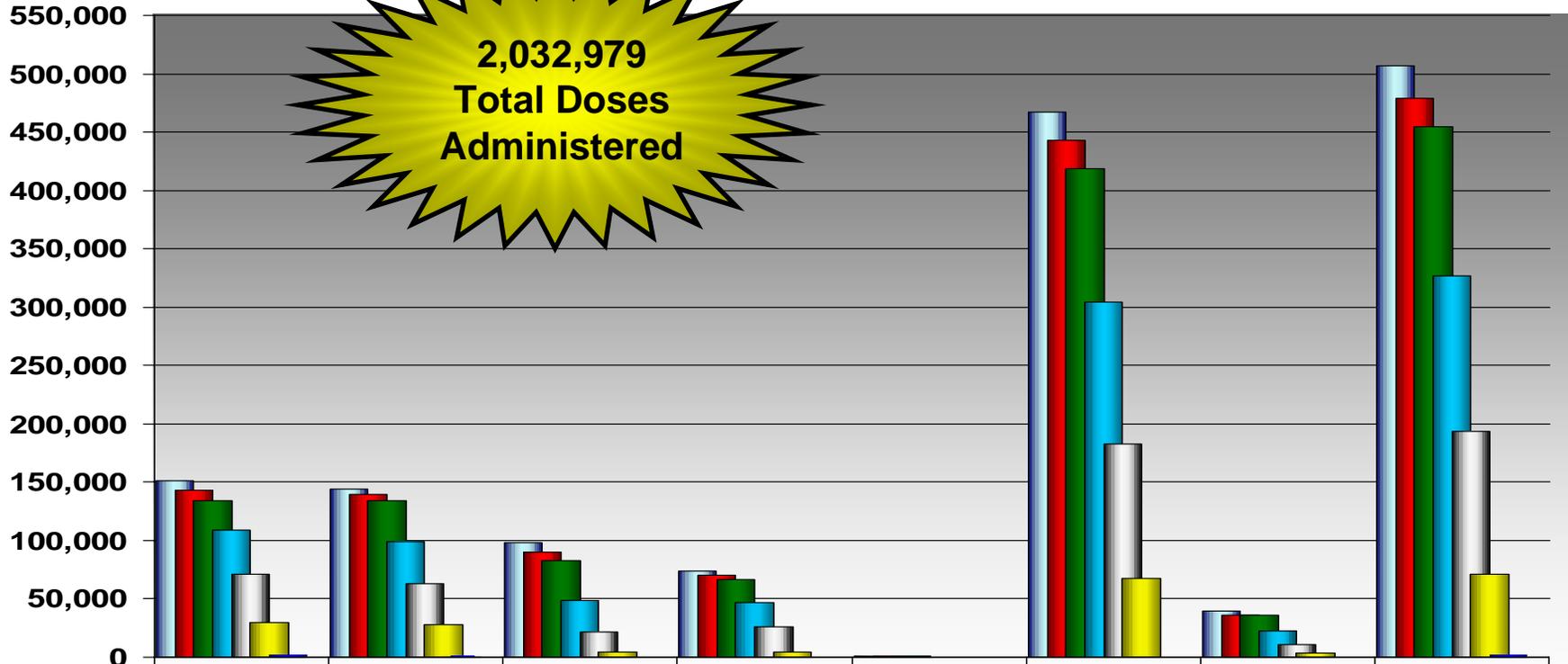


- **Force Immunization Status**
- **Program Slowdown**
- **BioPort Update**
- **Vaccine Stockpile, Availability, and Distribution**
- **Concept of Execution**
- **VAERS**
- **Vaccination Refusals**
- **Lessons Learned**
- **Research Initiatives**
- **Communications and Education**



Total Force Anthrax Immunization Status

**2,032,979
Total Doses
Administered**

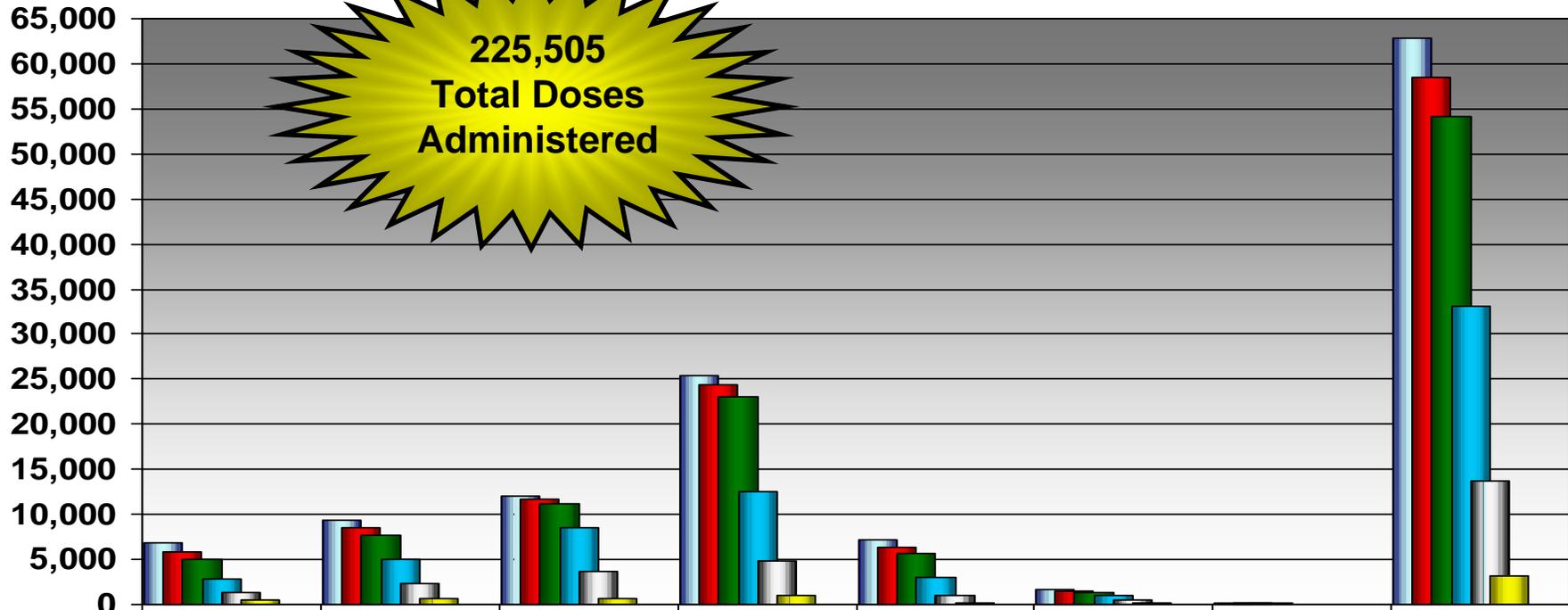


	ARMY	AIR FORCE	NAVY	MARINES	COAST GUARD	TOTAL (active program)	ARCHIVED IMMUNIZATIONS	TOTAL IMMUNIZATIONS
DOSE #1	151,328	144,417	97,863	73,416	575	467,599	39,186	506,785
DOSE #2	143,331	139,177	89,621	70,241	544	442,914	35,670	478,584
DOSE #3	134,519	133,831	83,149	66,489	514	418,502	35,690	454,192
DOSE #4	109,072	99,157	48,725	47,162	342	304,458	22,221	326,679
DOSE #5	71,092	63,108	21,596	26,494	135	182,425	11,105	193,530
DOSE #6	30,011	28,254	4,920	4,427	20	67,632	3,422	71,054
BOOSTER	1,487	620	1	0	0	2,108	47	2,155
TOTAL	640,840	608,564	345,875	288,229	2,130	1,885,638	147,341	2,032,979

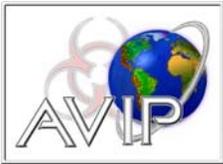


Reserve Components Immunization Status

**225,505
Total Doses
Administered**



	USAR	ARNG	USAFR	ANG	NAVRES	MARFORRES	USCGR	TOTAL
DOSE #1	6,845	9,390	12,083	25,402	7,243	1,731	142	62,836
DOSE #2	5,844	8,534	11,704	24,427	6,365	1,542	133	58,549
DOSE #3	4,984	7,744	11,242	23,064	5,636	1,413	120	54,203
DOSE #4	2,827	5,020	8,571	12,612	3,008	952	66	33,056
DOSE #5	1,372	2,411	3,681	4,857	951	431	2	13,705
DOSE #6	435	681	733	987	139	127	0	3,102
BOOSTER	12	20	7	15	0	0	0	54
TOTAL	22,319	33,800	48,021	91,364	23,342	6,196	463	225,505

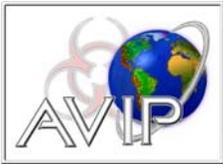


Recent AVIP Slowdown

- **Vaccine-supply shortage requires orderly, temporary slowing of AVIP**
- **Vaccinations to continue for personnel assigned/deployed at least 30 days in highest-threat areas (SWA only) other personnel deferred**
- **Next scheduled doses for other personnel to be deferred pending vaccine availability**
- **Other Force Health Protection measures--protective gear, biological-agent detectors, antibiotic treatment will help protect at-risk personnel**

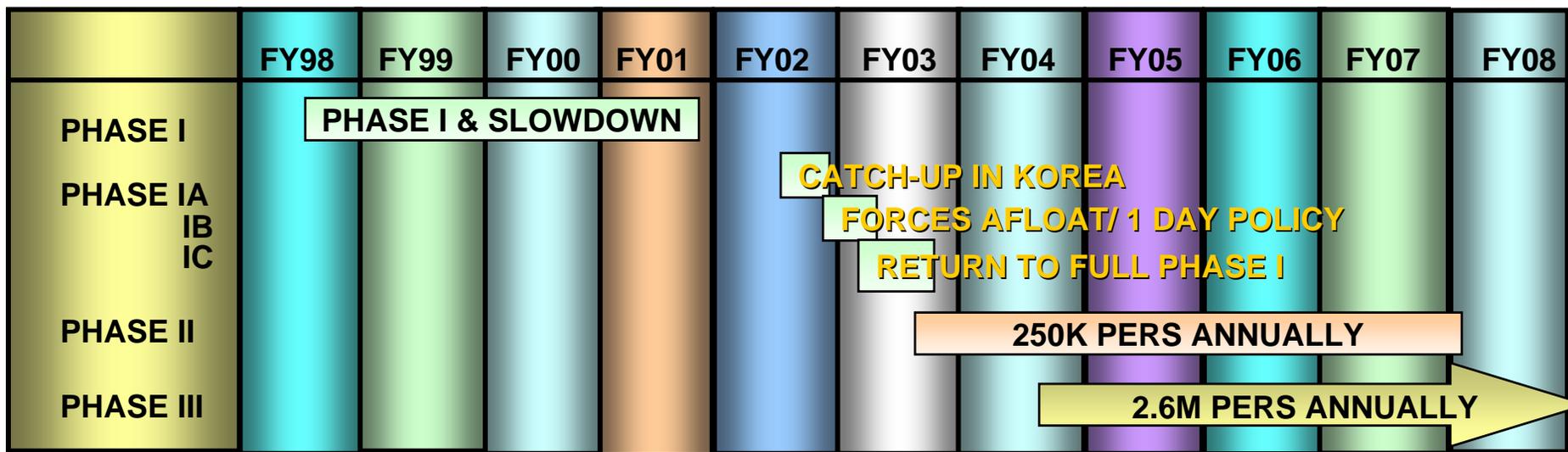


- **No new vaccine available from BioPort's renovated anthrax vaccine (AVA) production suite until FDA approves BioPort's Biologic License Application (BLA) supplement.**
- **Approval of BLA is iterative and complicated process--FDA considers both:**
 - ◆ Renovation of anthrax vaccine production suite
 - ◆ Validation of vaccine production process
(DoD estimates FDA approval/new lot release by Feb 02)
- **AVA stockpile doses update as of 6 Apr 01:**
 - ◆ Approx 25K FDA-released doses available
- **Bottom Line: Current and projected stockpile doses required additional temporary AVIP slowdown vaccinating just SWA; program run-out estimated to be Sep 01 w/no additional FDA-released doses**



Return to Full Phased Execution

- **PHASE IA:** Catch up in High Threat Area Korea (Trigger = BLA Approval)
 - IB:** Forces afloat & return to “1 Day Policy” (Trigger = Assured Prod)
 - IC:** Catch up in CONUS/ return to Phase I (Trigger = Assured Prod)
- **PHASE II:** Starts only after “assured production” of vaccine is guaranteed by BioPort/FDA approval and all deferred vaccinations are up to date. 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





Form VAERS-1 Reports

As of **19 April 2001**

506,785 people had been vaccinated with **2,032,979** doses of anthrax vaccine.

Reports Reviewed by the Anthrax Vaccine Expert Committee (AVEC)^a

Total Unique Form VAERS-1 Reviewed Through 03 Apr 01 ^b	Reports Other Than Serious (no loss of duty =/>24 hrs nor hospitalized)	Loss of Duty =/>24 hours (not hospitalized)	Hospitalized	
1530^c	1329	146	55	Total Reports
806	709	86^d	11^e	Certainly or probably caused by anthrax vaccine

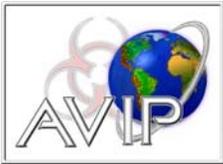
^a AVEC, a panel of civilian academic medical experts sponsored by the Health Resources & Services Administration of the U.S. Department of Health & Human Services, meets every 4 to 6 weeks.

^b VAERS-1 forms record events that happen after vaccination. Some events are caused by the vaccine, some are not.

^c Excludes 20 duplicate reports for a total of 1550 VAERS-1 forms reviewed; represents VAERS-1 forms for 1472 individuals.

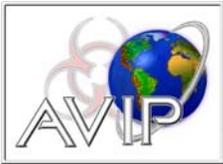
^d Includes injection-site reactions (50), acute allergic reaction (9), rash (9), “flu” like symptoms (8), gastroenteritis (2), myalgia (2), pruritus (2), bronchiolitis obliterans (1), paresthesia (1), photophobia (1), swollen lymph node (1)

^e All eleven were allergic, inflammation reactions at injection site.

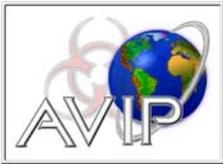


Anthrax Vaccination Refusals

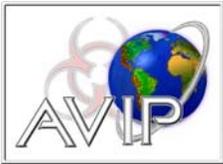
- **Services currently have had no formal reporting requirement**
- **By informal surveys, 441 DoD total refusals as of Aug 00:**
 - ◆ USA 71
 - ◆ USAF 129
 - ◆ USMC 86
 - ◆ USN 155
 - ◆ USCG 0
- **DoD Anthrax Vaccination Refusal Reporting Policy in draft; currently in staffing with Services**
 - ◆ DoD believes needed for better AVIP management, execution
 - ◆ GAO recommends
 - ◆ NDAA 01 requires
- **For service members refusing vaccinations, commanders take action, administrative and/or under the Uniform Code of Military Justice, case by case, based on individual merit.**



- 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



- **Completed:**
 - ◆ **Efficacy: 1 human, multiple animal studies**
 - ◆ **Safety: 13 human studies, > 366,000 recipients**
- **Underway, in Preparation:**
 - ◆ **Manuscripts describing completed studies**
 - ◆ **Add'l safety studies: longer follow-up of active-duty, former employees, tracing long-ago recipients, etc.**
 - ◆ **Animal studies for correlates of immunity**
 - ◆ **CDC-DoD route-change / dose-reduction study**
 - ◆ **Evaluation of risk-communication methods**
- **In Development:**
 - ◆ **Very long-term surveillance project (DoD / DVA)**



- **DoD AVIP Internet web site:** www.anthrax.osd.mil
- **Toll-free information line:** **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@amedd.army.mil
- **Message mapping per Risk-Comm Research**
- **Distributive training products**
 - New quadfold on web site 30 Sep 00
 - Program-overview videotape
 - Silent training aids
 - Interactive multimedia CD-ROM, early FY02