

ARMED FORCES EPIDEMIOLOGICAL BOARD

* * * * *

* * * * *

THE THAYER HOTEL
674 THAYER ROAD
WEST POINT, NEW YORK

* * * * *

* * * * *

WEDNESDAY, SEPTEMBER 18, 2002

* * * * *

NEAL R. GROSS
COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

BOARD MEMBERS :

STEPHEN M. OSTROFF, M.D., President
S. WILLIAM BERG, M.D.
DOUGLAS CAMPBELL, M.D.
JACQUELINE CATTANI, Ph.D.
BARNETT L. CLINE, M.D.
PIERCE GARDNER, M.D.
GREGORY C. GRAY, M.D.
L. JULIAN HAYWOOD, M.D.
JOHN HERBOLD, DVM
GRACE LeMASTERS, Ph.D.
LEON S. MALMUD, M.D.
KEVIN M. PATRICK, M.D.
GREGORY A. POLAND, M.D.
DENNIS F. SHANAHAN, M.D.
ROBERT E. SHOPE, M.D.

LtCOL. RICK RIDDLE, USAF
AFEB Executive Secretary

PREVENTIVE MEDICINE OFFICERS :

LtCOL. KELLY WOODWARD, AFMO
COL. BENEDICT DINIEGA, MC, USA
LtCOL. MAUREEN FENSOM, CFMS
CDR. SHARON LUDWIG, USPHS
COL. J. GUNZENHAUSER, MC, USA
CAPT. K.W. SCHOR, MC, USN
CAPT. ALAN J. YUND, MC, USN
COL. MICHAEL STAUNTON, L/RAMC

DESIGNATED FEDERAL OFFICIAL :

DR. KILPATRICK

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

A G E N D A

	<u>PAGE</u>
Opening remarks	
- Dr. Ostroff	4
- Dr. Kilpatrick	4
- LtCol. Riddle	5
Annual Ethics Training	
- Maj. Thomas Serrano	7
DOD Influenza Surveillance	
DOD Joint Influenza Surveillance Working Group	
- Col. Neville	25
Discussion	
AVIP Update	
AVIP Update - Col. Dana Bradshaw	
- Anthrax Vaccine Program	56
- Smallpox Preparedness	77
Question to the Board	
Screening Interval for HIV Testing	
in the Military	
- Ms. Lynn Pahland	111
DOD HIV Epidemiology - LtCol. Rubertone	114
Operational Requirements for HIV Testing	
- LtCol. David Jones	151
Discussion	159
Service HIV Testing Programs	
Army - Col. Guzenhauser	179
Navy - Capt. Schnepf	192
Air Force - LtCol. Woodward	211

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 As the Designated Federal Official of the Armed
2 Forces Epidemiological Board, a Federal Advisory Committee to the
3 Secretary of Defense, which serves the continuing scientific
4 advisory body to the Assistant Secretary of Defense for Health
5 Affairs and the Surgeons General of the Military Departments, I
6 hereby call this session of the Autumn 2002 meeting to order.

7 DR. OSTROFF: Thank you. Col. Riddle.

8 LtCOL. RIDDLE: I have just a couple
9 administrative remarks. If the Board members would please sign
10 the 1352s, your Travel Settlements, and get those back into Jean
11 after you return, and then we can process the payments. And,
12 also, when you get your payment voucher, if you could give her a
13 copy of that. That's the only way she has to track the actual
14 expenditures from the projected expenditures that we have.

15 Also, when you leave today, if you could turn your
16 name tags in to Lisa, and then we'll have those for you again at
17 the February meeting. If you have any taxi needs or
18 transportation needs or anything, please see Lisa or Karen and
19 we'll take care of those.

20 Also, we do need you to sign in again today for
21 the members here and the folks in the audience. We'll have
22 refreshments both this morning and this afternoon and, again, I
23 want to thank Jean and Lisa and Karen for all the support that
24 they provide us, and the speakers and the members for being here.

25 Thanks.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 DR. OSTROFF: Thanks, Rick. Our first
2 presentation is one that's a requirement, and we have Maj. Tom
3 Serrano, from the Army JAG, that will present to us about
4 standards of conduct and conflict of interest.

5 MAJ. SERRANO: Thank you very much. Just a couple
6 of things. I think better when I walk around, and so as
7 distracting as it might be to some of you, I'm just going to move
8 about here a little bit.

9 DR. OSTROFF: Unfortunately, since everything is
10 being transcribed, you have to be somewhere near a microphone,
11 and your alternative is to take one of them from --

12 MAJ. SERRANO: How's that? Is that better? I
13 can't think if I can't move, so if I'm stuck there I can't do
14 anything.

15 LtCOL. RIDDLE: Tom's slides are at Tab 7 in your
16 notebooks.

17 MAJ. SERRANO: Thank you very much for having me,
18 sir, and Dr. Riddle.

19 (Slide)

20 What I'd like to do this morning is talk to you about conflicts
21 of interest. We have about 20 minutes and, as most of you know,
22 that's not nearly enough time. And so what I'd like to do is
23 just touch on some of the highlights and major topics that you
24 probably will encounter during your time on the Board.

25 I'd like to highlight on the first slide there,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 our phone number. Since we are the retail advisor for the Board,
2 please feel free to call us at anytime. And I'd also like to
3 give you my personal phone number. It's Area Code 703-588-6717.
4 Please feel free to call me at anytime. I'd be happy to either
5 work directly with you or through Dr. Riddle, to get you any kind
6 of ethics support that you need while you are serving on the
7 Board. Why don't we just move on.

8 (Slide)

9 The thing I'm going to talk about this morning is
10 the ethics issues that most of you will encounter, which is
11 conflicts of interest in the financial realm. I also will touch
12 a little bit about conflicts of interest in your duties, but
13 mainly because all of you have to fill out, as Special Government
14 Employees, the OG Form 450. I'm going to talk a little bit about
15 conflicts of interest in the financial sense -- that is,
16 conflicts you may have with ownership of stock or the duties that
17 you perform. And this came about a long time ago because in the
18 late '70s and early '80s many of the scandals that we had with
19 Government employees having other interests that actually
20 affected or appeared to affect the performance of their
21 Government duties. And so back in the '80s, Congress came down
22 and enacted lots of conflicts of interest laws that are now at
23 Title 18 U.S. Code, that impact how we perform our duties. And
24 they are rather restrictive, and that's also why I'm here giving
25 this bloc of instruction. Next slide, please.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 (Slide)

2 I've got the actual criminal standard up there, 10
3 U.S.C. 208 regarding financial interest, and I'll let you read
4 that a little bit, but what I really want to do is go through a
5 little bit of the definitions for you. I'm going to read you the
6 formal definitions, then just give you examples of what or how
7 that might come to affect you.

8 The Federal statute means that if you have a
9 financial interest, it may prevent you from being entirely
10 objective in carrying out the official duties of your Government
11 post. Whether or not you are honest or not is not relevant. I
12 mean, it is relevant, but it doesn't really affect the law since
13 there is no honesty test. The fact that you may not be the final
14 decisionmaker is also not relevant with regard to the statute.

15 So, just to give you some of the definitions here,
16 "personally and substantially participate". To participate means
17 decision approval, a recommendation, an investigation, or
18 rendering advice, and this is a very low threshold, it's
19 virtually any action. I mean, obviously, there are some very
20 peripheral actions that you may take regarding a matter that
21 would not rise to this level, but essentially, if you are working
22 on something, you meet the test.

23 To participate personally means directly and
24 includes the participation of subordinates when actually directed
25 by Government employees.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Substantially means the employee's involvement
2 must be of significance to the matter, or form a basis for a
3 reasonable appearance of such significance it requires more than
4 official responsibility, knowledge, perfunctory involvement, or
5 involvement on an administrative or peripheral issue.

6 The find of substantiality shall be based not only
7 on the effort devoted to the matter, but also on the importance
8 of the effort. While a series of peripheral involvements may be
9 insubstantial, the single act of approving or participating in a
10 critical step may be substantial. Next slide, please.

11 (Slide)

12 Regarding a particular matter, a particular matter
13 is one that is focused upon the interest of a specific person's
14 or a discrete and identifiable class of persons, does not extend
15 to broad policy options or considerations directed toward the
16 interests of a large and diverse group of personnel.

17 Direct and predictable effect, a particular matter
18 will have a direct effect on a financial interest if there is a
19 close causal link between any decision or action in the official
20 matter, and any expected effect of the matter on the financial
21 interest. A predictable effect, if there is a real as opposed to
22 a speculative possibility that the matter will affect the
23 financial interest. The magnitude of the gain or loss does not
24 need to be known. The dollar amount of the gain or the loss is
25 immaterial. Next slide, please.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 (Slide)

2 I'd like to give you just an example of how this
3 normally comes up. For example, if one of you is a member of ABC
4 Corp. and you have ABC stock, if you are discussing matters
5 within the Board's area of responsibility that will directly
6 affect ABC Company or the value of its stock, then you would have
7 an actual conflict of interest. Next slide, please.

8 (Slide)

9 This interest can also be imputed to others --
10 spouse and minor children, if they own stock; general partners,
11 or non-Federal entities -- that is, the company you work at,
12 something that is non-Governmental -- where you are an officer or
13 director. Next slide, please.

14 (Slide)

15 Next slide, please.

16 (Slide)

17 Here are the main ways you deal with conflicts,
18 and I'm getting into very general terms here. There are many
19 exceptions. There are many regulatory waivers, and there are
20 also individual waivers. And so I'm not going to cover each and
21 every exception that's possible, but I will highlight some of the
22 big ones for you.

23 First of all, disqualification. Many of you, or
24 at least some of you, may be familiar with the Statement of
25 Disqualification, and that is a procedure where you actually fill

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 out or do up a memorandum, you explain your interest, and you
2 essentially vow to disqualify yourself from the interest.

3 Now, it is not necessary to actually do one of
4 these statements to disqualify yourself because you automatically
5 are disqualified from the get-go. The statement itself is
6 evidence of that disqualification, but if you have a conflict of
7 interest, you are disqualified automatically, and the fact that
8 you do or do not do the piece of paper does not make you any more
9 or less disqualified. But there are a lot of exceptions, and so
10 disqualification of yourself from the matter is not always the
11 correct solution although, if it is not acceptable, then that is
12 one of the solutions, or one of the few that are available.

13 Reassignment. I know that you may come to a
14 situation that I described, and so you may be just precluded from
15 acting on the matter within the Board. You may be excused from a
16 session, you may be excused from a mode or official action on the
17 matter, that is one option.

18 Divestiture. Divestiture would be if you are to
19 actually sell your stock or sell your interest in that matter.
20 Now, I know those of you who are civilians in here, are Special
21 Government Employees, you are not going to quit your job just to
22 satisfy that requirement of the Board. And so that's generally
23 not going to be an option, but for Government employees or other
24 employees with just a peripheral interest in that stock, selling
25 that stock may be an option.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Change of duties. Waivers. There are a couple of
2 different kinds of waivers that you can do. First of all, the
3 type of waivers that are regulatory in nature actually come out
4 of the Code of Federal Regulations. Some of the common ones I'd
5 like talk about.

6 Regarding stock interest, there are exceptions for
7 interest in Mutual Funds. For those of you who own Mutual Funds,
8 they are normally very widely diversified, and so the fact that a
9 Mutual Fund owns a particular stock does not disqualify you in
10 the matter just by the fact that you own that particular Mutual
11 Fund as opposed to owning the individual stock.

12 There are special rules for Sector Funds, or those
13 funds that may invest in a particular area. Let's say you have a
14 Sector Fund that invests in information technology, and you
15 happen to be doing a contract with the Government on a new
16 information technology system. The fact that the information
17 technology fund, that would prohibit you from owning that
18 particular fund but, for example, if you owned a biotech fund
19 that happened to invest in a couple of communications funds, that
20 would not be a conflict of interest. So, owning Sector Funds, if
21 they deal in that particular area, would be a conflict, but
22 owning a Sector Fund that dealt in a different area but owned
23 just on the periphery some other stocks would be a conflict.

24 There is also a dollar amount exemption. If you
25 happen to own stocks in the amount of \$15,000 or less for a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 particular item, that would be an exception and you would not
2 have to get rid of your interest in the stock or otherwise
3 disqualify yourself for owning \$15,000 or less.

4 Have all of you filled out your 450s, could I get
5 a show of hands if you are familiar with the 450s?

6 (Show of hands.)

7 Many of you have seen this. If you haven't seen
8 it, you will see it, the OG Form 450s, and so you will see a lot
9 of the disqualifications, a lot of the exceptions, when you fill
10 out the 450, and also you will be dealing with Dr. Riddle and
11 myself on making sure that those 450s are all squared away. I
12 know it's a headache, I apologize for that, but welcome to
13 Government.

14 There are also individual waivers available, and
15 there are special waivers available for Special Government
16 Employees. I'm not going to go into the Special Government
17 Employee waivers because, as a condition to your appointment
18 here, ordinarily you get scrubbed for conflicts of interest from
19 the outset, and so there are -- nobody here, I believe, has been
20 appointed with a conflict of interest that's direct and relevant
21 to the issues. Next slide, please.

22 (Slide)

23 The appearance of conflict. A lot of times, you
24 don't have an actual conflict, but you do have situations where
25 you might have a relative that isn't your spouse or dependent

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 child, that works for a particular company that the Government is
2 dealing with, so although there may not be a direct conflict,
3 there may be an appearance of conflict there. And so the
4 appearance of conflict can be virtually as bad as an actual
5 conflict. Next slide, please.

6 (Slide)

7 However, the test here is whether a reasonable
8 person in possession of all the facts would actually consider a
9 conflict of interest to be present. So, the test isn't
10 necessarily will your name end up in the Washington Post, the
11 test is more would a reasonable reporter who works for the
12 Washington Post, with all the facts, decide to print it. Let me
13 give you an example.

14 Let's say, for example, that you are a Government
15 employee and you are dealing with a contract with XYZ
16 Corporation, and your brother happens to be the Chief Financial
17 Officer for XYZ Corporation. Now, just knowing that, it sounds
18 pretty clear that it's at least an appearance of a conflict of
19 interest. However, if you are estranged from your brother and
20 you've had no contact with your brother for 20 years, you have
21 possession of those reasonable facts, it's pretty clear that
22 there would not be a conflict of interest. Just by the mere fact
23 that the person is your brother does not mean you have some kind
24 of close relationship. Next slide, please.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 There are some examples of "covered
2 relationships", like I talked about a brother, actually a brother
3 would be a little too close but, say, an uncle or something,
4 places where you have been an officer, employee or consultant
5 during the last year, so on or so forth. Next slide, please.

6 (Slide)

7 Next slide, please.

8 (Slide)

9 The resolution of appearance issues is done
10 ordinarily through your supervisor. There are no regulatory
11 waivers like we talked about with stock interests or financial
12 interests, it's just a determination by your supervisor, your
13 Government supervisor, that there is no appearance of a conflict.

14 There are procedures for that, obviously, but you disclose all
15 the facts or circumstances surrounding the issue, and then
16 ultimately your supervisor makes a determination whether or not
17 there is an appearance issue. Next slide, please.

18 (Slide)

19 18 U.S.C. 205, I want to touch briefly on this
20 because it is also relevant. In your capacity, those of you who
21 are Special Government Employees, if you are working for the
22 Government on, let's say, a widget project, you cannot go back to
23 your company and represent widgets back to the Government or deal
24 with widgets. That's a very narrow exception. However, let's
25 say, for example, that your company is dealing with -- there's a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 matter with widgets pending before the Government, although you
2 didn't discuss it directly. If you were a Government employee
3 for 60 days or less within the preceding 365 days, then you are
4 permitted to deal with widgets back to the Government.

5 And so I'm not sure exactly if that deals with
6 anybody in the room here, but from what I'm told most of you are
7 Government employees for less than 60 days, those of you who are
8 civilians, and so if you deal with -- just peripherally or in
9 general terms, deal with widgets here on the Board, you are
10 permitted, once you go back to your company, to also deal with
11 widgets or represent them back to the Government if you've been
12 an employee for 60 days or less. However, if you deal directly
13 with widgets in the Board, there is essentially a lifetime ban on
14 making representations back to the Government in dealing with
15 widgets.

16 Now, you can work behind-the-scenes at your
17 company, or do any of those things, but you could not directly
18 come back to represent your company to a Government employee and
19 deal with widgets. Next slide, please.

20 (Slide)

21 I think if you get absolutely nothing else out of
22 my presentation -- and I know it was rather short -- it's
23 important that you at least know the points of contact. As I
24 said, Dr. Riddle would be your primary point of contact.
25 However, if you do have a question, I'm acting as your Ethics

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Counselor, so feel free to give me a call if there's a specific
2 matter that you need to talk about dealing with your employment
3 as a Special Government Employee, or for those of you who are
4 uniform, if you have issues in dealing with you particularly,
5 please give me a call and I'll be happy to discuss that issue
6 with you.

7 I know I'm just a little bit early here, but I
8 know we're trying to stay on schedule. So, at this time, I'd
9 like to turn it back over to Dr. Riddle, and if you have
10 questions, please feel free to ask now, or you can see me during
11 the break, or whatever. Thank you.

12 DR. OSTROFF: Maj. Serrano, thank you very much
13 for the presentation and for staying on schedule.

14 I do have a question for you because this is an
15 issue that's come up in regard to Board membership a couple of
16 times, and that is that we previously had some very valuable
17 members of the Board -- and many that are on the Board may recall
18 that this issue arose -- that at the time they were nominated
19 were not working for private industry, and then subsequently took
20 positions with private industry, and there was a determination
21 made that that basically precluded them from being members of the
22 Board.

23 What is the current perspective on that issue?

24 MAJ. SERRANO: Sir, was it actually the fact that
25 they took a position in private industry, or was it the fact of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 that specific job that they took?

2 DR. OSTROFF: Well, they took positions with the
3 pharmaceutical industry, and it was felt that since many of the
4 issues that come before the Board potentially have either a
5 vaccine or antibiotic or potentially other medication
6 association, that that would pose an ongoing potential conflict
7 of interest.

8 MAJ. SERRANO: Sir, I would say that issue is
9 unchanged in that regard. I can't really speak to all of the
10 policymaking decisions as far as the appointments of the
11 individuals because that is a little bit above my Division, that
12 would take place actually at the Secretariat level. However, I
13 can tell you that that is essentially the major thrust of the
14 conflicts of interest, and that is if your company produces X-
15 vaccine and X-vaccine is often talked about within the purview of
16 the Board membership, then although you may get very helpful
17 information from that particular person, there is a determination
18 made on a policy level that that person will be excluded from so
19 many discussions that their membership on the Board would be
20 unhelpful, as a whole.

21 Now, I didn't want to get too deep into the
22 waivers. There is a waiver available for the Secretary to use in
23 the event that somebody is conflicted, and that is actually a
24 statutory exception that the Secretary can make, and make a
25 determination that this person's participation in the Board is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 just so important that they are going to essentially waive the
2 conflict and let that person be permitted to serve on the Board.

3 From what I understand, in speaking with Col. Chandler and Al
4 Novotny (phonetic), who many of you have dealt with before, that
5 waiver is not often exercised just because of the policy
6 considerations in conflicts of interest. However, I do -- I want
7 to let you know that if you feel a person's participation is that
8 vital to the Board's doing its business, then there is a waiver
9 available for you.

10 DR. OSTROFF: Thanks. Any other questions?

11 DR. SHOPE: I wonder if you could speak to the
12 question of the emoluments clause in the Constitution, and I
13 understand that we are prohibited by that clause from accepting
14 travel or per diem from a foreign government.

15 MAJ. SERRANO: The question is foreign government
16 payments to you? Sir, what is your particular status?

17 DR. SHOPE: I'm an SGE, I'm on the Board.

18 MAJ. SERRANO: Okay. Ordinarily, while you are in
19 Government service, that is correct, you can't receive payments
20 from any kind of foreign entity. In fact, we have also rules
21 that require Secretary of the Army waiver for ordinary Government
22 employees once you are retired from actually working for a
23 foreign government as well, without Secretary of the Army
24 approval. And so as far as I know -- and I'm relatively new to
25 the area -- when you are not acting in your capacity as a Special

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Government Employee, many of the rules do not apply.

2 And so I really can't speak to you regarding that.

3 I can get back to you on that issue in your capacity as an
4 ordinary civilian, however, regarding your capacity as a Special
5 Government Employee, that's correct.

6 DR. OSTROFF: Other questions?

7 LtCOL. RIDDLE: Just to clarify, that's only while
8 they are serving as a Special Government Employee?

9 MAJ. SERRANO: That's correct.

10 LtCOL. RIDDLE: While you are not in SGE status,
11 those rules wouldn't apply. So, when you are in normal day-to-
12 day duty, you could accept that gratuity for the payment for
13 travel or participation?

14 MAJ. SERRANO: Yes. I'm not aware -- I don't know
15 all the rules regarding the civilian world, I'm only speaking to
16 your status --

17 DR. SHOPE: Could you find out for us?

18 MAJ. SERRANO: Yes, I can, absolutely.

19 DR. OSTROFF: Dr. Poland?

20 DR. POLAND: Just to clarify, do you mean these
21 four days that we're functioning as an SGE, or do you mean the
22 two-year term in which you're an SGE?

23 DR. OSTROFF: No, the four days.

24 MAJ. SERRANO: It would be the time -- to clarify
25 what time I'm speaking about, it's the actual time that you serve

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 as a Government employee doing duties pursuant to -- the fact
2 that you may be on-call is not really -- you're not really acting
3 as a Government employee in that time. Although you are subject
4 to doing your duties, you are not an actual Government employee
5 during that period of time.

6 DR. OSTROFF: I would say that there are
7 occasionally instances where you perform as a representative of
8 the Board -- for instance, some of the things that John Herbold
9 did in between meetings, when he was working on the PAVE PAWS
10 issue, would be considered actual time that he was exercising his
11 SGE responsibilities, but if you are at Mayo or have some
12 relationship with the British Government that you're dealing
13 with, or something like that, that's outside the scope of the
14 Board.

15 Thank you, Major. Why don't we go ahead and move
16 on. Our next presentation is from Col. Neville, and I'll just
17 say he's from the Air Force because, seemingly, every year or two
18 the name of the organization that he works for seems to change.
19 So, I guess it's still AFIERA, and he's going to bring us up to
20 speed on where things stand with pandemic planning. This is at
21 Tab 8.

22 COL. NEVILLE: I feel privileged to be here, and I
23 want to make it clear that what I'm going to present is not my
24 work, it's the work of many people and organizations. So,
25 hopefully that will be clear. I wasn't even sure what emblems to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 use on the slide, but I stuck with what I know.

2 First, I'll describe just a very brief history of
3 the Influenza Surveillance Program, and then a few highlights,
4 and then describe each of the pieces of the program with their
5 results. Next slide, please.

6 (Slide)

7 Most of the Board and audience, I'm sure, is aware
8 of the DOD Surveillance Program. It was started in 1976 as
9 Project Gargle, by the Air Force, and has proceeded every year
10 since then, pretty much, but in 1998 it was expanded and enhanced
11 under the auspices of DOD Global Emerging Infections Surveillance
12 and Response System, which funds a large part of this effort at
13 this point.

14 In 1999 -- there should be a copy of that Health
15 Affairs letter in your packets -- Health Affairs officially
16 designated the Air Force Surgeon General as the Executive Agent
17 for influenza surveillance, and these other tasks are outlined in
18 that letter, I don't need to go through each one of them. That
19 last bullet there, "Reports to the AFEB at least annually", is
20 being accomplished even as I speak. And the next four slides
21 just a few selected highlights of the program. Next slide,
22 please.

23 (Slide)

24 The bottom here is just for the last three years,
25 and the numbers of Influenza A and B isolets that are found.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Back in May of '99, an isolet was discovered from Peru that ended
2 up being the same as the New Caledonia isolet, which was evidence
3 that that strain was more widespread than previously known, and
4 that discovery led to that particular strain being included in
5 the vaccine. Next slide, please.

6 (Slide)

7 A more local DOD interest, in July -- which is a
8 little bit of an odd time -- in July of '99, Influenza A was
9 identified at Lackland Air Force Base, and that allowed them,
10 naturally, to administer pertinent effective preventive measures.

11 Next slide, please.

12 (Slide)

13 There was an outbreak in Panama and, as I recall
14 being told the history, at the request of the CDC we were able to
15 get specimens from Panama where Howard Air Force Base was just
16 about closed, but just before the last person left they got some
17 isolets, and that ended up being an isolet that was -- because of
18 its growth characteristics, was used in the next three years'
19 vaccine as a CCC virus. Next slide, please.

20 (Slide)

21 More recently, a surveillance site was
22 established, with the help of DOD guys, in Uganda, and we haven't
23 received any specimens from there yet, but we're expecting some.

24 So, those are just four of the highlights. And none of these
25 things, obviously, could occur without that day-to-day, year-to-

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 year ongoing surveillance effort, which sometimes is kind of
2 boring because you get the same stuff and so on, but you never
3 know when a highlight will show up. Next slide, please.

4 (Slide)

5 There are three pieces of the DOD Influenza
6 Surveillance Program, two main components, and I'll describe this
7 briefly and then show some of the results or data.

8 The first one is the population-based component,
9 and that's really febrile respiratory surveillance, not
10 specifically influenza surveillance, and that's managed by the
11 Navy Health Research Center at San Diego, and they focus on
12 trainee populations in the DOD.

13 The next one is the etiology-based program or
14 piece managed at Brooks Air Force Base, which is really just
15 rolling for bugs, trying to get isolets from around the world,
16 and I probably should have put interactions with CDC above as
17 well under NHRC, I just don't know the extent of their
18 interactions as well as I probably should.

19 And the etiology-based program, which we'll see in
20 a moment -- and there's a map -- which has sentinel sites, but we
21 also get specimens from non-sentinel as well as at Brooks, and
22 those are in actuality in the surveillance thing.

23 And the Army MEDCENS each do viral cultures,
24 clinical cultures requested by the Docs in their day-to-day
25 clinical care, and that's not designed as a surveillance program,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 but we use the results of those clinical specimens and try to
2 roll those up into the overall picture of influenza in the DOD.

3 ;Next slide, please.

4 (Slide)

5 First, I'll just show -- this is the only slide I
6 have from the Army MEDCEN data, then I'll show some NHRC stuff,
7 and then some stuff from Brooks.

8 This is just the total respiratory pathogen
9 respiratory cultures sent to the Medical Centers labs, and the
10 results of them. This comes to us in an Excel spreadsheet from
11 each of the Medical Centers through the AMSI. We don't have
12 (inaudible) on there because the culture source wasn't clear, and
13 there were no influenza isolets anyway, so I just left that off.

14 If there are no questions, I'll go to the next
15 slide.

16 (Slide)

17 This is NHRC's population-based program. These
18 are the sites that they do surveillance on the trainees there.
19 They collect incidence of febrile respiratory illness and
20 population denominators so they can calculate the rates, and
21 systematically proportionately sample those with FRIs, and those
22 cultures are sent to San Diego and then they can do pathogen-
23 specific rates and so on. Next slide, please.

24 (Slide)

25 This is the results from those training sites.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 You'll see, obviously, there's a large proportion of adenovirus
2 because these are training sites, and that's a problem at those
3 training sites. Not very much influenza, but there's a few
4 scattered in there.

5 And Brooks and NHRC share isolets from time to
6 time, when necessary, whether it's adeno or influenza or
7 whatever, so pretty good working relationship there. Next slide,
8 please.

9 (Slide)

10 And one more -- this is actually influenza
11 infection rates at the sites, and it's seasonal peaks. Each year
12 is a little bit different, each site is a little bit different.
13 Next slide, please.

14 (Slide)

15 This will describe how the Air Force at Brooks
16 managed a piece of the puzzle. Go ahead and advance it a bunch
17 of times, I don't have to go through all of this. I probably
18 should have taken off some of this. Stop there for a second.

19 (Slide)

20 At Brooks, the epidemiology and lab people provide
21 input to the Surgeon General's Office to a varying degree, and
22 the Surgeon General's Office sends the annual message to the
23 sentinel sites and all the bases, but the sentinel sites
24 specifically have instructions in identifying who they are and
25 what they are supposed to do.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Brooks also sends the collection kits and the
2 supplies to those sentinel sites so they don't have any problem
3 with that. Those are then collected by the providers and the
4 clinics and so on, and sent to the Brooks Virology Lab. Those
5 results are sent back to the providers like any clinical specimen
6 would, whether it's a project at a surveillance site or a
7 nonsentinel site that's just a clinical specimen, and those
8 results are analyzed and so on.

9 And reports are sent everywhere. And Army and
10 Navy impute, based on the results that we get from the MEDCENS
11 and so on, and NHRC go into the whole analysis and reporting.
12 And selected isolates are sent to CDC, and there's a lot of
13 interaction with sequencing and all this stuff that's above my
14 understanding, but they share that quite a bit. And Linda,
15 Kannis (phonetic), if everybody knows her, she's been briefing
16 the VRBAC Committee on the results of the DOD surveillance, I
17 guess for three years now.

18 (Slide)

19 So, these are the sentinel sites, the Air Force
20 manages these. The choice of these evolved over many years, but
21 the idea is to focus on overseas cases, if possible, and the
22 overseas labs, like in Nepal up there, you can see in Thailand.
23 The stars don't quite exactly match geography, but that's
24 Thailand and Nepal, and South America, with the help of the
25 overseas labs. There's that one yellow star -- the yellow star,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 that's the Uganda site. It's yellow because we haven't received
2 anything from there yet, but hopefully soon.

3 And out there, that's Hawaii, which is Army and
4 Navy and Air Force sites there.

5 DR. OSTROFF: You may want to be more careful
6 where you put your stars, it looks like there's one in North
7 Korea.

8 (Laughter.)

9 COL. NEVILLE: Yeah, that's not intended. There's
10 three in Japan and two in South Korea.

11 (Simultaneous discussion.)

12 COL. NEVILLE: Next slide, please.

13 (Slide)

14 I just threw this in there, this is from the World
15 Health Organization Website, to show that the sites that we get
16 isolates from here and the World Health Organization, they're
17 either a no-report or not participating. There and -- well,
18 Korea, I guess, and Central Africa. You'll also notice -- go
19 back one slide.

20 (Slide)

21 We don't have any surveillance sites anywhere in
22 this area where there might possibly be sites that we could
23 collect some from, but we found it difficult to get culture
24 specimens from U.S. Forces that are deployed, for a variety of
25 reasons. That would be a handy place because there's no reports

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 from those areas, except for India, if you want to count that.

2 Next slide, please.

3 (Slide)

4 This is a week-by-week summary of the number of
5 specimens that we found that came into the lab, and the percent
6 of them that were positive for influenza. Actually, the peak was
7 like, say, Week 2 to 10, something like that. And this
8 represents a fair number of specimens that come in from around
9 the world. The peak are at like 220, I believe, one week. Next
10 slide, please.

11 (Slide)

12 And this is just from the CDC. It basically
13 parallels the same peak incidence of influenza -- the green ones
14 -- about the same weeks. Next slide, please.

15 (Slide)

16 The next six or so slides is just -- we can go
17 through them relatively quick, but it's just to show how the
18 season progressed.

19 (Slide)

20 The red dots are Influenza AH3. There's a yellow
21 dot that's H1, and there's a blue dot that's Influenza B. So no
22 need to pay a lot of attention to where the dots are showing, you
23 can just kind of watch it as it goes. At the beginning of the
24 year for the last two years anyway, Alaska at Elmendorf had the
25 earliest significant influenza activity throughout the DOD. Next

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 slide, please.

2 (Slide)

3 Next slide, please.

4 (Slide)

5 Next slide, please.

6 (Slide)

7 Spreading out a little more, a lot more numbers.

8 There's a little bit more B showing up. Next slide, please.

9 (Slide)

10 These little tiny dots are one case, so B is more
11 spread out by March. Next slide, please.

12 (Slide)

13 So the Health Affairs letter asked for a Joint
14 Influenza Surveillance Working Group, so that group meets every
15 year and it consists of representatives from the Services and
16 Health Affairs and DOD guys.

17 (Slide)

18 And these two slides are just bullet summaries of
19 our meetings. Go back one.

20 (Slide)

21 So all the isolates that we got this year were
22 similar to vaccine strain. There was nothing weird or new or
23 strange. NHRC presented some information that they'd done a
24 study on the rapid influenza tests, and I have the numbers here
25 and could make a copy if you want, but they were fairly limited

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 clinical usefulness. The specificity and sensitivity weren't
2 particularly great.

3 AFIP and NHRC are researching ambient temperature
4 shipping methods. One of the reasons it's hard to get isolates
5 out of deployed sites is because they have to be shipped frozen -
6 - liquid nitrogen -- that's a little bit of a problem. So, they
7 presented some information on this, but there's nothing complete
8 or available yet, but that would be an exciting advance.

9 Little Creek, I don't know if it's an amphibious
10 base or what the exact title of Little Creek is -- Naval
11 Amphibious Base -- they were added to the sentinel site list.
12 They submitted quite a few specimens last year, so they are part
13 of that. And that's sort of a port of entry area.

14 We tried to do sort of a low-budget vaccine
15 effectiveness study at Misawa Air Force Base, sort of an
16 operational site, to see if the vaccine seemed to be effective in
17 preventing influenza, but the numbers were too small. There was
18 no difference, but the numbers were too small to have any power,
19 so we can't really say anything about that.

20 We thought we ought to improve efforts to market
21 the program to medical leaders, which we've done that a little
22 bit in the Air Force with squadron commanders and so on, to raise
23 the visibility and understanding of why it's important.

24 We felt that the DOD pandemic plan needed some
25 work. Weren't sure exactly who should do that, but that's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 probably more not a surveillance issue. You can read the rest of
2 those. This seems to me to be a valuable thing to try to pursue,
3 deployed forces, and we're actually trying to put respiratory
4 pathogen surveillance into some of these exercises, annual
5 exercises, like Bright Star or one of those. That's a hard thing
6 to do, though, to get injected in those kind of exercises, but
7 we'll try. Next slide, please.

8 (Slide)

9 There was a VA representative at the meeting this
10 time, and we're just exploring the possibility of getting their
11 information from the VA Medical Centers around the country.
12 That's probably not going to happen, but that's okay. We
13 recognize there's a little bit of a problem with reporting all
14 the stuff to the Services and Health Affairs like the letter says
15 they're supposed to do, so we're going to tighten that up a
16 little bit.

17 The question came up whether we should process
18 animal influenza specimens, but we decided that's not what we're
19 supposed to do, so we're going to stick with human specimens.

20 NHRC applied for World Health Organization
21 Designation as the Collaborating Center, so we did that same
22 thing and waiting for -- I'm not sure NHRC ever got that final
23 word -- provisional. So, we haven't received any word back on
24 that ourselves. We just felt that that might facilitate some of
25 these overseas collection efforts.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 And you can read the rest of them.

2 This last bullet here, if I recall, it was
3 discussed sometime in the past with AFEB, and the point is that
4 in a highly vaccinated population, a lot of the cases you're
5 going to see are going to be vaccinated people, and that may just
6 be the way it is, the vaccine is not 100 percent effective, but
7 why isn't it in a young, healthy population. That's a question
8 that may not be answerable.

9 Okay. I think that's it. I wasn't going to go
10 over those other slides in your packages beyond this backup slide
11 but, if there are questions, I could entertain those.

12 DR. OSTROFF: Thank you, Colonel. Questions? Dr.
13 Diniega.

14 COL. DINIEGA: Not questions, but just a couple
15 additional comments. The Select Task Force that I mentioned
16 before is working on a DOD Response Plan for pandemic influenza
17 and, No. 2, Col. Neville mentioned the VRBAC presentation. We've
18 been attending those meetings for the last three years. They've
19 asked for input. They like to get our input, and their concern,
20 when Roland Levindowski (phonetic) called me in '98, was they
21 wanted us at the meeting because of a need for the military -- a
22 possibility we may need a different strain in the U.S. vaccine.
23 So, we attend every year. We get our input in, and we
24 participate in the discussions.

25 DR. OSTROFF: Thanks. I've always thought that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 this is a great system. It's proved to be very, very valuable
2 over the years, and I'm sure Greg Gray, who this is near and dear
3 to your heart, it's nice to see all the data about other
4 pathogens.

5 I did want to put this one up there to ask you, I
6 was curious about a couple of things. What's wrong with Madigan,
7 and what is all that "Other" at Tripler?

8 COL. NEVILLE: Madigan I can't explain. I'm not
9 sure --

10 DR. OSTROFF: I mean, they don't seem to be able
11 to isolate anything.

12 COL. NEVILLE: Well, I'm not sure if they actually
13 do cultures. I've never been able to clarify that. I think
14 these are rapid tests, I'm not sure. I couldn't tell, I couldn't
15 tell with the e-mails and so on. So, I'm not sure what that
16 means.

17 Now, though, Madigan, after much effort -- I got
18 an e-mail today that said Madigan -- from somebody at Madigan,
19 and I couldn't read the whole thing -- it was this week anyway,
20 that Madigan is onboard. I'm not exactly sure how that's going to
21 translate, but that would be -- others -- at Tripler, I think a
22 lot of those are RSV, and they're scattered, like adenoviruses
23 and parrot influenza, and occasional HSV. I think a lot of those
24 were RSV, though, I believe.

25 DR. OSTROFF: I guess it gets to the issue of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 data are only as good as the quality control over the system, and
2 I'm just curious as to what self-correcting mechanisms might
3 exist when people see data like this, and who actually looks at
4 it and tries to work with them to fix it.

5 COL. NEVILLE: We got this through Brook Army
6 Medical Center, and they did their own kind of -- I don't know
7 it's an ad hoc -- or something CHCS where they collected this
8 stuff from the other Medical Centers, and basically put it in a
9 spreadsheet and sent it to us, and we extracted the stuff. And
10 there were all virology tests at all these Medical Centers, which
11 includes the genital herpes and all that stuff. So we scrubbed
12 that out and did this, and that's what we came up with. That's
13 about the extent of what we could get.

14 COL. DINIEGA: The Project Gargle, I think, is a
15 very good system. I think participation from the Services has
16 been very, very -- I think what we'd like to see, as we discussed
17 in the Working Group meeting at Brooks is, personally I'd like to
18 see more participation not only from other Services, but from
19 overseas sites. In watching the spread of flu every year, most
20 of it comes from the Far East, and so those sites is where I
21 think we can add the most to an overall national surveillance.

22 The Army, for some reason, I think, Jeff, in our
23 discussions, they're going to try to see if they can get more
24 participation from Army sites, but I think the data we need is
25 mostly from overseas sites.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Keep in mind, the civilian system looks at
2 influenza and influenza only, so some of the questions that come
3 up at the VRBAC are questions on efficacy, questions on the
4 nonrecovery rate -- because the recovery rates for influenza are
5 very low and there's not that much effort in looking into other
6 etiologic causes for the febrile illness. So, they don't
7 routinely look for other categories, and whereas I think our
8 basic training surveillance always look for adenovirus, flu and
9 other causes, but it's a very good system, and it is a little bit
10 cumbersome in the shipment. And did you mention -- you mentioned
11 ambient shipping, but that means we don't get any chance to grow
12 any isolets, right?

13 COL. NEVILLE: Well, at the present time, just
14 like the PCR, that's what they're working on, is preserving the
15 virus particles so they are culturable when they get to the lab
16 using an ambient temperature transfer medium.

17 I forgot to say one other thing, NHRC did sort of
18 a retrospective vaccine effectiveness study using all the cases
19 from those training centers, the FRI cases, controlling for age,
20 category, gender, location, week of training, season, oral
21 temperature, and days of symptoms, and they had a sample size of
22 almost 5500 from nine sites over four seasons, and they said that
23 those who had a positive culture for influenza were 7 1/2 times
24 as likely to have been unvaccinated, or vaccinated less than 14
25 days. So, that's an indication that the vaccine seems to be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 working in this population.

2 DR. SHANAHAN: Pardon me if this is a bit of a
3 naive question, but related to that last comment you made, your
4 last bullet showed that 85 percent of your isolets were from
5 individuals who had been vaccinated. How does that stand with
6 other database -- to me, that's a rather surprisingly large
7 number.

8 COL. NEVILLE: It's surprising to me, too, but the
9 number of people who are vaccinated is pretty large, and the
10 coverage may be in the order of 80 percent of Active Duty are
11 vaccinated every year, something like that. Each site is a
12 little bit different, but something like that. So there's going
13 to be a lot of people who were vaccinated, and there's going to
14 be a lot of disease exposure out there, so there's going to be --
15 if a vaccine is only 70-some percent effective, there's going to
16 be a lot of cases in unvaccinated. And this isn't a systematic
17 sampling, this is whatever we get from the clinics. So, my guess
18 is that some Docs may be more likely to culture somebody who has
19 been vaccinated to see what's causing this illness, than somebody
20 who isn't vaccinated. There's no way for us to know that.

21 DR. GARDNER: Just a point of clarification.
22 Several places you're doing influenza vaccine effectiveness
23 studies, you're doing what you call a Survival Analysis. I
24 assume these aren't deaths, so tell me what you mean by that.

25 COL. NEVILLE: Survival to a respiratory visit.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 DR. GARDNER: Survival of what, the patient, or
2 the soldier?

3 COL. NEVILLE: Survival just means that they are
4 healthy, healthy, healthy, get a respiratory visit at the clinic,
5 that's the event, survival to that event. That's just the term
6 of that analysis.

7 DR. SHOPE: Is your system set up so that you
8 would collect data in the Southern Hemisphere? I notice you have
9 Peru on there, and Ecuador. Ecuador is on the Equator. And if
10 we were going to deploy troops in the Southern Hemisphere
11 sometime, would the season be different for influenza?

12 COL. NEVILLE: Yes, the season is different, and
13 we don't have military bases in that area, so we depend on the
14 overseas labs who have contacts and so on in those countries, and
15 I believe the Peruvian cultures were from Peruvian military
16 personnel, and Greg will talk about NHRC's efforts down there a
17 little bit, too, I guess.

18 DR. GRAY: This is Greg Gray. I know that Col.
19 Sanchez in Peru has got a network I think that will soon involve
20 ten South American nations, and they will be receiving -- I think
21 they initially go to Lima and then they are shipped to San
22 Antonio, at the laboratory Project Gargle. So, in the very near
23 future -- I think he's already maybe got five or six sites up,
24 but in the very near future it will be even broader and better.

25 COL. NEVILLE: And the laboratory -- I can't

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 remember her name, from Peru -- she came to our lab to see how
2 it works and to set up a lab in Peru to do that same culture
3 stuff.

4 COL. DINIEGA: There are two issues with influenza
5 besides the pandemic response that I think are very pertinent to
6 the military. No. 1 is the Southern Hemisphere issue and the
7 influenza vaccine that is used there. And when we deploy to
8 those areas, that vaccine is not licensed for use in the U.S.
9 So, technically, we can't access that vaccine for routine use in
10 our soldiers or military personnel.

11 The other issue that is important to the military
12 is one of expiration date. We like to vaccinate our recruits
13 year-round with influenza. The expiration date, the last several
14 years, of the vaccine has been June 30th. So, until we receive
15 new vaccine for the next season, our recruits go unprotected
16 against influenza. And Jim and Greg can tell you that we do have
17 cases of influenza year-round.

18 COL. NEVILLE: In part because -- at least at
19 Lackland -- that we get trainees from South America, Spanish-
20 speaking countries, year-round. And there's that one a couple of
21 years ago in July.

22 DR. OSTROFF: I guess I'd ask Pierce or whoever to
23 comment on the protective efficacy during peak influenza season,
24 if you are administering the vaccine that far in advance.

25 DR. GARDNER: I think the ACIP certainly feels

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 that the vaccine does offer protection that far in advance.
2 Although there are some waning antibody levels, it's still
3 thought to be useful, and the antibody wanes less rapidly in
4 younger populations. So, I think it would be useful to give.

5 COL. NEVILLE: And we're also looking for coverage
6 during those training months that are early on in their career
7 during the summer and fall.

8 DR. GARDNER: I'm surprised that the expiration
9 date is that rapid of the vaccine. I'd like to know a little bit
10 more about that and whether that's valid or not.

11 COL. DINIEGA: There's been a few occasions in the
12 past where the expiration has been a year, it's lasted a year,
13 but my understanding is most people prefer the early expiration
14 so that there's no confusion when the new vaccine comes out.

15 COL. NEVILLE: It's relatively arbitrarily set
16 just to avoid --

17 COL. DINIEGA: You have to buy more. You know,
18 Roland Levindowski at FDA says there's no issue with the potency.

19 DR. OSTROFF: Jeff.

20 COL. GUNZENHAUSER: Just a comment and a question.
21 I can try to help with this particular issue here. I presume
22 this has all been informal. I'm not sure how the lab data comes
23 in and all that, I don't know if our lab consultants are
24 involved, et cetera, but I can certainly get involved and try to
25 clear up what this slide means and get some good communication.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 For example, this rapid diagnostic test issue, I just didn't know
2 that the NHRC had done some type of analysis. I think it might
3 be good to get that information and get that shared among our
4 MEDCENS and get some discussion going on best how to do that but,
5 anyhow, I can try to help with this.

6 One question I had, on the slide you showed, I
7 think, about influenza at basic training. I thought I saw rates
8 per hundred per week and some peaks that were rather higher than
9 I was aware. I don't think we have visibility really on that.
10 Is anybody analyzing specifically those rates and what they mean?

11 Has somebody taken that lab data and gone back and looked at the
12 real morbidity experience and trying to look at what that means?

13 COL. NEVILLE: I don't know. That's NHRC's -- I
14 don't know if they've done looking back at morbidity, hospital
15 days, that kind of thing. I don't know that.

16 COL. GUNZENHAUSER: Okay. Because I think that's
17 something that needs to be -- I saw, for example, on the slide --
18 for example, there -- I mean, it's a little while ago, but it
19 looks like you've got a peak approaching .5 per 100 at an Army
20 Basic Training Base there in Ft. Jackson. In other words, that's
21 pretty high respiratory disease rate, even though it's not an
22 epidemic, but it's a pretty high background rate of flu that I'm
23 not sure we had visibility on certainly at that time. And more
24 recently, we've had some problems again, but I don't think that
25 within the Army training community we have knowledge of this

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 going on. So, I think we've got to tie that together better.

2 COL. NEVILLE: That's a good point. That's a good
3 point. The cutoff of 1.5 per 100 per week is for FRI general and
4 this is cause-specific, so there probably should be a lower
5 threshold for an outbreak.

6 COL. DINIEGA: Then I guess the question would be
7 like the discussion yesterday concerning here at West Point how
8 much of this is truly diagnosed influenza -- this is isolets?

9 (Simultaneous discussion.)

10 COL. BRADSHAW: This is Col. Bradshaw. The
11 problem with this is it is viral culture proven, but the time
12 sensitivity is limited by how long it takes to get a specimen
13 back, get that actually viral culture done. And what's your
14 turnaround at the lab, is it a couple weeks?

15 COL. NEVILLE: Well, it's a couple of days when
16 one grows positive, but a negative result won't get reported for
17 two weeks.

18 COL. BRADSHAW: So there's some delay in being
19 able to really sensitively interact, which is why when we
20 mentioned earlier using ADS and ESSENCE to do ILI surveillance,
21 then we can get in there and maybe get these specimens turned
22 around faster so we get culture confirmed sort of things.

23 We've had problems in NHRC and actually an EPI
24 outbreak investigation that Brian Feiner (phonetic) did that
25 showed that the rapid diagnostic test had some cross-reactivity

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 with adeno, and in a training center that's a problem, thinking
2 you have influenza when it's really adeno. So we really do need
3 viral confirmation in settings like this.

4 COL. NEVILLE: That NHRC program wasn't designed
5 as a rapid response public health thing, but more of a
6 surveillance thing, so the level of specimens are back-shipped
7 and so on, so the tie-in was made really to that.

8 COL. GUNZENHAUSER: I understand. I just think,
9 even retrospectively looking at the disease experience and
10 understanding the etiologic fraction that flu might be
11 contributing would be a very useful thing to make sure we do.

12 DR. OSTROFF: Other comments or questions? Greg?

13 DR. GRAY: This is Greg Gray. I'm aware that the
14 DOD has been contemplating coming up with a pandemic response
15 plan for the number of years, and I applaud Col. Diniega's
16 comment that they're working on it. I just want to emphasize
17 that I think that's really important and something that the Board
18 would be interested in given the recent pandemic in Madagascar
19 with some 500 deaths and some other reports of some unusual
20 combinations of influenza antigens. So, it just seems very
21 prudent to have something in the works.

22 COL. GIBSON: This is Col. Gibson, Health Affairs.

23 Could you expand on that Misawa effectiveness study, what was
24 the sample size and how many months did you run that study?

25 COL. NEVILLE: It was through the whole season, so

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 October through April, I believe. I have the numbers in front of
2 me, but it was the whole base population, which is about 5,000.
3 And we were looking for -- sort of passively looking -- we didn't
4 do any interventions and "come get your flu shots" or "if you get
5 sick", you know, any of that kind of stuff. We just wanted to
6 passively observe what happened at an operational base. We
7 picked overseas because all the health care visits are likely to
8 occur at the MTF, not in the community -- some, but not many.

9 COL. GIBSON: And your end point was visits for --

10 COL. NEVILLE: Respiratory illness.

11 COL. GIBSON: Okay. Thank you.

12 COL. NEVILLE: I guess I should ask one other
13 question, which was mentioned by Dr. Riddle yesterday. This is
14 supposed to be an annual summary briefing to the Board, and the
15 question is whether the fall is better, or the spring, or which?
16 Here, we have all the information from the whole year. In the
17 springtime we'll have preliminary information. It's up to you
18 all.

19 COL. DINIEGA: As far as timing, historically, the
20 Board did have a lot of say in the VRBAC, what the VRBAC does,
21 the flu strain selection, and recently it's become an info to the
22 Board because the offsite going to the meetings never coincided,
23 and our input wasn't really asked for until about three years
24 ago, and that's when activity started picking up as far as
25 participating in the national effort.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 The VRBAC meets the end of January, and the first
2 two strains -- the A strains are selected during that -- well, at
3 least two out of three strains are selected at that meeting.
4 Usually, the B strain is the one they have difficulties with.
5 And they want to mesh that with the WHO selection, and the WHO
6 meeting occurs February, and the last strain selection for the
7 U.S. vaccine occurs no later than March because of the nine-month
8 -- or the six-month timetable needed by the manufacturers to
9 produce vaccine.

10 So, if there's going to be any input or review of
11 the program with recommendations, it would have to be done before
12 the VRBAC meets the end of January. And I know there's a meeting
13 in February for the AFEB. So, unless we can use the Infectious
14 Disease Subcommittee prior to that to help review the available
15 data so that we can get any comments or recommendations before we
16 go to the VRBAC meeting --

17 DR. OSTROFF: I don't have particularly strong
18 feelings about when we receive the annual report because I agree
19 with Ben, I think that there are things that have to be done with
20 the data that shouldn't be necessarily timed to the annual
21 report. My personal preference would be that we have the report
22 after the flu season, and that would mean preferably in the
23 spring meeting.

24 I do think that for those of us that are on the
25 Disease Control Subcommittee, I don't have any problem with

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 having some sort of a conference call or something like that, to
2 review where you stand and what your recommendations are going to
3 be for the VRBAC meeting sometime in January. I think that would
4 be fine. Does anybody else have any thoughts about that?

5 COL. DINIEGA: The other comment I have is that
6 the Laboratory Surveillance Working Group meeting is usually held
7 in May, and then this year we had a DOD Influenza Program review
8 in June, and we want to do that again next year. I think it
9 worked out very well. There was an effort to try to combine the
10 Lab Surveillance meeting and the DOD Program Review at the same
11 time. It didn't work out. So, if you want to get the annual
12 report during the May meeting, then we can work at moving our DOD
13 Annual Program Review earlier so that you can see what the
14 recommendations are that the annual review is.

15 DR. OSTROFF: Any other thoughts? I mean, that
16 would be my preference, if at all possible. The spring meeting
17 tends to be in mid-May, so that would work for us.

18 Thank you very much. We're running a bit ahead,
19 which always warms my heart, so let's go ahead and take our 15-
20 minute break, and if we could all be back by five minutes to
21 9:00, since it's 20 of.

22 Rick has one or two comments, administrative
23 matters.

24 LtCOL. RIDDLE: One request, for those individuals
25 who are going to the airport today, whether you need a ride or

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 have a ride, like a rental car, if you could get with Karen and
2 let her know so that we can group the rides and group the taxi
3 needs, and also for individuals going to the airport tomorrow,
4 we'll try to group the rides and group the taxis and get folks
5 there.

6 DR. OSTROFF: One other question, Rick, when do
7 you want to do the group photo?

8 LtCOL. RIDDLE: Let's do the group photo before we
9 adjourn for lunch, and that will get everybody, because I know
10 some people are leaving early this afternoon.

11 DR. OSTROFF: Okay. Five of.

12 (Whereupon, a short recess was taken.)

13 DR. OSTROFF: Let's go ahead and get started. As
14 I think was mentioned yesterday, John Grabenstein, who has been
15 such a regular presenter to the Board, is unable to come up to
16 the meeting because he's fully engaged in a variety of different
17 issues related to what Col. Bradshaw is going to be talking about
18 over the next few minutes. So, Dana, thank you very much for
19 being willing to give the presentation, and we'll hear the AVIP
20 update on anthrax and smallpox.

21 COL. BRADSHAW: Would you like me to go through
22 these consecutively and then we'll discuss both of them at the
23 end?

24 DR. OSTROFF: I think why don't we take them one
25 at a time.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 COL. BRADSHAW: Okay. First of all, I just want
2 to send regards from John. He would have loved to have been here
3 but, as you can well imagine --

4 DR. OSTROFF: And probably would have preferred.

5 COL. BRADSHAW: Yes -- he has certainly had his
6 candle burning at both ends and stretched all directions, as you
7 can imagine, but I will try and fill in and give a poor
8 substitute here but, in that respect, I will rely upon Col.
9 Diniega, who has also been obviously very involved in these
10 situations, and folks like Ken Schor, who worked closely with the
11 anthrax program, and others to give their input. And at any
12 moment, if anybody wants to interrupt or add, feel free to, and
13 then we'll leave time at the end to discuss collectively these
14 very important issues. So, first of all, we'll begin on the
15 update on the anthrax vaccination. Next slide, please.

16 (Slide)

17 As you are well aware, the AVIP program began in
18 March of 1998, and we had program slowdowns more recently in the
19 year 2000-2001. We've had up to the present time over 2 million
20 doses given to just over half a million service members. And
21 during this time, the FDA has approved BioPort's license
22 supplement. That occurred as of 31 January of 2002, this current
23 year.

24 Some of the lessons it learned in the travails
25 that we've had during this time are highlighted here. One is we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 want to ensure a continuous supply of vaccine. I'll show a slide
2 later that kind of demonstrates what's kind of happened because
3 of our supply problems.

4 We want to make sure also that we do our job on
5 risk communication well, which means that we have to educate all
6 of our customers as early as possible and as completely as
7 possible, and that includes not only the troops, but the family
8 members, certainly our health care professionals who are actually
9 the first on the front line in terms of communicating with people
10 about safety of vaccine, and we encounter problems if they don't
11 really know their risk communication messages well either, and
12 then also the general public because we have a larger public that
13 has become involved in this issue.

14 The risk-benefit ratio is a problem because it is
15 perceived differently for biowarfare vaccines. Until October of
16 last year, we actually had never had an anthrax attack of any
17 type, and people were getting vaccine, and the perception of risk
18 sometimes differed with what they actually felt like it might be,
19 and they perceived that the risk from the vaccine in some cases,
20 to them, was larger than actually the risk of being attacked with
21 anthrax. Now, that has changed. It will be interesting to see
22 how things go now.

23 The other issue is that published science is
24 critical to credibility. There is a quote that I found from Mark
25 Twain that I think is relevant here, where he says at one point

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 that "A lie will travel half-way around the world before the
2 truth pulls on its boots". And that certainly pertains to rumor
3 versus published peer-reviewed science. And it's very difficult
4 here. We all know that risk communication is a lot about
5 emotions more than it is about facts, but it's still important to
6 get those facts out there for the rational public, and that maybe
7 80 or 90 percent of the people may not be swayed by emotion one
8 way or the other. So, that's just a point about that. And,
9 fortunately, we've got the IOM review of anthrax vaccine that's
10 occurred recently, and has been very helpful, I think, to the
11 situation.

12 We also need command and leadership involvement,
13 that's definitely a key to local success. Unfortunately, we had
14 one example of a failure of that that happened a few years ago.
15 Next slide, please.

16 (Slide)

17 This is a slide that I want to mention. The real
18 delay in the program completion or progression has really been
19 the delay in supply of vaccine. And while we were waiting for
20 FDA licensure BioPort, we had a significant drop, of course, in
21 the number of our service members that could be protected with
22 the vaccine. Now that we've had FDA approval, the supply of
23 vaccine has gone up significantly, and we are ready to try and
24 progress with this program. Next slide, please.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 So, here is where we are. The Deputy Secretary of
2 Defense signed a memo in late June. DOD has decided we will
3 resume the AVIP consistent with the FDA guidelines and our, of
4 course, best practice of medicine. Our policy currently is to
5 immunize personnel deployed more than 15 consecutive days in the
6 highest threat areas. Any exceptions to policy will be through
7 the Chairman of the Joint Chiefs of Staff and the Assistant
8 Secretary of Defense for Health Affairs. Areas are specified in
9 Service messages, and these are focused mainly on the area of the
10 Arabian peninsula. Next slide, please.

11 (Slide)

12 Again, implementation imperatives, just to revisit
13 the message. We want to educate and communicate early and often.

14 We have revised the trifolds that are given out to service
15 members and others. We have vaccine information sheets that have
16 been developed with the cooperation of the Centers for Disease
17 Control and Prevention. We have briefings together. We have the
18 telephone hotline that is available. The number is up there. We
19 have the Website, and we have e-mail messages that may be
20 submitted. So, all this is in place and has been updated.

21 We want to, of course, document promptly in our
22 immunization registry so that we can do post-marking surveillance
23 and safety surveillance very well. We need to do that with high
24 precision. We've had some questions about that, and we certainly
25 want to try and make sure that's the best that we can do.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Certainly, if people experience problems, we want
2 to get them good health care, take care of the service member
3 first. We also need more support for the Reserve Components, and
4 we're going to try and do that through the Military Medical
5 Support Office. And, again, just do things with common sense and
6 with flexibility, that's always important.

7 In addition, though, we now, after, again, October
8 of last year, have the issue of trying to act in concert with
9 civilian and other Government requirements, and there's been a
10 significant need and request on the part of the Department of
11 Health and Human Services for anthrax vaccine, so we have some
12 doses reserved for them and for the civilian needs. Next slide,
13 please.

14 (Slide)

15 Some details, the memo from the Under Secretary of
16 Defense for Personnel Readiness on 6 August '02. The Army
17 remains the Executive Agent for implementation of the anthrax
18 vaccine program. We've discussed medical exemptions and
19 administrative exemptions and tried to make sure the services are
20 all consistent with those.

21 The services will audit documentation, that's to
22 improve the issues that have been raised about our immunization
23 registries, making sure that we have the right information in
24 there. These things will be reviewed by the Department of
25 Defense IG.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 The Service Implementation Plans are ready for
2 signatures by the various service SGs. Vaccine distribution, the
3 pump is primed at over 100 locations, and we will escort large
4 shipments of vaccine.

5 We have the new safety resource. Renata Engler is
6 heading up the Vaccine Healthcare Center at the Walter Reed Army
7 Medical Center. That is our first one. We're looking into
8 actually getting additional Vaccine Healthcare Centers.
9 Discussions are currently underway with Portsmouth, Norfolk, and
10 also Wilford Hall Medical Center.

11 Shots again are to be made over the deltoid, not
12 over the triceps. There were some signals in the safety data
13 that there were some peripheral neuropathies which would, of
14 course, be more of a problem with inflammation and an injection
15 given over the triceps, so we've moved to recommending that
16 everybody gets that in the deltoid area.

17 All previous doses will count, so people like me
18 that had four, and we went through the supply problem, if I
19 restarted, then I would just resume where I had left off. The
20 shots are slated to resume later this month, on the 20th of
21 September and, again, as I mentioned, the higher threat areas
22 will be the first to receive shots.

23 And, again, just to beat the message in, we want
24 to do this with flexibility and common sense. Next slide,
25 please.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 I guess that's actually the end of our brief. So,
2 I'll pause at this moment and welcome comments or questions.

3 DR. OSTROFF: I have one, or a couple of
4 questions. One is, the first thing you mentioned is assuring
5 that there is a steady supply of the vaccine. Given recent
6 discussions about the potential for conflict with Iraq, I assume
7 that that would be considered a higher risk area and would be
8 consistent with the Arabian Peninsula.

9 Is there enough vaccine to ramp up receipt by
10 large numbers of personnel, since you are basically talking three
11 doses here?

12 COL. BRADSHAW: My understanding is that I believe
13 there would be, although I don't have the specific numbers on the
14 tip of my tongue and, of course, some of those things would get
15 into any issues about OPS planning and et cetera, which specific
16 numbers we probably wouldn't be able to give out anyhow.

17 CAPT. SCHOR: This is Capt. Schor. That's the
18 central question that we're being asked from the service
19 leadership, and I think that's true for most of my colleagues.
20 When are we going to have enough to support the President, and
21 it's a very time-dependent answer. It changes month-by-month.
22 That's the best answer I can give you in this fora.

23 DR. OSTROFF: The problem is, that's not a great
24 answer. That's where we were before.

25 DR. CAMPBELL: I have a related question. If you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 are only going to be immunizing people deployed to forward areas,
2 do you have plans in the future to immunize everybody in the
3 military, even in the Continental United States, because of the
4 potential for attack here in the United States? What are the
5 plans for overall military immunization?

6 COL. BRADSHAW: Ken, go ahead, because you've been
7 more involved actually recently than I have.

8 CAPT. SCHOR: This whole issue prior to the
9 DEPSECDEF memo of 28 June was there are a number of contentious
10 issues that the CINCs and the service Chiefs were very adamant
11 about and, to a large degree, lost on.

12 One of the issues was there is no specific
13 language for a total force policy in the current policy
14 announcement, it is only based on threat. So, the answer is no,
15 unless SECDEF decides to change that.

16 There are some other issues about the 15-day rule
17 that we have to live with, that's in stone right now. We wanted
18 to be able to, as vaccine became more available, go down to a
19 one-day or zero-day same thing. You know, one day in a higher
20 threat area, you should be covered.

21 So, that's just part of the things that we have
22 been struggling with since February.

23 DR. GARDNER: Can you bring me up to date as to
24 whether the looking at different vaccine schedules and total
25 number of doses, is that the same as previously, or are we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 looking at some modifications?

2 COL. BRADSHAW: There are studies underway and,
3 actually, I don't know if Greg Poland could speak to this, he
4 probably could, but there are studies underway to look at that,
5 but I don't think we're anywhere near getting a package insert
6 change. Greg, go ahead.

7 DR. POLAND: So the current system will be the
8 same dose, same route of administration, we and four other sites
9 are right now conducting a study looking at the feasibility of
10 reducing it to as few as four doses, to as little as every other
11 year boosters, and administering it IM rather than
12 subcutaneously. Those interim results won't be available for
13 another year or two.

14 I might just make one comment about that since
15 we've given -- you know, it's not a huge experience so far, but
16 150-some-odd doses, a number of people have received three or
17 more doses already and, frankly, we just don't find even the
18 local reactinogenicity that you see in some of the older
19 literature. We just don't see it. I mean, people rate their
20 local reactions zero to 1. We have yet to have a 2, 3 or 4.

21 COL. BRADSHAW: Greg, is that sub-Q or IM?

22 DR. POLAND: We don't know.

23 COL. BRADSHAW: No, I mean are you giving it sub-Q
24 or IM?

25 DR. POLAND: We're giving it both. We don't know.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 COL. BRADSHAW: Oh, you don't know yet.

2 DR. POLAND: We're blind to it. And we just don't
3 see any reactions.

4 DR. OSTROFF: John.

5 DR. HERBOLD: Dana, could you refresh my memory
6 just briefly about how the injections are documented and how that
7 -- is that stored electronically for --

8 COL. BRADSHAW: Yes, all three services have
9 immunization, electronic immunization registries. For the Air
10 Force, it's AFCITA, Air Force Complete Immunization Tracking
11 Application. It's MODs, MEDPROs for the Army, and then it's SAMS
12 for the Navy. And so it's entered electronically, includes all
13 the requirements including lot numbers and site, et cetera. The
14 service member by name, including his Social Security Number.
15 That information is transmitted to a common immunization registry
16 or archive at DEERS, and then data is also forwarded to Mark
17 Rubertone's shop with the Defense Medical Surveillance System.
18 So, what we have set up, which is similar to the Vaccine Safety
19 Data Link Program, is the ability to link that immunization
20 registry information with health outcomes that we get from the
21 Ambulatory Data System and the inpatient data record. So, that's
22 part of our safety surveillance and post-marketing surveillance.

23 CAPT. SCHOR: I would just like to make one
24 comment, and that goes back to the last slide that has
25 implementation details and talks about service implementation

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 plans, and the comment or question is how ponderous does a
2 program like this have to be in order to execute?

3 I look at perhaps the first five bullets here and
4 I see nothing but barriers, having suffered through them over the
5 last six to eight months. This is too hard, far too hard, to
6 cover and protect a force. Maybe it's an issue with how we have
7 all of our overall vaccine policies, but if we had to execute
8 programs for tetanus, for influenza, for all of those vaccines
9 like we're trying to do for anthrax, we would not be ready for
10 any of those other endemic diseases.

11 So, I would just ask the question -- and perhaps
12 the Board at some point could have a comment -- and that is, how
13 do you balance this as a special immunization program for BW
14 preparedness against trying to get this done and deal with it
15 just like another vaccine? Why are we treating it so
16 differently? Why do the services have to brief that to OSD
17 level? I mean, it's just -- and that's for consistency, I can
18 understand some of that, but we don't brief influenza programs to
19 -- you know, back up the chain. It flows in one direction, and
20 these are barriers. I see huge barriers because I've run into
21 them over the last four or five months, head on, repeatedly. And
22 we still don't have shots in the arms.

23 DR. OSTROFF: Well, I guess my concern is, you
24 know, a start date of September 20th, by my watch, is two days
25 from now. Do all of the services have in place what they need to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 have in place to actually begin implementing this, and are there
2 tracking systems in place, and do we know where the vaccine is
3 going -- because in many ways, logistically, this particular
4 policy is much more difficult to implement than full Force
5 protection because it's a lot easier when everybody gets it than
6 to try to pick-and-choose who's getting it and who isn't, and
7 when they can deploy and when they can't deploy, et cetera. So,
8 in many ways, even though you're talking fewer numbers of shots
9 in people's arms, the tracking cure and the selection process is
10 really problematic. And I'm just curious as to comments from the
11 various services about how they are going to do this because I
12 personally don't see it.

13 LtCOL. WOODWARD: This is LtCol. Woodward, from
14 the Air Force. We are actually, certainly, very ready and, in
15 fact, we're probably having to rein in our people who are ready
16 to implement this program immediately, poised with the education
17 materials. Our tracking system is ready across the Air Force and
18 has been exercised for a couple of years.

19 And the other thing I guess I would say is that --
20 from a different facet to what Capt. Schor is saying -- is that
21 this, for the Air Force, is a line program. This is a force
22 protection program that is being endorsed and championed by the
23 Chief of Staff of the Air Force who has assigned program
24 ownership for the anthrax program to a line General Officer. And
25 so we think that this is being marketed and advertised, and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 expectation is that line commanders will make sure that the
2 troops who are designated for anthrax vaccine get the vaccines
3 they need, and the medical support is ready to do that and to
4 make sure that that happens, as well as all the tracking actions.

5 DR. OSTROFF: Jeff.

6 COL. GUNZENHAUSER: I think the plan here is we
7 have a service implementation plan. I know ours has been very
8 well staffed. There's been a lot of discussion and questions
9 about it. The information products are out there.

10 It's a question of which troops need it, and I
11 know before there were very good systems in place to make that
12 communication happen, and I know there's been discussion about
13 that now. And I realize that with deployments there's going to
14 be confusion about which units. I've gotten lots of queries
15 myself from lots of folks, and it will be a challenge. I agree
16 that that's going to be a challenge, but I think there's been a
17 lot of planning in place that I'm aware of to, if not guarantee,
18 will be nearly completely successful as this. That's the way I
19 see it.

20 DR. OSTROFF: The other Jeff.

21 CAPT. YUND: This is Jeff Yund. I'd just like to
22 mention that while certainly the program has been quite a bit
23 contracted from before when it was total force, but in addition
24 to that it's going to be phased in, and what's going to start on
25 the 20th of September will be people who are already in-theater.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 So, there isn't going to be a big rush to get everybody who is
2 eventually going to be covered immunized right away, it's being
3 done in a steady phased fashion with the people who are at
4 highest risk, those people who are already in-theater, being
5 covered first.

6 DR. OSTROFF: That sounds great if nothing
7 happens. If nothing happens, then you can phase in gradually
8 over time those who you want to vaccinate, but I'm concerned that
9 events are going to overtake you, and that raises the question
10 that I said before. No. 1, is there enough vaccine to cover that
11 and, No. 2, are those contingency plans in place -- because it
12 might be great to plan for just dealing with those people who
13 currently are in-theater, but I don't know what relevance that
14 has over the next two months. Again, I realize that we're
15 talking about things that we can't talk about in this venue.

16 COL. BRADSHAW: I think this is the same
17 difficulty, I think, whether you're thinking about anthrax or
18 smallpox --

19 DR. OSTROFF: Or flu.

20 COL. BRADSHAW: Exactly. Where is it going to pop
21 up, and how do you prepare for that? And so you have to take, to
22 a certain degree, some knowledge about the agents and do some
23 probabilistic thinking about it, and then try and put it -- if
24 you can't do everybody at once, then you have to do it in some
25 kind of prioritization. And so this is sort of where we're at

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 with it. I think anthrax -- my own thinking about it is it's
2 more of a tactical kind of weapon, and so you really need to get
3 your people in the areas, especially where you think it might be
4 used, done first. And so that's part of the thinking here.

5 It may change a little bit when we talk about
6 smallpox, but -- and then if you find that it pops up somewhere
7 else, then obviously you're going to have to move it to where it
8 needs to be moved, and hopefully your supply will support all
9 those things.

10 DR. OSTROFF: Other comments? I just feel, based
11 on the track record that we've had with this particular vaccine,
12 I see red flags all over the place, and maybe I'm being a little
13 too pessimistic about your ability to pull this off, but I do
14 think that this is an issue that the Board is going to want to
15 follow very closely. And I might suggest that being that our
16 next meeting isn't until February, that we may want to take the
17 opportunity possibly to have a conference call in the interim, to
18 see how everything is going because I have real concerns, and I
19 usually don't express them this openly, but I have real concerns
20 about this. I just think it's going to be very problematic, and
21 we want to make sure that you're able to do this in a way that
22 will mitigate some of the difficulties that we had before.

23 COL. BRADSHAW: Are your concerns -- and I just
24 want to make sure I'm clear on what concerns you're raising --
25 one, documentation and, two, being able to find these people or

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 whomever has been designated and actually get the shots in arms.

2 DR. OSTROFF: And No. 3 is supply.

3 COL. BRADSHAW: Supply, which has been a
4 significant problem in the past, that's true.

5 DR. OSTROFF: Okay.

6 DR. PATRICK: Steve, I'm trying to figure out a
7 way to operationalize your concerns because I think I, too, share
8 some of them. Are there benchmarks? I mean, essentially, what
9 you're talking about is sort of the operational feasibility of
10 these plans, and then the rapid scalability of them. And are
11 there quantitative benchmarks that could be the subject of that
12 discussion that might occur two months hence -- the conference
13 call -- how can where we think we need to be benchmarked in
14 some way so that there can be a marker, if you will, that the
15 Board could be informed of as to whether the scalability plans
16 are, in fact, working? I'm afraid I'm not being entirely clear
17 on that. Ken, can you help me out on that?

18 CAPT. SCHOR: Perhaps. One of the thoughts that
19 we're trying to provide, that I'm thinking of, to provide the
20 Commandant a one-slide update is over the secure Internet,
21 classified Internet, is to develop a Web reporting tool that
22 allows him to identify the proportion of forces identified as at-
23 risk, as being up to date on their immunization, whether they are
24 restarts or new-starts, and probably 70 percent of the operating
25 forces of the Marine Corps are going to be new-starts.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 DR. PATRICK: This is almost a basion kind of
2 thing. I mean, if there's some projected number of folks that
3 might be, that what we could say now would be deployed -- and,
4 again, I don't want to get into the secure sorts of things -- but
5 if there could be some estimate, and we say it's unacceptable to
6 have less than 80 percent of those clearly in the pipeline, or
7 whatever, that that might give us some benchmark, and it might
8 also clarify what our thinking is as a group and a little bit of
9 how we put whatever pressure we can put on to assure that the
10 concerns that you are raising are, in fact, addressed.

11 CAPT. SCHOR: The population at-risk is right now
12 projected by the services, whether it's under the current scope
13 of the program or anything beyond that. That will get refined in
14 the near-term through some planning conferences to see if there's
15 enough seats on planes, or ways to get people there, or how
16 acceptable the plans are. That's when there's some refinement of
17 numbers and you can more clearly identify the population at-risk.

18 DR. PATRICK: Are the population at-risk numbers
19 classified?

20 CAPT. SCHOR: Absolutely. They've been
21 compartmented.

22 COL. BRADSHAW: I can envision where without
23 putting denominators in, you could show a percent vaccinated, but
24 even that might have strategic or tactical implications. I mean,
25 it's something we'll have to talk with the Joint Staff and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 program.

2 COL. DINIEGA: The benchmark is 100 percent of
3 those at-risk. I mean, that is the benchmark.

4 CAPT. SCHOR: That's the Commandant's benchmark,
5 by the way.

6 COL. BRADSHAW: We could show you a percentage of
7 those at-risk who have been vaccinated, without showing
8 denominators, but we'll have to see --

9 CAPT. YUND: You could make a good argument that
10 that percentage would be classified.

11 COL. BRADSHAW: Yeah.

12 DR. OSTROFF: We'll work on it. Okay. Well, if
13 that one wasn't difficult enough, let's move on to smallpox.

14 (Laughter.)

15 COL. BRADSHAW: You ain't seen nothing yet.

16 We'll go ahead with smallpox, then, smallpox
17 preparedness. Just a little brief history update.

18 (Slide)

19 As you'll recall and probably many of you are
20 aware, in the Revolutionary War time frame, the U.S. -- it wasn't
21 the U.S. at the time -- but the Continental Forces lost the
22 Battle of Quebec, and one of the issues that was there was the
23 issue of smallpox -- DNBI, if you want to put it that way -- and
24 after that time, Washington decided to order the variolation of
25 the Continental Army, and the reason, of course, for that -- our

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Canadian colleague might have actually been in a different
2 uniform this week if he had been this earlier, but it didn't turn
3 out that way -- but this is one of the first examples of a
4 military commander, at least in the United States, ordering a
5 prophylactic vaccination in order to prevent the incapacitation
6 of an army, and that's really what we're talking about here.

7 Now, we're not using variolation now.
8 Fortunately, with Jenner using cowpox virus from a milkmaid, he
9 was able to successfully show that it could prevent subsequent
10 smallpox in a young boy that he used this process with.

11 And then over a number of years, it's come to what
12 we currently use, which is the vaccinia virus, for the same
13 purpose, what we now know as the smallpox vaccine, although it's
14 not smallpox virus itself, it's the vaccinia virus which cross-
15 reacts another type of orthopox virus.

16 In 1949, as part of the success of this program in
17 the United States, we actually had our last case -- I believe
18 this was in New York City -- and then in 1972, the childhood
19 smallpox vaccine recommendations were rescinded. Now that has
20 resulted in anybody in this country who is 30 years old or
21 younger has probably never had smallpox vaccination.

22 In 1976, that same recommendation for healthcare
23 workers was also rescinded. And in 1980, the World Health
24 Organization officially declared smallpox eradicated as a result
25 of the worldwide campaign, of which D.A. Henderson and many

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 others were instrumental in kind of doing this historic and
2 landmark kind of first eradication of a disease by vaccination.

3 In 1984, even despite that, the military continued
4 to vaccinate recruits, and in 1984, really because of limitations
5 with the availability of vaccinia immune globulin, we had kind of
6 fits and starts, and actually interrupted that due to shortage of
7 VIG. And in 1990, the DOD actually "temporarily discontinued"
8 smallpox vaccination, but we have not vaccinated in the U.S.
9 military for smallpox since then, except for the special
10 immunization programs in laboratories such as at Ft. Detrick,
11 USAMRIID, where people are actually working with orthopox type
12 viruses, and other laboratory workers. So, that's the
13 limitation. We no longer have vaccinated recruits or military
14 at-large.

15 So, where do we stand today in 2002? Well, about
16 two-thirds of our Active Duty personnel we calculate have never
17 been vaccinated against smallpox and, as a result, especially
18 when you consider waning immunity in those of us who are old
19 enough to have had the smallpox vaccination at one time or other,
20 we all have some degree of susceptibility, or at least we have to
21 assume that. Next slide, please.

22 (Slide)

23 So, where are we? The DOD Smallpox Response Plan,
24 currently Version 3.03 -- sounds like a Microsoft release -- and
25 this is dated as of 6 September 2002, involves 360 pages, modeled

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 very closely after the CDC plan, which is another 300-plus pages,
2 but I want to give credit to the Joint Preventive Medicine Policy
3 Group and many others that have kind of helped put this thing
4 together.

5 We have the Base Plan and several annexes, which
6 you see enumerated there, and the status is that it is now ready
7 for signature by Dr. Winkenwerder, and actually it will be signed
8 out at a higher level and the Secretary of Defense. Next slide,
9 please.

10 (Slide)

11 Now, in terms of surveillance, right now we would
12 be in the status of wanting to report, and promptly, a suspicious
13 case which is in the category of what we call a Generalized
14 Febrile Vesicular-Pustular Rash Illness". Now, most of the time
15 this will probably be chickenpox or some version of that, but we
16 want to make sure that our clinicians who are out there on the
17 front lines don't miss this. Most of the imported cases that
18 we've seen in the past usually presented to a healthcare provider
19 because they were ill, and so the first place they usually got
20 recognized was in the healthcare arena. So, we want to make sure
21 our people know to report this and how to report this. This
22 details how this would happen. Certainly, if you have a
23 suspicious case, you'd want to get in touch with CDC Laboratory
24 Response Network, and make sure you get a laboratory
25 confirmation. And then, of course, that will put all the things

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 in gear. If necessary, if you are overseas, you would want to
2 notify the state health department also, and work with your local
3 host nation. Next slide, please.

4 (Slide)

5 Right now, we are at the point where we are with
6 the services trying to form our Epidemiology Response Teams, and
7 also the medical teams and get these team members vaccinated,
8 work with the specialized treatment teams, and we have an IND for
9 use of Cidofovir, if needed, as a backup. We have IND
10 implementation teams that go with that, and then the medical
11 teams at hospitals and clinics.

12 The installations will have to kind of adapt this
13 locally. It will be like a form of a disaster plan for the local
14 commanders, and they will need to apply this to their specific
15 local circumstances. The plan at the CDC and the DOD level
16 involves identifying supporting facilities -- these are the Type-
17 C for confirmed cases, the Type-X for suspected cases, and then
18 the Type-R residential isolation facilities. Those will have to
19 be identified at every local installation.

20 And then the services will need to, of course,
21 train the healthcare providers to recognize smallpox and then
22 also implement the surveillance that we discussed before for
23 these fever-rash type illnesses. Next slide, please.

24 (Slide)

25 In terms of policy, our principal issues are

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 these, and they differ maybe a little bit from the CDC plan,
2 although for healthcare workers and security and law enforcement
3 personnel they actually may be similar in some ways, but we
4 certainly, in the military, need to protect our ability to
5 accomplish mission and preserve capabilities, and for that reason
6 we may appear to be more broad or aggressive in how we implement,
7 ultimately, policy. Of course, the central issue is to save
8 lives in the event of attack, but we also want to preserve our
9 mission capabilities. In addition to that, we want to be able to
10 support the civil authorities in any homeland response, so we
11 would be supportive in any types of national kind of disaster
12 response scenario.

13 Of course, what are the issues that are relevant
14 to that that we have to balance against these objectives? Well,
15 certainly, the issue that smallpox vaccine or vaccinia vaccine is
16 a live-virus type vaccination, and it has a very well described
17 set of serious adverse events. Now, fortunately, these are
18 relatively rare. The most serious events include post-vaccinial
19 encephalitis, progressive vaccinia and eczema vaccinatum, and
20 those are the ones that death are associated with. But these
21 occur -- if you clump those together about 34 cases per million
22 adults, the death rate aggregate is somewhere on the order of 1-
23 to-5, 1 is probably the number 1 per million that is deaths
24 documented, but with some unknowns out there about the number of
25 immunosuppressed folks and whatnot, an upper range of 5 could be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 a possibility, especially in certain populations.

2 The historic death rate after military vaccination
3 is rare, but you have to remember that these side effects and
4 adverse reactions are less common in people who have previously
5 been vaccinated with vaccinia vaccine. So, the risk is most
6 significant for those who are getting primary vaccination, but
7 when we look back over time -- and I'll show you some of these
8 numbers later -- it looks like that military populations tending
9 to be very healthy in the past, revaccinated, that these numbers
10 are probably lower than what you see up there.

11 Again, just to re-emphasize, about two-thirds of
12 our people would be in that primary vaccination status, however,
13 right now.

14 The other thing to consider with vaccinia virus
15 is, because it is a live virus, it can spread to contacts of
16 vaccinees. Now, these are usually close contacts, usually
17 household members, siblings of children, et cetera. But about 20
18 percent of adverse reactions overall in the 1960s studies were
19 actually contacts of vaccinees who incurred those adverse
20 reactions. And we calculate these to be about 8 serious events
21 per million vaccinations, based on those same studies I just
22 mentioned. Next slide, please.

23 (Slide)

24 This just shows the adverse -- you have this in
25 your handout, but I just wanted to show it to you. It shows the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 one death. You can kind of look at the different categories of
2 vaccinations and see how it differs from primary vaccinations to
3 revaccinations. These are based primarily on the 1968 national
4 study that the CDC did, and also the ten-state study that was a
5 survey of physicians in ten states. That particular study has
6 probably the highest rate -- because it was probably the most
7 sensitive and complete in picking up even minor type
8 complications, and then below that we have what we have been able
9 to glean from military records. Interestingly enough, some of
10 the few records we were able to obtain were from old AFEB meeting
11 transcripts, and beyond that it was the book that was published
12 about preventive medicine in World War II, and then we have some
13 Israeli data that's published in the literature recently, in the
14 last few years, that kind of looks at their experience with the
15 vaccine. So, that's really given to you more as a reference just
16 to kind of peruse some of these different issues. Next slide,
17 please.

18 (Slide)

19 I just wanted to show this very briefly as an
20 addendum to what John had submitted to you, but this is from the
21 dilutional study that was done by Frye and colleagues, and it
22 just shows that there's a significant degree of immediate kind of
23 reactinogenicity particularly in the first two weeks after
24 vaccination. These are moderate to severe events that occurred
25 with a frequency of greater than 5 percent. And the things that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 seem to predominate are things like fatigue and muscle aches and
2 pain at the vaccination site. And in their study, they said that
3 at least up to one-third of the individuals might have either
4 loss of sleep or inability to go to work or to go to school, but
5 those were lumped together in a category.

6 (Slide)

7 And so if you actually go to the next slide and
8 look at your table that you have with you, when they mention the
9 severe symptoms, those are the ones that actually precluded
10 performance of routine activities. And no single category was
11 more than 3 percent, so we actually think the number of people
12 that actually might not be able to work or do their job might be
13 around 3 percent or more, depending on how many different
14 categorical symptoms you might have lumped together. But it does
15 have some significant impact in the short-term around the time of
16 vaccination. Next slide, please.

17 (Slide)

18 Just to show these things, the most common
19 complication other than those things that I just showed you is
20 inadvertent inoculation. About 80 percent of inadvertent
21 inoculations are infections of the eye. Inadvertent inoculation
22 is where a person might scratch or rub the vaccine site, then rub
23 their eye or some other part of their body, and then transfer the
24 vaccine to that area and get a secondary infection, basically, is
25 what it is. Next slide, please.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 (Slide)

2 This is generalized vaccinia, another systemic
3 kind of complication. This one is not as severe as some others.

4 It's generally relatively benign. Doesn't usually require VIG.

5 Next slide, please.

6 (Slide)

7 This is eczema vaccinatum. This one can sometimes
8 cause deaths and VIG is indicated for this adverse reaction.

9 Next slide, please.

10 (Slide)

11 And this is progressive vaccinia, usually occurs
12 in immune-suppressed of one way or another, and without VIG was
13 usually uniformly fatal, but the case fatality rate decreased
14 significantly after use of VIG. This is one of the concerns we
15 have with HIV population, people in chemotherapy, et cetera.

16 Next slide, please.

17 (Slide)

18 So, what is the military adverse even experience,
19 in general? Well, we did note that adverse reactions are four
20 times to ten times more common after a primary smallpox
21 vaccination, compared to re-vaccinations.

22 The experience in World War II, from 1942 to '45,
23 we had eight cases of post-vaccinial encephalitis. One of those
24 individuals became partially blind, and there were three deaths.

25 And that was a rough estimate, about 16 million people that were

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 called up to World War II, so that's just a very rough
2 denominator to get a rate.

3 The DOD experience in the '70s and '80s, when
4 almost everyone had been vaccinated initially as a child, the
5 AFEB transcripts give a rate of 54 complications per million, and
6 the complication that seemed to be reported most often was
7 generalized vaccinia.

8 There were no confirmed deaths reported during
9 this time, although is it possible we could have missed
10 something? It may be, but at least none that were linked
11 directly to smallpox vaccination.

12 And then just to remake the case, two-thirds of
13 our people would be in this category of not having received a
14 primary vaccination. And many of the rest, their waning immunity
15 would be more than 15 to 20 years previous. ;Next slide, please.

16 (Slide)

17 Okay. Some assumptions that we used in trying to
18 develop the DOD policy and smallpox response plan, smallpox
19 virus, we assume, may exist outside of sanctioned stockpiles.
20 Smallpox attack could be in more than one place at a time. If
21 it's being used as a weapon, you might expect that they would hit
22 you in several places. It could be here in this country
23 domestically, or it could happen to us overseas in a forward
24 deployed capacity, so we have to have plans that would deal with
25 all those contingencies.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Again, just to mention, our DOD objective is that
2 we need to preserve and sustain the capability of our military
3 and emergency-essential civilians, the contractors that help us
4 do our job. Policy for families, retirees, and other DOD
5 personnel would be consistent in lock-step hopefully with the
6 DHHS policy, and we would consider an exception for family
7 members that would be overseas, especially once the vaccine
8 supply is expanded because we may have to take care of them.

9 The DOD policy, again, must be coordinated not
10 only with our interagency partners here, but obviously we'll need
11 to be talking with our coalition partners and allies as well.
12 Next slide, please.

13 (Slide)

14 So, what are the policy options? Well, currently,
15 they range from small to large. Initially, of course, the small
16 option is that the Epidemiology Response Teams and the medical
17 treatment teams and the vaccination teams would be the first that
18 you would want to consider vaccinating. This would be anywhere
19 from 1,000 to 30,000 individuals. That is pretty much consistent
20 with what the recent draft recommendation of the ACIP stated.

21 The medium option is to add deployed personnel and
22 early deployers and also strategic transport -- obviously, our
23 folks that do airlift, a lot of the OPS planning is really
24 contingent on them being able to get those people to the theater.

25 And so it's important to get them because they will be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 traversing, going back and forth, and you can't be bringing
2 smallpox back and forth, obviously.

3 And then the larger option would add more Active
4 Duty personnel and Reserve Components, could be anywhere up to
5 over 2 million people, if we added all those people in.

6 If attacked, we would, of course, want to
7 supplement these search-and-containment or surveillance-and-
8 containment approach with wide-area vaccination, if needed. And,
9 of course, the key criteria, once again, is mission-critical. We
10 need to preserve our agility to cross borders and we want to
11 consider the distance from medical reinforcement or the
12 availability of medical support. The final decisions on these
13 are still pending and still being in consideration. Next slide,
14 please.

15 (Slide)

16 Just a review of smallpox vaccine issues. The
17 Dryvax vaccine is the preferred source currently, it's the
18 vaccine originally made by Wyeth that has been the stockpile at
19 CDC. That has been 50 million doses, with the 1-to-5 dilution
20 study that we've been able to demonstrate that that could be
21 expanded up to 75 million individuals vaccinated from that
22 stockpile.

23 It is currently IND. We are hoping that FDA may
24 be able to approve that as early as mid-October or late-October.

25 And then there is negotiations underway with the DHHS and CDC to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 give 1 million doses to DOD. And we think with wastage and
2 whatnot that we'll be able to use about 800,000 or so of that
3 million doses.

4 There is vaccine that you may have seen in the
5 press that Aventis-Pasteur found in Pennsylvania. There's about
6 85 million doses there, but relicensing is unlikely because they
7 apparently do not have the manufacturing records to support that
8 vaccine. So, that would be kind of a "use of last resort".

9 There's also the newly manufactured Acambis
10 vaccine, which is human cell culture rather than the old calf-
11 limb type process. There's 209 million doses contracted, about
12 150 million are available in bulk and 10 million are bottled.
13 They are having some problem, I think, with labeling and some
14 other procedures there, but the license estimate is for late Fall
15 2003.

16 And then we have DynPort, which is the DOD
17 contract, about 16,000 doses or so, license estimate is similar.

18 And then the vaccinia immune globulin, which currently DOD has,
19 we have enough for about 5 million vaccinations, and we're
20 negotiating with CDC to kind of share that with them. And we
21 have more due to be delivered. Next slide, please.

22 (Slide)

23 The AFEB recommendations have been very helpful in
24 this regard, that you've given us. We could need more advice --
25 and I'll mention that briefly here on this slide. One of these

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 is the issue of contact transmission, which is theoretically a
2 fairly preventable type occurrence. ACIP is looking at revising
3 or adding to their recommendations, but it may take them longer
4 to do that, and so if we had some interim guidance from the AFEB,
5 it might be helpful. So, a memo may be going out. It might be
6 helpful if the Subcommittee on Infectious Diseases could give us
7 some assistance in that. But these are very, very draft, kind of
8 off-the-top-of-the-head, I think from John, sort of thoughts, but
9 certainly hand hygiene is important. Simple things like infants
10 and age is also another concern for adverse reactions, and so you
11 might want to avoid doing things like changing your infant's
12 diapers.

13 Covering the vaccination site may be helpful, and
14 there are certainly several iterations of what could be used
15 there that would do this. I think the evidence basis is probably
16 best for protection with the semi-permeable membrane transition
17 type of dressings, but there's issues of maceration, et cetera,
18 and cost with that. It may be just more simple to put a bandaid
19 on and a tee-shirt. But there's other thoughts about if you've
20 got a susceptible person at home but you still need the
21 vaccination -- do you isolate that person? Do you cohort them
22 away from their family? What do you do with healthcare workers,
23 would they be a population that the semi-permeable membrane and
24 gauze might be an option? Do you use alcohol gels to wash your
25 hands, or do you use regular soap? So, these are the sort of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 things that we might like some assistance from the AFEB to help
2 us with later.

3 I think that's it.

4 DR. OSTROFF: Questions? Let's start with Bill,
5 and then Ben.

6 DR. BERG: Bill Berg. Dana, the 1 million doses
7 of the Dryvax that Health and Human Services is going to commit
8 to DOD, is that 1 million doses that will be diluted to 5 million
9 doses? How many net doses is the DOD likely to end up out of
10 that?

11 COL. BRADSHAW: The preference is to use that as
12 licensed, so if we did it licensed, probably the earliest
13 licensing would be for undiluted. It would be IND to use it
14 diluted, and it will probably take longer to get the ability to
15 have it licensed as diluted. So, that will be maybe a
16 contingency.

17 DR. OSTROFF: The only reason that product is
18 currently in IND status is because of the diluent, and it was
19 known that it would be much easier to get the alternative diluent
20 to licensed product than it would be to get the 1-to-5 dilution
21 in licensed status, and so we would fully anticipate licensure of
22 the full-strength product well before there would be licensure of
23 the dilute.

24 LtCOL. WOODWARD: And if I could clarify about the
25 MOU, it's 1 million net doses undiluted, but if it's a diluted

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 use, either licensure or intended, it's a net 3.5 million diluted
2 doses, is what the MOU states.

3 DR. OSTROFF: Ben.

4 COL. DINIEGA: Just a comment. There is a ACIP
5 Smallpox Working Group next week, Monday and Tuesday. Some of
6 the issues they are going to talk about is site care, work
7 furlough issues, and the screening methodologies, looking for
8 medically exempt people.

9 DR. OSTROFF: Jeff.

10 COL. GUNZENHAUSER: This is a point of
11 clarification. There was a vaccinia associated death in a
12 trainee, I think it was 1984. It was reported, I think, in the
13 New England Journal by Robert Redfield, when he was at WRAIR.
14 And it was rather sensational because the fellow did have HIV,
15 and that's what caused a lot of concern at the time. I'll talk
16 with John Grabenstein and make sure that's updated on the Web.

17 COL. BRADSHAW: I'll go ahead and speak to that
18 issue. The individual that had that that it was reported,
19 developed the complications of AIDS, and his first manifestation
20 was actually getting I guess it was eczema vaccinatum. He was
21 treated with VIG successfully, and he died more than a year later
22 from other complications. He had also, I think, acryptococcal
23 (phonetic) meningitis, so you would kind of have to actually
24 split the mortality determination to say he actually died of
25 vaccinia complication.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 COL. GUNZENHAUSER: That would be good to clarify.
2 I think there's a lot of institutional memory about that case,
3 and people are going to wonder. It's a small point, but just for
4 clarification.

5 COL. BRADSHAW: Right. And it's actually quoted a
6 lot of times as a vaccinia death, but if you read the paper, it's
7 not that clear that that's actually what happened.

8 DR. OSTROFF: Either way, he shouldn't have
9 received the vaccine.

10 COL. BRADSHAW: That's true.

11 DR. POLAND: Dana, one issue, particularly for the
12 military because of the size, is the long list of
13 contraindications for receiving the vaccine in family members.
14 So, in other words, military personnel who would not be able to
15 receive the vaccine because they have a family member at home
16 with a contraindication, unless you were able to isolate them
17 from their family potentially, depending on the kind of dressing
18 used, for as long as a month, how are you all thinking about
19 that, and would not receiving that vaccine make them
20 nondeployable?

21 COL. BRADSHAW: The current thinking is it would
22 not make them nondeployable, that they would go ahead and be able
23 to be deployed. We think -- I mean, just very raw estimates,
24 anywhere from 5 to 10 percent or more of people might have one of
25 those contraindications, and it can be anything from a family

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 member with eczema or some other type of dermatitis, to a wife
2 who is pregnant, infant in the home perhaps --

3 DR. POLAND: I was hoping you were going to say
4 that.

5 DR. BRADSHAW: -- immunosuppressed individuals, et
6 cetera, et cetera. But this is where, you know, do we bring them
7 on-base in quarters for 21 days? do we consider whether or not
8 they just sleep in a different bed at home and they have a semi-
9 permeable membrane? Are these options? Should we think about
10 that or not?

11 DR. POLAND: One advantage here is, were they to
12 be exposed either here or abroad, they can always be immunized
13 post-exposure --

14 DR. BRADSHAW: Exactly, within four days or so.
15 Exactly.

16 DR. POLAND: At that point, if it were here rather
17 than abroad, then there is no contraindication for anybody.

18 DR. BRADSHAW: Right.

19 DR. OSTROFF: I don't know if you can comment in
20 terms of policy development what considerations have been made
21 concerning HIV testing, since we're going to be discussing that
22 in the next session, and also what's going to be done in terms of
23 pregnancy testing, since that's been a major concern related to
24 anthrax.

25 DR. BRADSHAW: Right. Ben, go ahead.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 COL. DINIEGA: Those issues also are faced by the
2 civilian population vaccination, and I think our preference is to
3 wait and see what they're going to do, but the same issues -- we
4 do test for HIV at different intervals and for different reasons.

5 Certainly, IND protocols that CDC and NIH and other people have
6 been running with smallpox vaccinations, they are testing
7 immediately just prior to vaccination, both pregnancy and HIV.
8 So, I think those are very critical issues for the military, and
9 as we discuss the HIV screening issues, we should keep in mind
10 the smallpox vaccination issue. I don't think there's any good
11 data that says that if you're positive, your exemption or
12 disqualification depends on CD-4 counts or symptomatology or
13 anything, there's no data. So, even if you're positive and
14 you're healthy or have adequate CD-4 counts, the question is can
15 you still be vaccinated. We don't have any of that sort of data.

16 So, rather than getting ahead of the civilian
17 discussions, I think it would be better, as much as possible, for
18 the military to wait for the CDC and ACIP deliberations and their
19 recommendations on many of these issues because we don't want to
20 be out-of-step or different, and most of the expertise is on the
21 civilian side on this issue.

22 DR. PATRICK: This is probably more relevant to
23 the civilian side, but what's the status of vaccine availability
24 on a global basis, in other nations, and I'm thinking that that
25 may intersect issues here related to humanitarian delivery of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 this should there be an outbreak somewhere else? What's the
2 status in Europe or the developed world?

3 DR. OSTROFF: Well, I think that WHO has been
4 doing inventories to find out what's available elsewhere. There
5 certainly is product elsewhere, but we, I think, as a government,
6 have had a policy that any case of smallpox that would occur
7 anywhere in the world would represent a direct threat to the U.S.
8 population. And based on that fact alone, that we would have a
9 very liberal policy in terms of making vaccine available to
10 contain a smallpox event anywhere in the world.

11 DR. PATRICK: Would there be a scenario in which
12 something might occur somewhere else in the world and the U.S.
13 military might go in to assist with the delivery of vaccine in
14 those areas, in a humanitarian sense?

15 DR. OSTROFF: Oh, I don't know about that.

16 COL. DINIEGA: That's always a possibility. The
17 usual procedures for responding to national and international
18 incidents, for the nation we have the Federal Response Plan, so
19 you go local, state, federal. When it comes to the Federal
20 level, medical is in the realm of DHHS. It's their emergency
21 specialty function response area. And if they need any
22 additional help, then they would come over to DOD to request
23 help.

24 In an international incident, the normal request
25 to get the U.S. military involved has to go through State

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Department channels, and then it all depends on what State does,
2 if they request help from the military or from other Federal
3 agencies, but certainly that's a possibility. And in the DOD
4 Response Plan, within our borders, our installations and medical
5 treatment facilities already have emergency response plans to
6 coordinate efforts with local response efforts. And overseas in
7 other countries where we have DOD installations, there are local
8 planning initiatives being taken. But the formal request has to
9 go through the State Department.

10 DR. OSTROFF: Ben, if I could just make one
11 comment concerning your comment about waiting to see what ACIP
12 does, that's all well and good, but it's already very clear that
13 what will be done within the military is diverging from what
14 would be done within the civilian sector both in terms of using,
15 for instance, full strength versus dilute, voluntary versus
16 mandatory, et cetera, et cetera, et cetera. There are just a lot
17 of different considerations within the military setting, and I
18 don't think that it's appropriate to just sit and wait for what
19 the civilian sector does because there are different contingency
20 considerations within the military. That is not to say that we
21 should highly diverge. I think given the special nature of the
22 circumstances, there's clearly going to be different policy
23 that's going to show up in each sector, and I think the Board was
24 very clear about that in their prior recommendations. There are
25 special considerations.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 COL. DINIEGA: I agree, Steve, and I think any
2 divergence between the two policies and the programs need to have
3 good reasons for diverging. And certainly the time sensitivity
4 issues are being considered. But as far as the screening things
5 -- you know, we participate in ACIP deliberations, so we'll have
6 at least a feel for where the ACIP is headed on many of these
7 issues, and we work closely, as you all know, with the CDC group
8 on the response and the screening and IND implementation
9 programs.

10 DR. BRADSHAW: I just might mention, too, though,
11 as you can imagine -- and you'll get into the more detailed
12 discussion of current HIV screening policies in the services
13 based on Joint Staff recommendations -- but most of our people
14 that deploy are supposed to have an HIV within 12 months of
15 deployment, and then there's varying periods of HIV screening
16 that's currently going on among the services.

17 So, the question really comes down to how recent
18 would it be -- and we're already doing HIV screening -- so, how
19 recent is recent enough for somebody who would be receiving the
20 vaccine, and then some plans that I've seen elsewhere,
21 particularly on the civilian side, may just say "Do you have any
22 of this group of screening" -- so, high-risk sexual behavior
23 might be one of those, and this would be similar to what we do
24 with our post-retirement Hepatitis C screening where you would
25 ask a list of questions and say, "Do you have any of these

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 contraindications", and the person would say yes or no, and they
2 don't necessarily have to specify which one. That might be just a
3 way of doing it by questionnaire, but we could buttress that with
4 the HIV screening that we already have in place. And many of our
5 people that deploy frequently, that would certainly be among the
6 mission capabilities type people, would probably already have an
7 HIV somewhere in the last year or so.

8 DR. OSTROFF: Dr. Cline.

9 DR. CLINE: I understand that there have been some
10 reports of cellulitis at local vaccination sites. I'm not really
11 clear on how common that is or to what degree that is a concern,
12 but could that be discussed a little bit? Could we have some
13 clarification on that?

14 DR. BRADSHAW: I'll speak briefly to that, and
15 anybody else that has expertise, Greg or others, can certainly do
16 this. Looking and talking with Dr. Belshi (phonetic), with the
17 group that did the 1-to-5 dilutional study -- and there's been
18 some controversy and discussions back and forth in the literature
19 on this -- his opinion is that a lot of it is people just aren't
20 to seeing this degree of inflammation and reactinogenicity with a
21 vaccine, so that what's perceived as cellulitis a lot of times,
22 if you don't give antibiotics, goes away over that two-week over
23 that two-week time frame or so, and it's probably more represents
24 an inflammatory response from the vaccinia itself and the
25 vaccination itself, not that secondary infections don't occur,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 and that's one of the concerns about using a more occlusive
2 dressing, is that it would maybe predispose to secondary
3 infection and maceration, et cetera. And so those do occur, but
4 a lot of what's being seen is I think people just aren't used to
5 seeing how reactinogenic this can be. And Greg maybe can speak
6 to that.

7 DR. POLAND: I would concur with that. In fact,
8 senior CDC people who have been involved with the smallpox
9 eradication program confirmed that, that their opinion was this
10 was typical reactinogenicity, it just looks bad to those of us
11 who are not used to seeing it.

12 DR. OSTROFF: And if I could comment, since I was
13 involved in all that at CDC, that there were -- I mean, this
14 problem was seen in CDC personnel who were vaccinated. It was
15 seen to a certain degree in the dilutional studies. And the
16 veterans all said this is basically what you see, and the
17 experience was that whether these individuals were placed on
18 antibiotics or not, it didn't seem to make any difference in how
19 rapidly it went away, which suggested that it probably wasn't an
20 active bacterial cellulitis. There has been an individual who
21 was the contract physician for many of the facilities in the D.C.
22 Metropolitan Area, who has been administering vaccine, who's
23 published, I think, several Letters to the Editor in various
24 medical journals, claiming that this seems to be an increasing
25 problem to him, and he has a lot more experience than many of us

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 in actually administering the vaccine. And we've done some
2 investigations looking into the circumstances of those claims,
3 and we haven't been able to necessarily substantiate that there's
4 really anything different going on.

5 DR. GARDNER: Although there certainly have been
6 cases of toxic due to staph colonization, and even in tetanus --

7 DR. OSTROFF: Well, that's, as pointed out,
8 secondary to maceration.

9 DR. GARDNER: True, there's a lot of redness that
10 goes on with the vaccination, but there -- just as in chickenpox,
11 there's a secondary bacterial infection --

12 DR. OSTROFF: And the other issue, I think, was
13 the degree to which the site was occluded by dressings, et
14 cetera, also played a role in how often this occurred. Dr.
15 Malmud.

16 DR. MALMUD: This may not be an issue for us, it
17 may be more of an issue for the CDC than for the AFEB, but when I
18 was a child some 29 years ago -- (laughter) -- we were
19 vaccinated. It was a matter of great pride among us -- we were
20 all vaccinated at the same time, by the same GP -- to have the
21 nastiest, crustiest, largest black pustule among the group, and
22 it was a matter of pride, not a matter of shame, and it also
23 indicated that it took. So, the word spread quickly among the
24 children this was a good thing, and I think we probably need some
25 public education as to what these things were like at that time.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Now, there was no immunosuppressed population
2 comparable to our reactinogenically immunosuppressed population
3 or the HIV population today, but a little education would go a
4 long way to calming fear that's unrealistic.

5 DR. OSTROFF: Greg.

6 DR. POLAND: Can I ask a different question, Dana,
7 just a clarification. In the chart that you have where you list
8 the number of doses of VIG, when you say for 5 million
9 vaccinations, do you mean enough VIG for the calculated
10 complication rate that would require it, or do you mean you've
11 got 5 million doses of VIG?

12 DR. BRADSHAW: I think -- I'll get back to the
13 horse's mouth here, if I can, and quote this. I think it was
14 something like -- we have enough for 5 million vaccinations at
15 one treatment per 10,000 vaccinations.

16 DR. OSTROFF: Since we've run a bit overtime, let
17 me just raise two other issues before we adjourn for a break.
18 One of them is I'm wondering if our Canadian and British
19 colleagues would comment on what the current thinking is within
20 their hierarchy regarding potential vaccination of personnel in
21 the Canadian and British militaries.

22 LtCOL. FENSOM: Certainly. As I alluded to
23 yesterday, there is a hope that widespread vaccination can be
24 held off until the next generation vaccine is available. My best
25 guess on where the policy will go in the near future is very

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 similar to what you are talking about, although I think it will
2 be a much more limited threat-based type of vaccination of
3 service personnel. But I see in the very near future that we'll
4 be doing response teams and whatnot.

5 And in answer to the other question from Dr.
6 Patrick, there is currently in Canada enough vaccine to do entire
7 population.

8 COL. STAUNTON: Col. Staunton, U.K. My best guess
9 is that our policy in the U.K. will go along very directly with
10 the outcome policy decisions here. Regarding my concerns -- and
11 I would imagine the Canadians will have much the same concerns --
12 that we do not have any mandatory screening for HIV. So, that is
13 my main concern as to how we go forward with our policy.

14 I would foresee, as I say, that we will vaccinate,
15 I think, certainly, for the services, and I think if we look at
16 it in terms of scale, roughly speaking, we're looking at service
17 personnel being something in the region of, I suppose, ten times
18 smaller than yours. But in terms of an immunocompromised
19 population within that, we have got means of identification and
20 people come forward. We haven't had a problem with that. Our
21 policies coincide very consistently regarding deployments or,
22 should we say, not deploying personnel who are immunocompromised.

23 However, as we have no means of identifying them right now, we
24 are well behind the curve. And why I am particularly interested
25 in looking at what you are doing for that population or that side

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 of the community is that I feel that both from the outcomes here,
2 from AFEB, from your thinking, and also in talking with other
3 people on GPPM-PG, that I've really got to give to U.K. -- I've
4 got to recommend some policies. So, that's my position.

5 LtCOL. FENSOM: Same in Canada with regards to the
6 HIV testing, and I think this issue is going to push forward a
7 trend that we're already seeing towards introducing some HIV
8 screening within the forces.

9 DR. OSTROFF: Last question that I have. You
10 know, by all appearances and without giving away the ending in
11 terms of policy, that there's going to be significant divergence
12 to what's being done between anthrax and smallpox, how are you
13 going to explain that?

14 DR. BRADSHAW: We have a slide that kind of looks
15 at the differences between the two vaccines and what the issues
16 are. I think I mentioned earlier that anthrax, to me, is more
17 like a tactical weapon, and I think there are some aspects to the
18 smallpox vaccine that make it more of a strategic weapon, one of
19 which is the long incubation period and the communicability,
20 which makes it a little bit harder to put in a box, in some ways;
21 in other ways, not. But I think the overriding issue, I think,
22 is the issue of being able to preserve our mission capability
23 that may make us different and maybe have a little bit more
24 divergence from the DHHS plan. We're going to try and stay as
25 much in lock-step with it as we can, while still trying to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 address the issue of can we do our mission.

2 There's been a lot of discussion about just-in-
3 time vaccination, a lot of discussion about the fact that you can
4 vaccinate somebody within four days or so, and still decrease
5 morbidity and mortality significantly, and that in some ways
6 gives us more flexibility than anthrax vaccine which takes three
7 vaccinations at least to get a significant degree of immunity.
8 So, all those things have been discussed, but I think it's the
9 mission capabilities that makes the biggest difference in some
10 respects. And then the unpredictability in other ways.

11 COL. DINIEGA: Just a comment. On this and several
12 other issues in the working groups, there's been a lot of diverse
13 opinions, and this is -- I guess we make the best medical
14 recommendations we can, and then let the politics and the senior
15 leadership make their decision, and we have to live by whatever
16 decision they make. There are certainly differences between the
17 two approaches, and the main approach for reasoning has been one
18 is threat-based and one is capabilities preservation-based.

19 DR. OSTROFF: I can assure you, I think those
20 nuances will be lost on the troops.

21 COL. DINIEGA: I agree.

22 DR. OSTROFF: Why don't we take a ten-minute break
23 and come back at 10:30 and get started with the next session.

24 Thank you very much, Dana.

25 (Whereupon, a short recess was taken.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 DR. OSTROFF: This session regards HIV screening
2 policy, and there is a specific question before the Board
3 regarding the issue of harmonization of HIV testing schedules
4 among the various services. And our first presenter is Lynn
5 Pahland.

6 MS. PAHLAND: Yes, you did. Good morning.

7 Since the late 1980s, we've had a policy in the
8 Department of Defense for HIV. I've been at Health Affairs, DOD,
9 for the past five years, and for the past four years we've been
10 rewriting the DOD Directive, which is the highest level of policy
11 in the Department of Defense. It almost was signed off
12 approximately two years ago, by the Secretary of Defense under
13 the Clinton Administration. It did not get through all the
14 wickets prior to the change in Administrations, so it has to be
15 re-coordinated. And in looking at it again, there are many
16 questions that are coming up about the relevance of having a
17 policy for one disease, even though HIV is, in many people's
18 minds, a very unique disease.

19 The coordination of the development and building
20 of this new policy has been with many areas throughout the
21 Department of Defense -- Force Management Policy and, of course,
22 with the clinical people in Health Affairs and the services.

23 (Slide)

24 The question that we want to bring forward to the
25 AFEB is for your recommendation for appropriate, if any, routine

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 screening interval or status for HIV testing. We don't need to
2 have a policy or a directive in place just to follow clinical
3 indications for HIV screening, but we, of course, are very aware
4 of the fact that we have a very special population and that there
5 are readiness requirements that we have to take into account.
6 Therefore, we're bringing the question to this group.

7 One of the qualifiers in us asking the question is
8 to look at the question and not take into account the impact on
9 the Serum Repository. I have no position on the Serum
10 Repository, and that's not my area to discuss here. But the
11 question, the very narrow pointed, but very relevant question is
12 should we have a policy at a Department of Defense level that
13 talks about routine screening for our Armed Forces?

14 Any questions?

15 DR. OSTROFF: Can I ask you to clarify a little
16 bit what you mean concerning status as opposed to -- interval, I
17 understand.

18 MS. PAHLAND: The reason I put that in there was
19 to allow for the Board, the Services, to determine whether or not
20 pre- and post-deployment, or pre-deployment status, or a
21 situation if someone is outside of the United States or in a
22 particular military setting, whether or not that would require
23 HIV screening. For example, if someone was stationed overseas,
24 would that then increase your recommendation or change your
25 recommendation for routine screening? If they were in some sort

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 of forward deployed situation, would that impact routine
2 screening?

3 DR. OSTROFF: Thank you. Are there any questions?
4 Ben?

5 COL. DINIEGA: Lynn, would status also pertain to
6 Active versus Reserve status?

7 MS. PAHLAND: The way that we want the question to
8 come forward is that we're talking about the Armed Forces, and
9 that particular differentiation would probably come up during
10 your discussions, so it's a very sweeping question. It does talk
11 about the Reserves, cadets, people currently on active status.
12 Thank you.

13 DR. OSTROFF: Thank you very much.

14 Our next presentation is Col. Rubertone, who will
15 talk about the current screening policies in the Department.

16 LtCOL. RUBERTONE: Actually, I won't be talking
17 specifically about the screening policies, the Service
18 representatives are going to follow, I believe, lunch and talk
19 about that. I am going to be talking about HIV screening in the
20 DOD and, by nature of the fact that at the Army Medical
21 Surveillance Activity we run and manage the Defense Medical
22 Surveillance System is the reason Rick asked us to provide this
23 talk, and I'm always happy to provide a talk on a
24 noncontroversial subject where I present DOD data.

25 (Laughter.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Next slide, please.

2 (Slide)

3 Just in terms of the outline for this talk -- and
4 I won't take the hour that's on the schedule, I'll leave plenty
5 of time for questions -- I do want to go over the background and
6 history of the HIV screening program, but not really to delineate
7 all the nuances of the policy, but just to put it into context.

8 I'm going to briefly, in one slide, describe the
9 Defense Medical Surveillance System to orient the Board members
10 who may not be familiar with that system, and then I'm going to
11 turn my talk to really the heart of the talk, which is a lot of
12 data -- and it's in the handout, so I won't spend too much on
13 each individual slide, I think we'll all fall asleep, but I'll go
14 over HIV screening in the Active Duty, screening in the Reserve
15 Component. One omission on your handout actually, and
16 unfortunately, is screening in civilian applicants. It is in the
17 slides, but those particular slides didn't make the handout.

18 I'll then look at the impact of changing the HIV
19 screening frequency just based on a very simple model that we've
20 put together; look at then the objectives of an HIV screening
21 program, and although Ms. Pahland said not to consider the Serum
22 Repository, I think that there is certainly a consideration for
23 the DOD about the Repository, so I'll just put that onto the
24 table. Next slide, please.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 In terms of the history of the HIV screening in
2 the DOD, in 1985, DOD directed that HIV testing programs be
3 established. In March, the screening test for HIV was licensed.

4 In the spring was the first sort of formal and routine testing
5 for HIV, and that was on all donors at military blood banks.
6 beginning in October 1985, we started testing civilian applicants
7 for military service, as they were processed through the MEPS
8 stations. October of '85, the routine testing of Active Duty
9 soldiers began.

10 I don't have all the data on the other services
11 for the Reserve Components, but I can say that I was able to find
12 that in June of 1986, the testing of the Army National Guard
13 began, and then I'll skip to May of 1987, testing of Army
14 Reserves began.

15 In September of '86, the AFEB was asked to address
16 the question of HIV screening in the DOD, so here we are 16 years
17 later -- kind of like the locusts -- we're going to readdress
18 that issue.

19 In October of 1985, the U.S. Army HIV Data System,
20 or USAHDS, was established to monitor the testing program and to
21 track the epidemiology of HIV. And I mention that because seven
22 years later, in 1992, USAHDS migrated and became the Army's
23 Medical Surveillance System, and then five years after that
24 became the Defense Medical Surveillance System. So, the roots of
25 the Defense Medical Surveillance System actually began with the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 HIV testing program and the efforts to track that. Next slide,
2 please.

3 (Slide)

4 Some of the justifications for HIV screening that
5 I could uncover for this presentation roughly fall into these
6 four categories. Readiness, as we've discussed already -- Col.
7 Guzenhauser brought out -- there is a contraindication with
8 receiving live virus vaccinations. There's also a
9 contraindication to give multiple immunizations to
10 immunocompromised individuals.

11 Deployment-related justifications were really to
12 protect the health of the individual infected -- that's potential
13 exposures to exotic diseases -- and the limited access to
14 sophisticated care in a field setting. The third was to protect
15 that infected soldier's buddy where you might have a field
16 transfusion of unscreened blood.

17 In terms of the health of the individual, early
18 diagnosis and early treatment was certainly a justification for
19 screening.

20 And, finally, the public health justification of
21 decreasing any "unwitting" transmissions of HIV. Next slide,
22 please.

23 (Slide)

24 This one slide -- and it's a rather busy slide --
25 does depict the Defense Medical Surveillance System, and I'll

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 spend just a couple of minutes on it because it is kind of
2 critical to the remainder of my talk. And the reason it's
3 critical -- I've learned never to say "the rate in the Navy is
4 this", or "the rate in the Air Force" -- what I can tell you is,
5 based on the data we have in the Defense Medical Surveillance
6 System, this is the rate -- it's almost like in an argument when
7 you say, "Well, that's my opinion, I can't be wrong" -- so I
8 can't be wrong because, if it's not in the DMSS, I can't quite
9 present on it. So, that's sort of my soapbox for having the
10 Services provide the data to the DMSS as is required for
11 surveillance purposes. And for the most part, we do get the
12 majority of the data that we need.

13 But starting up here in this Active Duty box,
14 we've been tracking since 1990, 5.2 million persons who have been
15 on Active Duty. The 52.5 million records goes to speak to the
16 longitudinal nature of the DMSS and how we have many records over
17 time, as people change different status demographic -- you know,
18 their marital status, or where they're assigned, deployed, et
19 cetera.

20 We also are tracking another 2.1 million person in
21 the Reserve Component.

22 I'm going over here to the serologic data and say
23 we've got information on 29.8 million specimens that have been
24 drawn for the HIV testing program. All of the data that I'm
25 going to be presenting relates to these 29.8 million specimens

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 and one these specific individuals. So, sometimes the testing
2 programs might say this was an Active Duty test. Well, if we
3 can't relate that particular test on that day to a person that we
4 get in our Active Duty file from the Defense Manpower Data
5 Center, then we don't call that an Active Duty test. So, that's
6 part of the way we operate, is that we validate all of our data
7 against other sources as we integrate it into the DMSS.

8 There are other information inn the DMSS that I
9 won't really get into right now, but it's been relevant to some
10 of the other discussions during these two days, the pre- and
11 post-deployment health assessments, the DNBI data that we heard
12 discussed yesterday, all of the medical outcomes. But for the
13 most part, we're looking at the population here which is Active
14 and Reserve Component, and also the Military Entrance Processing
15 Stations, the civilian applicants, and then the serologic
16 specimens. Next slide, please.

17 (Slide)

18 This is the total number of persons tested within
19 the DOD -- again, I put this on all slides, as maintained in the
20 DMSS because if we haven't received the information, there's
21 really no way for me to have it on the slides, but I feel that
22 it's pretty accurate. These are people tested, you can see,
23 going back to 1990. Prior to 1990, the only tests we have in
24 DMSS are on the Army and MEPS, so I didn't include that on all
25 the slides. Some of the slides, where appropriate, I did include

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 that. Starting in 1990, in the early part of the '90s we tested
2 roughly 550-600,000 people in the Army, that's both the Active
3 and Reserve Component combined. You can see that the Navy tests
4 about 450,000 people for that period of time. Civilian
5 applicants, about 400,000. The Marines, roughly 180,000.

6 In the second half of the '90s, more in concert
7 with the decreasing end-strength of the various components and
8 services, that testing did go down and we're very close to
9 450,000 a year for the Army, although we did have a jump last
10 year which corresponds -- you can't quite tell, but in here there
11 was a buildup for the Persian Gulf War, so we saw some increased
12 HIV testing, and this line here is for Operation Enduring
13 Freedom, with all the activated Reservists and people who were
14 deploying, so you do tend to see a little bit of a jump with
15 major deployments.

16 '95, this little blip I should have pointed out is
17 related to Bosnia, and the deployments to Bosnia. But, for the
18 most part, we're testing 450,000 people in the Army, another
19 400,000 in the Navy, as you can see.

20 The Air Force is interesting. Up until 1996, with
21 Bosnia, we didn't receive any information. That's why the
22 testing is so low. They had a testing program -- and I'm sure
23 they can produce the numbers of people tested back in the early
24 '90s -- we don't have that data in the DMSS. The reason that
25 line is not exactly on zero is that there are some Air Force

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 people who are tested through the Navy and the Army testing
2 contracts, and we would subsequently get that information. So,
3 it runs 5- or 6,000 people that we know had tests, but obviously
4 that wasn't the Air Force testing program.

5 In '96, because of the deployment to Bosnia and
6 the requirement for a pre-deployment serum specimen on people who
7 deployed, they mandated in the Air Force that the serum specimens
8 from their testing programs down at Brooks be sent to the Serum
9 Repository. So, in '96 we started receiving the specimens and
10 it's been very interesting that that's been ramping up to what
11 probably now will be an annual testing of about 275,000 people in
12 the Air Force.

13 The Marines, very steady over time. That's very
14 close to their end-strength. They tend to test almost everyone
15 once a year. That's not totally true because it doesn't take
16 into account people coming and going from the service, but they
17 have been very consistent over time.

18 (Slide)

19 The next slide is not to be confused with the
20 number of persons tested, but these are the total number of HIV
21 tests that we received. And I show that just to illustrate that
22 in any given year we have close to 50- to 100,000 people in the
23 Army who are tested twice. So, because of various policies,
24 programs, going through clinical evaluation or STD clinics,
25 whatever is the reason, we have more tests than people tested, of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 course, and that's a consistent theme across all the services,
2 even with the Marines. They have about 10 percent of people who
3 are tested more than once in any given year.

4 So, all these numbers here would add up to
5 basically 29.8 million tests that we have information on in DMSS.

6 (Slide)

7 The next slide shows those HIV tests where we
8 actually have results of the HIV test. And the reason I have
9 this slide is because when I go and present the results, I want
10 to make sure everyone understands where the numbers have come
11 from.

12 You'll see two things here. There is a gap for
13 '93, '94, and '95 in the Navy and in the Marines. We have the
14 fact of tests. We can relate to the serum in the Serum
15 Repository. We know the date of tests. We do not have the
16 actual results. We did try to get that data from NHRC at one
17 time, and it was just not able to be provided to us.

18 You also might have noticed that the Air Force
19 line completely disappeared. We have no test results on the Air
20 Force in the DMSS. That's been a policy in the Air Force since
21 '96 when they started contributing information about the test and
22 serum to us. They do not give us the actual test results, so the
23 test results -- HIV infection rate that I'll present later came
24 from LtCol. Woodward, from the Air Force. Next slide, please.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 These next four slides are going to go through the
2 rate of new diagnoses of HIV in the various services -- Army,
3 Navy, Air Force and Marines -- and I'll just mention on this
4 slide that although I say rate -- and I'll use that phrase
5 throughout the talk -- it is not an incidence rate, it is, as it
6 says down here, the rate is defined as the number who tested
7 positive over 1,000 persons. So, we don't really know what the
8 true incidence is in any of the services since we don't have
9 complete screening, but I think, as maybe later it will show,
10 with an active and periodic testing program, the number that test
11 positive and the rate of people who test positive over a tested
12 population more or less mimics the incidence over time. So,
13 these are very close to incident numbers.

14 This data goes back to 1985-86. For the Army, you
15 can see the total number of tests, total number of persons
16 tested, et cetera. This is the total number of HIV-positive
17 individuals identified by the testing of HIV, 2711 individuals,
18 which we have 295 infected individuals currently in the Army,
19 remain in the Army. Of note, we have 8 persons who were tested
20 positive in 1985-86 who are still currently on Active Duty. So,
21 the standards for release from Active Duty certainly aren't
22 linked to being HIV-positive or infected, it's more with the
23 health of the individual and other symptomatology.

24 It used to be easy to remember .2 for about three
25 or four years. People would ask me what the rate of HIV

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 infection is, I'd say .2. The last few years, that's kind of
2 gone -- bounced around a little bit. A comment on 2002 data.
3 The number of positive in the identification of positive always
4 lags the number of negatives because it goes through other
5 testing. Sometimes that data doesn't get to us quarterly,
6 depending on our source for the data. So, really, I present what
7 we have as of this day in the DMSS, but we expect that this rate
8 will go up as we get in complete information. So, calendar year
9 2000 is quite incomplete, but this is the data that we have to
10 date. Next slide, please.

11 (Slide)

12 This shows the data that we have for the Navy, and
13 as far as possible I tried to keep the slides exactly the same,
14 and I'm not doing that to have you focus on the gaps in data, but
15 just to be consistent across the services.

16 This is the data that we have information on in
17 terms of actual results of tests, and you can see that it has
18 varied a little bit over the last few years, but the rate of
19 tested positive is fairly similar to the Army in that regard.
20 According to our records, we only have test results on 1,052
21 persons tested positive. The majority of people who tested
22 positive in the services happened in the late '80s, we don't have
23 that information for the Navy. And, again, 320 individuals,
24 according to our records. Now, that the Navy certainly could
25 correct and tell you a more accurate number of individuals, but

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 based on the data, again, as I said, in the DMSS, that's what we
2 have known positive who tested positive in various years. Next
3 slide, please.

4 (Slide)

5 This is the Air Force data and, again, from LtCol.
6 Woodward, I received this data. We did have information on total
7 number of tests. Our information on the total persons tested is
8 quite close to this. We do have more people tested in 2001 than
9 I received, and I didn't get a chance to share that with Kelly
10 before this talk, but -- so this .19 actually may be lower, and I
11 think I can share that with you. This was provided to me by the
12 Air Force. Next slide, please.

13 (Slide)

14 And the Marines similar to the Navy in terms of
15 the three-year gap that we don't have data, and prior to 1990.
16 And similar, but lower, especially in certain years, rate of
17 tested positive infections. Next slide, please.

18 (Slide)

19 The next slide graphically shows the same data,
20 and you can see that for the most part somewhere between .1 and
21 .2, .25 is the number of persons testing positive per 1,000
22 persons tested. Next slide, please.

23 (Slide)

24 Just to break the data down a little bit by
25 various demographic groups, this is Army Active Duty by gender.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Males have consistently been higher except for one year, in
2 calendar 2000. Next slide, please.

3 (Slide)

4 It's hard to see the Other, but it's on your
5 slide. Hopefully it comes out a little better. Single
6 individuals have always had a higher rate of testing positive
7 than Married, but the Other has varied and it sometimes has been
8 high. It's a smaller group of individuals, so there's a little
9 bit of fluctuation with those rates. Next slide, please.

10 (Slide)

11 This is the Army Active Duty broken out by
12 Race/Ethnic. Blacks being the highest, and then Hispanic.
13 Other, again, kind of bouncing around. Then Caucasian/White
14 towards the bottom. I don't have these same slide breakdowns for
15 the other services. I didn't think that they illustrated
16 anything different than this, which is pretty much what you would
17 find in the literature. Next slide, please.

18 (Slide)

19 Age doesn't look very well when you plot it over
20 time, so it's a lot of up and down. It really is hard to
21 interpret. But if you take all the years of all people tested
22 and plot it by different age groups, you do see an interesting
23 phenomenon where the highest rate of infectivity in the screening
24 program is in the 30-34 year olds, which is a little different
25 than in the civilian population. You'll see in a couple of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 slides that this holds true even for the Reservists, although
2 it's a flatter curve or flatter distribution. Next slide,
3 please.

4 (Slide)

5 Army Reserves, same data as the Active Duty going
6 back to 1985-86. It's all in the handout, so I won't go over
7 this. They are running approximately .2 or so per 1,000 tested.

8 We do have some issue in the Reserves that sometimes when they
9 are tested, they have their first test and then they don't show
10 up to follow-up. And that's more of an issue in the Reserves
11 than certainly in the Active Duty, so a few more -- and I should
12 say that these are confirmed positive and, by confirmation, that
13 requires two separate tests that are confirmed to be HIV-positive
14 by Western Blot. So, we do have some loss of follow-up in the
15 Reserves. Next slide, please.

16 (Slide)

17 Broken out Males and Females, same pattern pretty
18 much with the Active Duty, a little bit more erratic rates. Next
19 slide, please.

20 (Slide)

21 And this is the age group that I was mentioning in
22 the Reserves. Still see the peak in 30-34, but not as dramatic.
23 Mimics a little bit more the civilian side. Next slide, please.

24 (Slide)

25 This, unfortunately, is not in your handout -- the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 next three slides were inadvertently left out of the handout, but
2 this is rates of new diagnoses of infections in the civilian
3 applicants for military service. And you can see since the
4 program began, we've identified almost 4200 individuals who were
5 positive upon applying for military service -- I'm sorry, that
6 was Males, 4700 duly identified HIV-positive. And then you can
7 see the rates which are very remarkably similar for the Men and
8 Women per applicant, and that is just around .3, .32 for men and
9 women. Next slide, please.

10 (Slide)

11 Early on, men were certainly higher, but in recent
12 time -- although men have still been above women in each year,
13 they are very close in terms of the rates. 2002 I wouldn't
14 really pay much attention to. Next slide, please.

15 (Slide)

16 This is by race. We don't get a Race/Ethnic from
17 the MEPCOMs, so we only have White, Black and Other. We can't
18 break down Hispanic, but the same kind of pattern holds with
19 Black higher than Other races, and then White the lowest. Next
20 slide, please.

21 (Slide)

22 Okay. That was the boring part of the talk,
23 hopefully we're past that, but the data is in the handout.

24 What are the effects of changing a screening
25 interval? Well, it's hard to really say because we have a lot of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 different policy that leads towards testing for HIV other than
2 just Force testing. But what I want to delineate is just really
3 two points, what you would see by changing the screening interval
4 for a periodic testing program.

5 There's a bunch of assumptions, all of which are
6 easily debated or you could throw stones at, so this is a rather
7 simple model, but the assumptions are that the population numbers
8 are stable, and that one is a fairly good assumption. The
9 infection rate is stable in that population, and that's also a
10 pretty good assumption in our Active Duty and Reserve population.

11 The infection risk is felt to be independent of
12 time since last test, and I think that also can be defended as
13 being a true statement. The number who are tested in each year,
14 this model assumes that service members are only tested in their
15 last year of the screening interval. So, if we're on an every
16 two-year screening interval, service members are only tested in
17 their second year. If you're on a five-year screening interval,
18 you're only tested in the fifth year. That one certainly does
19 not mimic the current military situation because of all the other
20 adjunct testing and deployment-related testing. But for this
21 model, for these purposes, just to focus on the effects of
22 screening, we need this to be the case.

23 And then, lastly, there are no informed losses to
24 follow-up. People aren't finding out from other sources they are
25 HIV-infected and then getting out of the service before being

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 tested. That's what this model would assume.

2 In terms of the specifications, I'm going to look
3 at a ten-year period. The number of undetected infections in any
4 given year will equal the number of new infections plus any of
5 the undetected infections from a previous year for a particular
6 group, and also just to make it easier for the math, I kept a .2
7 per 1,000 persons tested rate of infection. Next slide, please.

8 (Slide)

9 So, with that sort of as a preface, here is a two-
10 year screening cycle. I chose a population size of 200,000,
11 again, just to make the math simple, and the incidence rate is .2
12 per 1,000 tested, or approximately 20 cases in each group of
13 100,000. Next slide, please.

14 (Slide)

15 The first group which is Group A consists of
16 100,000 persons, and they are tested every other year and, in
17 fact, they were tested last year. So, in this particular year,
18 they do not undergo testing, so the number of new infections this
19 year will be 20, and the number of undetected infections from
20 last year will be zero because they were tested last year, so
21 they don't have any undetected infections. Next slide, please.

22 (Slide)

23 In the year that they are tested, they have
24 another 20 cases that occur annually, but they carry over this 20
25 to here, so they actually have 40 undetected cases that will all

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 be detected -- all 40 of those will be detected this year in this
2 model. Next slide, please.

3 (Slide)

4 And this goes on. You can see that each
5 alternating year, they either carry over some undetected
6 infections or not. Next slide, please.

7 (Slide)

8 In Group B, they are the group that they are
9 tested this year, so they've got the 20 infections, plus 20
10 infections from the previous year when they weren't tested. Next
11 slide, please.

12 (Slide)

13 The following year, they have another 20
14 infections plus zero. I think you all can follow this. Next
15 slide, please.

16 (Slide)

17 And it tracks like this. Next slide, please.

18 (Slide)

19 So, in terms of all the groups combined, which
20 would be the whole population you are testing, the number -- this
21 isn't quite prevalent infections because later on I'm not
22 counting everyone who is infected. This is really undetected
23 infections, but I didn't want to say undetected and then
24 detected. So, you identify 60 -- or 60 people are infected that
25 are previously unknown at the time. That's 40 from this group,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 20 from this group. You will detect the 40 in this group that
2 undergoes testing. Next slide, please.

3 (Slide)

4 You can see that that holds true for each year.
5 So, in each year, there's 60 undetected infections, of which you
6 detect 40.

7 (Slide)

8 And, finally, the last slide shows 67 percent.
9 So, it's not quite 50 percent, as you might think, in an every
10 two-year screening cycle. You're actually detecting 67 percent
11 of the undetected infections. Next slide, please.

12 (Slide)

13 I'm going to just do this for the three-year and
14 then I'll stop and show sort of the punch line or the results.

15 For the three-year cycle, I'm going to start with
16 a 300,000 population, again, for ease of the math, keep the .2
17 per 1,000. Group A was tested this previous year, so they have
18 20 new infections and no undetected infections. Next slide,
19 please.

20 (Slide)

21 They have 20 new infections this year and they
22 carry over 20. Next slide, please.

23 (Slide)

24 They finally are tested and they have 20 new
25 infections and they carry 40 from previous two years. So,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 basically, in a three-year testing model, the prevalence of any
2 group that's being tested is going to be 3 times the annual
3 prevalence or incidence for that group. So, that's how you get
4 20 new infections, 40 carried over, a total of 60 infections,
5 which would be actually a .6 per 1,000 prevalence. Next slide,
6 please.

7 (Slide)

8 Group B, different 100,000 who were tested two
9 years ago, so they carry 20 over from this past year. Next
10 slide, please.

11 (Slide)

12 And next. Next slide, please.

13 (Slide)

14 And you can see that the pattern sort of follows.

15 If it's not making sense to anyone, if you look at it, I think
16 it will with a little bit of time. And, finally, Group C. This
17 is the year that they are tested. So, they have 20 new
18 infections, they have 40 that have occurred over the past two
19 years. Next slide, please.

20 (Slide)

21 And next. Next slide, please.

22 (Slide)

23 That pattern for them follows. Next slide,
24 please.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 So, in terms of all groups, now we have on a
2 three-year testing policy, every year we have 120 undetected
3 infections of which half, 60, which is 50 percent, will be
4 detected by that three-year testing program. Next slide, please.

5 (Slide)

6 And next. Next slide, please.

7 (Slide)

8 So, with that sort of orientation to what the
9 effect is, I'm now going to -- the next slide --

10 (Slide)

11 -- will show graphically that depending on the
12 screening interval, the prevalence in that group that is screened
13 actually goes up, as is probably very intuitive to most of you,
14 so that in a two-year screening, even though the annual incidence
15 is .2 -- during the first year, that would be the prevalence, but
16 there would be .4 in the year they are actually tested, and way
17 over here in a five-year testing window, since you accumulate
18 more time at-risk to become infected, you'd have actually a 1 per
19 1,000 prevalence in the year that you are tested. Next slide,
20 please.

21 (Slide)

22 And try next because it's not showing up

23 (Slide)

24 No, go back.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 This, on your handout, hopefully shows that in a
2 two-year screening interval, there's 67 percent of the undetected
3 infections are being detected each year. In a three-year, it's
4 50 percent, 40 percent for a four-year, and 30 percent in a five-
5 year, and that follows from the previous two slides. Next slide,
6 please.

7 (Slide)

8 So, what is the result of all this changing in
9 screening? Well, it's sort of counterintuitive -- at least to me
10 it was -- that it doesn't matter what your screening frequency is
11 in terms of the number of individuals that you will detect each
12 year. Regardless of the screening frequency, over a stable
13 period -- which we are rather stable, having done this for 16
14 years -- you are going to detect the same number of people, but
15 you are, of course, screening people who have a higher prevalence
16 because they've had more time to get infected than they are
17 screened. Next slide, please.

18 (Slide)

19 Where you see the big difference in changing the
20 screening program is in the number of undetected cases whereas in
21 the two-year screening cycle, you detect basically, which is the
22 incidence rate -- that's the number you're detecting, that's what
23 I said earlier, the rate per 1,000 tested is very close to the
24 incidence -- your number of undetected in any given time is half
25 the incidence, and the three-year would be the incidence, and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 then in a five-year, as you can see, it actually approaches twice
2 the number of people undetected that you are detecting each year.

3 Next slide, please.

4 (Slide)

5 So, if we look at some of the initial objectives
6 of the HIV Screening Program -- I won't read them again -- but it
7 was to improve readiness, protect deployed individuals, protect
8 the health of an infected individual, and protect the public
9 health. All of those have as their basis for justification or as
10 an objective, to minimize the number of undetected infections.

11 Well, you have to draw a line somewhere. I mean,
12 we could test daily, I suppose, or annually, or every other year,
13 and the policies have kind of been somewhat erratic, but for the
14 services and their own specific needs, which I'm sure the service
15 representatives will be discussing. Next slide, please.

16 (Slide)

17 I bring this up not to be contrary to what Lynn
18 Pahland said about to ignore the Serum Repository, but to point
19 out that there is another objective right now currently in the
20 policy of DOD policy, and that is the requirement for HIV
21 screening is linked to medical surveillance of service members.

22 Now, I was, five years ago, very vocal that I felt
23 the policy for doing medical surveillance and pre-deployment
24 screening should not be linked to the HIV program because I
25 thought the HIV program could lose its funding, or they could

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 convene an AFEB Board to make a decision about the testing
2 program, anything could happen, but that's not what happened.

3 They decided to link the HIV testing and screening
4 with medical surveillance, and I excerpted from the different
5 Directives and Instructions, DOD Directive 6490.2, the
6 Instruction 6490.3, and Health Affairs Memo in '98, that
7 basically say that there will be a Serum Repository for medical
8 surveillance, for clinical diagnosis and epidemiologic studies,
9 the CHPPM operates this DOD Serum Repository, and this last one
10 basically states that the pre- and post-deployment related blood
11 sample collection required by this Instruction is met by the
12 routine participation of the services in the HIV Program. So, it
13 is linked. If you change the policy, another policy will have to
14 be changed, which it is not an impossible task, but currently
15 today there is a link and, for deployments, they basically say if
16 you don't have an HIV screen test within 12 months, you need to
17 get one, and that serves as the pre-deployment blood sample. The
18 post-deployment blood sample is just a routine testing that
19 occurs in the military. Next slide, please.

20 (Slide)

21 So, that's how I will segue into the DOD Serum
22 Repository, just to end by describing what it currently has in
23 terms of its inventory. It has the remaining serum from the HIV
24 -- I say "force" testing, and that's a true statement, although
25 it has a fair amount of adjunct testing in there as well, and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 it's hard to really separate it out, the policies have been
2 different over time, but it basically has most of the testing
3 done in the Army, Navy and MEPS from '85 to present, testing in
4 the Air Force -- serum resulted from testing in the Air Force '96
5 to present. It's got over 30 million HIV-negative specimens, and
6 that increases by 2.3 million per year.

7 Deployment specimens, at one time we drew specific
8 deployment specimens, 150,000 of those that were not HIV tested.

9 That doesn't exist anymore because it is linked with the HIV
10 testing program. We also have a small 100,000 specimen HIV-
11 positive collection. Next slide, please.

12 (Slide)

13 The Repository is, at least as far as I can tell,
14 the world's largest Serum Repository. Unrivaled potential for
15 sero-epidemiological studies, just based on the enormity of the
16 number of people we have tested and serial specimens on over --
17 you know, serial specimens on over 7.4 million individuals is
18 quite remarkable and facilitates a number of different studies.
19 And it's all linked to the demographic, military and medical
20 outcome data that we have in the DMSS. Next slide, please.

21 (Slide)

22 This last graph shows the number of specimens per
23 individual, so just basically, on the left side is the number of
24 specimens. So, we've got 3 million individuals with one
25 specimen, 1.4 million individuals with two specimens. You can

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 see, basically half a million people who have five specimens, and
2 over a million people that have five or more specimens in the
3 Repository.

4 On this second Y-axis here, it shows the time
5 between -- the range in time between the first and the last
6 specimen, and for the most part it's a remarkable mean of about
7 one year time between the first and last. So, people with nine
8 specimens, about nine years between the first and the last. But
9 there is a range, and that is -- you can see on the graph, people
10 with five specimens, that's five specimens in a two-year period,
11 all the way up to spread out over 11 years. Next slide, please.

12 (Slide)

13 I won't go over these studies, but just to show
14 that in addition to supporting HIV studies and the other -- from
15 the HIV community, the Serum Repository has supported a number of
16 other studies. And Hepatitis C is a good example of a study that
17 went from conception -- this was studied by Craig Hymes and Rick
18 Riddle -- and went from conception to published manuscript in
19 under two years. So, we really address the prevalence and
20 incidence question of Hepatitis C in the military, which had
21 significant impact on the potential testing program and the cost
22 of that in a very short time, just because we had stored samples
23 and people.

24 (Slide)

25 And the next three slides are just pictures

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 showing the Serum Repository. Some of the members were able to
2 visit it at the last meeting, last Board meeting.

3 (Slide)

4 That's the freezers, our main area. We have 13
5 freezers in this area and two large freezers in another area.
6 Each of these freezers is 34 by 30 feet and can hold about 4.5
7 million specimens. It can hold more than that if we pack them in
8 tightly, but the last slide --

9 (Slide)

10 -- shows that all of our specimens are on the
11 aisle. So, it's kind of like we've got American Airlines beat.
12 When we go in to retrieve a specimen, we just pull out a tray.
13 The most we'll have to do is kind of lift up these four trays to
14 pull out a specimen. They've been catalogued and it makes them
15 very accessible to do studies. We've got about six different
16 studies going on right now that are pulling specimens. And
17 that's all I have.

18 DR. OSTROFF: Thanks very much. Let's open it up
19 to questions or comments. Jeff.

20 COL. GUNZENHAUSER: I've just got one comment. I
21 think there's one error, and I wonder if you could check this out
22 later, I'd appreciate it, but you have two slides -- I think it's
23 about the fourth page of the slide set -- fifth page has to do
24 with Army Reserves, and the first slide is a listing by year of
25 the counts and the rates, and the second one is a Male/Female

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 slide. I think there's an error in the scale on the Male/Female.

2 There's four years in there where the Male and Female are very
3 close, so you can interpolate what the prevalence should be, and
4 it looks like the rates, for example, in 1992, it shows Males .6
5 and Females about .56. You'd guess about .6 average, and on the
6 table it shows .3, and there's a number of other years. I think
7 that there's a scale problem on the Male/Female chart.

8 LtCOL. RUBERTONE: And I didn't point out in the
9 handout -- I apologize -- for 1992, the handout is wrong for the
10 Navy Active Duty. I caught that last night and corrected it. So,
11 what was on the slide I think was a rate of about .48 rather than
12 what's on the handout.

13 COL. GUNZENHAUSER: I think the table is correct,
14 so I think if everybody looks at that Male/Female realized that
15 the rates there I think are twice what they should be, and if you
16 can correct that, that way on the Website when people are looking
17 at Male/Female rates for the Army Reserve, it gets posted and we
18 can have that correct.

19 LtCOL. RUBERTONE: I'll certainly look into it.
20 Thank you.

21 MS. PAHLAND: I have a comment, please. I just
22 want to clarify the question that we've brought forward to the
23 Board. We really did not want to have the question of interval
24 HIV testing talked about as being the main support for the Serum
25 Repository. It's a separate issue. So, we're just asking that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 clinical question.

2 DR. OSTROFF: We understand that. Can I ask one
3 question, which is have there been studies to look at why there
4 is this peculiar age distribution in terms of when individuals
5 become sero-positive?

6 LtCOL. RUBERTONE: I'm aware of one study that
7 demonstrated that fact, by Phil Renzulo (phonetic) of the HIV
8 research community, found the same actual thing at incidence in
9 that age group, but I'm not sure whether they actually addressed
10 the reasons and the why.

11 We don't have any information on either behavioral
12 risk factors or other specific risk factors that might delineate
13 that. So, I know Phil Renzulo's study did mention it and pointed
14 it out, I'm not sure whether he actually addressed it.

15 DR. OSTROFF: Is this similar in the other
16 services?

17 LtCOL. RUBERTONE: I'm not aware.

18 DR. CAMPBELL: The AFEB addressed this issue in
19 1986, and I'd like to know what their recommendations were then,
20 that's No. 1. No. 2 is, why don't all the services have the same
21 testing interval now?

22 LtCOL. RUBERTONE: Right, and I'll leave that to
23 the service reps to get into a little bit more why they don't
24 have the same interval. My own personal observation was it had
25 to do with different nuances of the services. The Navy basically

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 tests everyone before they go aboard ship for a deployment on
2 ship, so that drove their policy.

3 The Air Force came close to following the AFEB's
4 recommendations in 1986, with one major exception. The
5 recommendation -- I almost put up a slide, but I thought it
6 wouldn't be very proper. I was going to say this isn't the way
7 to come up with a recommendation because it said do every five-
8 year testing, but because we know that's not enough to capture
9 our younger service members between 20 and age 30, they
10 recommended mandatory testing with each hospital admission. They
11 also recommended testing which does occur in STD clinics, and for
12 something else. The AFEB recommendation -- I'm sure Rick can
13 provide this, I've got it in my briefcase --

14 LtCOL. RIDDLE: It's actually at Tab 10 in your
15 notebook, all of the prior Board recommendations on HIV are in
16 Tab 10. I think there's five in there. And the '86 Memo is in
17 there.

18 LtCOL. RUBERTONE: The '86 Memo basically alludes
19 to doing testing every four years in conjunction with the
20 physical exam, although I don't believe the services even do a
21 four-year physical exam. But then it sort of caveats and says,
22 well, you should do testing with each hospital admission, and
23 then prenatal testing also.

24 So, kind of what grew out of that was the
25 services' own sort of interpretation of those recommendations,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 and maybe they can say why that is, but there's always been
2 different policy.

3 DR. OSTROFF: And I'll point out that much of it
4 also discusses HTLV-3, which goes to the fact that this was
5 pretty early in our knowledge and understanding of both HIV
6 testing as well as the epidemiology of what was going to
7 subsequently happen. So, I would argue that by and large they
8 are almost irrelevant to the situation today. John.

9 DR. HERBOLD: Let me make a comment on that. At
10 that time, we were also very precise that we were talking about
11 HTLV-3 antibody because we didn't understand the natural history
12 of the disease, and the proponents for hospital admissions,
13 pregnancy and STD testing -- and Bob Redfield was one of the main
14 drivers on that -- was to try to help us define the natural
15 history of the disease at that time. So, a lot has changed over
16 time, and the drivers, the reasons for doing lots of things.

17 DR. OSTROFF: Other comments or questions?

18 (No response.)

19 Let me then thank you. That's a tremendous amount
20 of -- oh, I'm sorry.

21 LtCOL. EDMONDSON: Mauhee Edmondson, Accession
22 Policy in OSD. I just want to share with you all the policy that
23 governs the entrance of medical standards for an individual to
24 enter into the military is the Department of Defense Directive
25 and Instruction 6130.3 and 6130.4, and some of you may well know

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 that. But in that we say if an individual is tested for HIV and
2 is positive, they cannot enter into the military whereas, on the
3 Active Duty side, if you are already in the military, you are
4 tested, you're HIV-positive, you stay in the military
5 until/unless you test positive for AIDS. So, I'd just share that
6 with you all as you're gathering your information to make a
7 decision because that will impact the Directive and the
8 Instruction that comes out of our office and Col. Behm's office.

9 In addition to that, one other thing I would add,
10 we say that this policy is mandated by one standard. We are to
11 provide to all of the services and to the Coast Guard, because
12 they come under the Department of Transportation, basic minimum
13 medical standards for any applicant to meet for worldwide
14 deployability. So, as an outlier with that premise, whatever
15 decision that comes out of your all's recommendation is, is this
16 a standard then that this individual is available for worldwide
17 deployability in the light of the smallpox, et cetera -- of the
18 vaccinations that an individual is going to receive.

So, I would ju

19 DR. OSTROFF: Thank you. Why don't we move on to
20 Col. Jones' presentation. He will update us on operational
21 requirements for HIV testing, and this will be the final
22 presentation before lunch.

23 LtCOL. RIDDLE: And I'll have Mark's slides up on
24 the Board Website, so if you want to refer to those slides later
25 on, it will be the corrected ones that he had here -- and also

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 larger, and you'll be able to see the graphs.

2 DR. OSTROFF: And your slides are in Tab 10 as
3 well.

4 LtCOL. JONES: Thank you very much, sir. I do
5 appreciate the opportunity to address the Board on operational
6 aspects of HIV testing. Some of the issues have already been
7 discussed, which is good because that means that these will
8 amplify what I have to say or else I can go over them much more
9 quickly.

10 The perspective I'm going to address is more the
11 Joint Staff and combatant command perspective. I realize that
12 the services are going to get time to talk about their rationale
13 for screening, and so I know that they may have other operational
14 aspects that are either unique to their service or that transcend
15 the services as well. So, without further ado, I'll go on to the
16 next slide.

17 (Slide)

18 This is what I'm going to cover -- current
19 requirements in terms of the combatant commands, operational
20 issues, of course, is the main issue I'm supposed to address, but
21 there are some other considerations and some of those have
22 already been mentioned by Col. Rubertone, and that's the agenda
23 I'll follow. Next slide, please.

24 (Slide)

25 I did query the combatant commands in terms of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 what their requirements are for deployment to their AORs, and the
2 response that I got back was that most of them require screening
3 within 12 months of deployment.

4 Now, the only one that I didn't get a clear
5 reading on was Southern Command, and that doesn't mean that they
6 do not have a requirement, but I didn't get a clear read on that.

7 So, the policies that I was able to review for them and the
8 response I got back, it's a little unclear if they have a
9 definite mandatory requirement or not. But you can see that most
10 of those that have geographic responsibilities do have a
11 requirement for pre-deployment screening that it would be within
12 at least 12 months of the deployment.

13 The only one that I could see that specifically
14 mentioned post-deployment HIV screening was the Pacific Command.

15 Now, of course, there is a note that it would be based on
16 service requirements, but they specifically mention post-
17 deployment as well.

18 And the definition of deployment, one factor to
19 consider is -- because we are talking about pre-deployment
20 screening -- the definition of deployment can vary, although the
21 CJCS Memo that's listed at the bottom there gives the definition
22 that's used for deployment health surveillance purposes. Of
23 course, the operational commands could go with a more stringent
24 policy. So, I was told that Special Operations Command, anything
25 greater than one day would be considered a deployment for them.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Next slide, please.

2 (Slide)

3 I'm going to start now into some of the
4 operational issues, and to some extent I've listed these sort of
5 in what I think are in order of significance, although certainly
6 others might disagree with me.

7 The Walking Blood Donor System, this is an issues
8 that's already been, I think, mentioned. The Armed Services
9 Blood Program does, of course, strive to provide tested blood
10 products throughout all casualty care levels, but clearly
11 situations do arise that do prevent using fully tested blood
12 products from being available, particularly aboard ships and in
13 forward locating. Again, Special Operations soldiers, sailors,
14 airmen in particular, face the issue of often having just a medic
15 that's out there with them in very forward-deployed locations.
16 And medics have identified the need for platelets, currently
17 available source if you are forward deployed, especially
18 collected whole blood.

19 And, again, U.S. Special Operations Command, they
20 mentioned that on some days they could have personnel deployed to
21 140 countries worldwide, in some cases very small teams.

22 And there are some recent incidences that were
23 mentioned where we actually did use untested blood products. The
24 U.S.S. Cole bombing was mentioned, and Operation Enduring
25 Freedom. There have been times when collection and transfusion

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 of untested blood have occurred.

2 And I did talk to the Armed Services Blood Program
3 about the issue. They verified the issue that's presented there
4 basically, and also mentioned that they would, in addition to the
5 operational commands supporting pre-deployment testing, that they
6 would support that as well for this reason. Next slide, please.

7 (Slide)

8 Well, some of the other issues, again, when you
9 think about universal precaution, certainly in a battlefield
10 situation or the idea that to medics and buddy-aid, that that can
11 be done is certainly not going to be possible, and what that will
12 lead to, of course, is not that folks will not get care, that's
13 not an issue. The issue is protecting those who are providing
14 that care.

15 Personnel deploy to high prevalent areas, of
16 course, I mentioned that Special Operations Forces could be
17 deployed to 140 countries worldwide. We have, of course, our
18 forces deployed in a number of areas that have a very high
19 prevalence for HIV. And we also do have a lot of our operations
20 now are combined operations where we deal with Coalition Forces,
21 and they mentioned one particular incidents in one of the
22 headquarters recently where a Coalition member was sent back home
23 because of testing positive for HIV.

24 Of course, it does give us somewhat of a baseline
25 with regard to at least you knew what the pre-deployment status

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 was within 12 months. Pre-vaccination screening has been
2 mentioned, so I don't think I need to go into that in anymore
3 detail, but in many cases we may have to do vaccination on very
4 short notice based on post-exposure/post-outbreak type events,
5 and these forces might be quite far deployed, and the ability to
6 do quick HIV screening may not be possible. So, that's another
7 factor to consider. Next slide, please.

8 (Slide)

9 And the last operational issue I wanted to mention
10 is this issue -- and, again, I think this is one of the less
11 significant issues from an operational perspective, but
12 nevertheless it was an issue that was mentioned by some of the
13 combatant commands, so I'm bringing it up here. I don't think it
14 would necessarily disrupt operations, but they are deployed in
15 many cases to areas where the disease threats of various kinds
16 are severe and the conditions are severe, so it's something to
17 keep in mind. Next slide, please.

18 (Slide)

19 Some of the other health public health issues come
20 into it, not so much operational aspects, but things that were
21 mentioned by the combatant commands. Again, the potential to
22 spread HIV abroad. I did look at the country clearance
23 requirements. I did a quick screen of those. These country
24 clearance requirements are based on bilateral arrangements
25 between the U.S. and foreign government officials, and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 principal purpose is to obtain permission to enter countries
2 outside the United States from officials that are exercising
3 authority over that area. And, of course, the thing with those
4 is they could be modified anyway, or exempted based on things
5 like exercise operation orders, unit deployment orders, and
6 Unified Command travel directives. So, there are some exceptions
7 that can be granted for those requirements anyway, but when I
8 screened those requirements for several countries, I didn't find
9 much in terms of HIV screening. So, I don't think that that in
10 particular seems to be a major issue.

11 Again, I guess there's also the political aspect
12 of it. Would there potentially be a perception that U.S.
13 personnel are spreading HIV, and does the screening impact on
14 that perception, that might be an issue to consider.

15 Screening decreases transmission -- again, this is
16 nothing new in terms of public health type perspective. And this
17 issue of recruits only being screened at entry -- maybe they
18 would be screened if they didn't reach a particular interval, if
19 we didn't do some kind of interval screening, was also mentioned
20 as an issue.

21 And, again, this issue of highest risk -- of
22 course, that's incorrect based on the information that we were
23 just shown. Next slide, please.

24 (Slide)

25 And then some related issues which have already

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 been brought up, so I don't really need to say much about. This
2 idea of the blood sample for HIV testing now serving as a pre-
3 deployment serum sample, I would agree that those issues don't
4 have to be linked, but it's important to realize the practical
5 consideration that right now they are linked, probably for
6 convenience sake. Next slide, please.

7 (Slide)

8 And the frequency of screening. Now, most of the
9 combatant commands indicated that they would prefer if there was
10 a consistent screening interval among the services. Of course,
11 you'll hear the service perspective on why they may have unique
12 differences but, from the combatant command perspective, most of
13 them indicated it would be easier for them, and I think it's more
14 of an administrative aspect. If it was consistent among the
15 services, they would have to focus less on those unique
16 differences among the services and focus on the unique
17 operational aspects more for particular operations. Next slide,
18 please.

19 (Slide)

20 And, in conclusion, again, HIV screening, I think
21 it certainly is a value from an operational perspective. There
22 are some unique operational issues, of course, that need to be
23 considered as you make your recommendations. And as I've just
24 mentioned, most of the combatant commands would prefer a common
25 screening interval, if that was possible.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 DR. OSTROFF: Thank you very much. Let me open it
2 up to questions, but let me ask one beforehand, which is where
3 did the 12-month interval come from, and how long has it been in
4 place?

5 LtCOL. JONES: Sir, the only combatant command
6 that mentioned where they thought that the origin specifically of
7 that was, they looked at all the service policies and they took
8 the one that was most stringent. That was Central Command, in
9 particular, that mentioned that. So, with one year being sort of
10 the tightest time interval for consistency sake, that was the
11 only group that mentioned, but somebody else may be able to
12 provide more info on that.

13 LtCOL. RUBERTONE: I recall when we were asked to
14 look at pre-deployment tests for Bosnia based on test samples
15 that were currently in the Repository that we could use, they
16 varied greatly from one to five or six years prior to the
17 deployment. And I recall the discussion that some test they may
18 want to do on stored blood potentially could deteriorate over
19 time, so I also heard it from that point of view. Health Affairs
20 -- maybe Rick can chime in -- where we're looking to have some
21 specimens close to the actual deployment. That's where the one
22 year kind of grew out of it as well.

23 CDR. LUDWIG: I also recall the host nation
24 concerns being historically maybe more important than they are
25 now, and it seems to me that there were some host nation

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 requirements for testing and maybe one year was the minimum of
2 those, but I think that it's changed since the early days of the
3 screening program.

4 COL. DINIEGA: I concur with Sharon. In the early
5 days of the HIV epidemic, there were legal requirements, country
6 entrance requirements, and also host nation support agreements
7 that had things written in, and I think it ranged from as short
8 as six months proof of HIV negativity. Certainly, I was in Korea
9 in the late '80s and early '90s, and the Korean government wanted
10 to screen people as they entered the airport.

11 DR. OSTROFF: Another question that I have is if
12 one of the major considerations for the policy is the Walking
13 Blood Donor System. Are there any screening requirements for
14 other chronic blood-borne infections at all in pre-deployment
15 situations, such as Hepatitis C?

16 LtCOL. RIDDLE: Let me comment on at least my
17 knowledge on the Walking Donors, those individuals are identified
18 prior to, and they are screened as a unit of blood is screened,
19 and literally have a Walking Donor card, and that's managed by
20 the Armed Services Blood Program Office, showed that the
21 individual was screened for everything that a unit of blood would
22 be screened for. But, like Col. Jones said, in certain
23 situations, that available supply of Walking Donor is not
24 adequate to meet the demand. I don't know if you all know --
25 because we looked at this with the Hepatitis C issue, and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 issue of the Walking Donor and a program of force screening for
2 that. That's what I understand the Walking Donor Program is.

3 LtCOL. JONES: And I did go to the Armed Services
4 Blood Program. They did not mention the particular type of
5 screening that you're talking about. It was a quick response,
6 though, so maybe it wasn't a full response. But, again, the idea
7 was, as you mentioned, there would be certain situations where
8 you would exceed even that capacity, and that has happened.

9 DR. OSTROFF: Capt. Schor.

10 CAPT. SCHOR: I think the Walking Blood Donor
11 Program has hopefully decreased in need along ships and things
12 like that, but having managed one of those about five or seven
13 years ago, you get your screen right as close as you can before
14 you leave home port, and you hope for the best for the next six
15 months, and you hope that the exposures that may occur during
16 port visits don't result in HIV exposure. And it's just the best
17 guess and the best thing you can do.

18 COL. GUNZENHAUSER: To answer your specific
19 question, there is no screening requirements other than HIV in
20 terms of blood-borne infections prior to deployment. The Army
21 doesn't have any requirements, and to the best of my knowledge
22 none of the other services do either.

23 DR. CLINE: I was not aware that anthrax
24 vaccination was contraindicated with HIV positivity.

25 LtCOL. JONES: I was just looking at the clinical

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 and administrative guidance that just got published back on the
2 6th of August, and I believe that that was on the list. I
3 specifically looked at that, and I think they had anthrax down as
4 one of the contraindications. I may be wrong, but I did
5 certainly mean to check that, and I think I did, and specifically
6 looked at the current clinical and admin guidance. 6 August it
7 was signed by Dr. Chu (phonetic). We can verify that, sir, but I
8 did check that and that's why I wrote it specifically on the
9 slide, so I think that's correct.

10 DR. OSTROFF: I'm not aware of it being absolute
11 contraindication, but the current policy of a foreign power for
12 deployment.

13 LtCOL. JONES: Maybe that's too strong a wording,
14 but in the policy they particularly talk about that would be one
15 of the categories for not giving the vaccination.

16 DR. OSTROFF: Why not?

17 CAPT. SCHOR: I think it's mentioned for a
18 different focus. It has to do with giving anthrax vaccine to
19 those individuals who are HIV-positive and the issues that they
20 may have less sero-positivity as a result of the immunization.
21 So I think that's a different issue.

22 COL. GARDNER: And also they are not deployable,
23 so they don't -- there's no reason for them to have anthrax
24 vaccine. That's an exclusion from anthrax vaccine under the
25 current threat.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 CDR. LUDWIG: As I recall, it was a reason for
2 giving a waiver for anthrax vaccination. So, when it got to the
3 point of total force vaccination, the people who were
4 immunosuppressed, including HIV, and I think there are also some
5 other examples given of immunosuppression, but they would be
6 exempt from receiving the anthrax vaccination, not necessarily
7 contraindicated, but that they could receive an administrative or
8 medical exemption.

9 LtCOL. JONES: Thank you for clarifying, I'm sure
10 that's correct.

11 DR. OSTROFF: Ben.

12 COL. DINIEGA: Is there information available --
13 well, on the Walking Blood Donor thing, I think one of the easier
14 things to do is to ask the Blood Banking Office how many units of
15 untested blood and blood products have been used in DOD over the
16 past year. But on the issue of undetected or new incident cases
17 of HIV, is there a way to find out the contact tracing
18 information on these new cases -- where they acquired their
19 infection from, and who they may have potentially spread it to --
20 to take a look at the impact of undetected cases?

21 LtCOL. RUBERTONE: Up until about five years ago,
22 that information was collected and actually centrally collected
23 in terms of specific risk factors, risky behaviors, contacts, and
24 even to the point of being able to trace that. I maybe misspoke.
25 Maybe seven years ago, that was stopped. So now any of that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 information just exists locally except for some of the research
2 that is currently being done by sort of the behavioral
3 researchers over at the HIV research community, I know in the
4 Army -- and maybe the Navy will be able to say about in the Navy.

5 So, in terms of a central collection of all that information
6 where it is now analyzable, I don't believe that exists other
7 than specific studies or if you could go to large facilities that
8 do have a number of HIV-infected individuals, and they would
9 maintain it locally.

10 LtCOL. RIDDLE: And I polled the Subcommittee to
11 consider this issue, every published study in the peer review
12 literature dealing with HIV and military personnel, U.S. military
13 personnel, plus a variety of studies looking at the issue, along
14 with the CDC guidelines and other guidelines.

15 DR. GRAY: This is Greg Gray. One factor that
16 maybe I missed, but I haven't heard discussed, is cost savings if
17 we do change the intervals. What are the costs of the testing,
18 the storage, everything else associated?

19 CAPT. SCHNEPF: Glen Schnepf, from Navy HIV
20 Program. Depending on what the interval is that is currently
21 being tested, of course, if it is less than whatever set is going
22 to be recommended, it will be more expensive, that's obvious.
23 It's just a matter of adjusting accordingly in the budget. I
24 mean, if the interval is every five years and the recommendation
25 will be every two years, that's going to be an increase in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 testing cost.

2 DR. OSTROFF: Let's wait until we hear the
3 afternoon presentations from the various services. Let me ask
4 you a question that's probably going to be difficult to answer
5 since it is not highly quantifiable. Do the various commands
6 seem happy with the current policy? Has it caused any
7 difficulties that you're aware of?

8 LtCOL. JONES: Sir, I think it's more just an
9 administrative convenience type thing that they would like a
10 consistent interval among the services. So, I think that that's
11 not a huge issue, I don't think. I think it's just more that
12 they would prefer that because it would be easier for them to
13 administer and look after. But because they are setting their
14 own policy in terms of the deployment screening side, they each
15 have set that 12-month interval. I don't believe that that comes
16 from any particular DOD Instruction or Directive, but somebody
17 could correct me if I'm wrong on that. So, they are setting that
18 themselves. So, a lot of their issues I think are taken care of
19 by setting that less than 12-month screening interval.

20 COL. GARDNER: If there is a consistent policy of
21 every 12 months among all the service members, that would
22 eliminate the need to be drawing these during their pre-
23 deployment three days, as they are trying to get ready to get out
24 the door, and we've, in fact, had people where they drew the
25 blood three days before they left and they got the result the day

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 after they left, and then they had to go find them in Afghanistan
2 and bring them back.

3 CAPT. YUND: It is mentioned in the Joint Staff
4 Memo on deployment health surveillance that if an HIV has not
5 been drawn in the last 12 months, then one must be drawn.

6 LtCOL. JONES: Sir, was that related more, though,
7 to the Repository issue, because when I looked at it they
8 mentioned the two together. And that's why I'm wondering if it's
9 more in that Instruction, it seemed to be based more on the
10 Repository issue.

11 CAPT. YUND: Well, that may be, but as has been
12 mentioned a number of times up to this point, we're still dealing
13 with linkage of those two issues.

14 DR. OSTROFF: Capt. Schor, and then Pierce.

15 CAPT. SCHOR: And I recall that with the 1998, the
16 original Staff Memo, I think, put that linkage, and there was
17 just a feeling of -- I don't think there was any science
18 particularly applied to it, so that the 12-month interval seemed
19 to make some sense. I think that's been systematically
20 continued. And my suspicion is that that is what the combatant
21 commanders then said, "Well, it's in the Joint Staff Memo, it
22 must be based on something. We'll just go ahead and go with 12
23 months". So, I think that has created a systematic 12-month
24 interval, rightly or wrongly.

25 DR. GARDNER: Just thinking military preparedness,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 it seems very unlikely that someone who was sero-negative would
2 be unprepared or unable to -- who would be clinically ill a year
3 later, or even two years later. So, from a strictly once you've
4 tested someone and they are negative, the idea that they are
5 going to be bad soldiers, it seems to me we could lengthen the
6 interval. The issues we've heard are the Walking Blood Bank,
7 obviously, is something that if that's important feature, but
8 we're hearing that downplayed considerably, that's a feature that
9 would push you toward very frequent testing. The need to give
10 contraindicated live-virus vaccines in a hurry, such as smallpox,
11 would be another fairly significant issue that might be solved by
12 giving the smallpox vaccine immediately after the first negative
13 test.

14 And the third, I guess, is one I'd like to hear
15 more about at some point, are the political issues about
16 countries saying "We don't want your soldiers here unless they've
17 been tested more recently than that". But I think from strictly
18 a fighting force point of view, it would seem that one could
19 lengthen the interval because I think the idea of somebody
20 getting infected the day after they were tested, they are still
21 going to be hale and hearty almost always a year later or two
22 years latter.

23 LtCOL. RUBERTONE: One comment about sort of this
24 inevitable linkage of the two policies, Col. Jones is correct, I
25 think the 12-month interval has more to do with making sure

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 there's a pre-deployment test on file than on making sure there's
2 an HIV-negative service member on the deployment.

3 And just one other piece of information. This
4 might come out later, but for about a year and a half there was
5 actually a policy in place that said pre-deployment specimens,
6 you need to define deployments needed to be drawn, which was very
7 separate from the HIV program. And like I pointed out, we did get
8 150,000 specimens during that period of time. All the services
9 that communicated to me felt it was logistically very difficult
10 to try to do this pre-deployment screening as these individuals
11 were getting on the plane. Same with the post-deployment. And
12 what grew out of that was sort of a reliance on the HIV testing
13 program which had already mechanisms for transporting specimens,
14 funding laid out -- the Air Force had a big problem with who was
15 going to pay for the FedEx of these pre-deployment samples, local
16 people? Someone centrally? And they just said, "Look, we've got
17 an HIV thing that works, let's just continue to use that", and it
18 was really out of convenience that it was linked to the HIV test.

19 So, the requirement then just said you need an HIV test prior to
20 -- because they didn't want to say you need a pre-deployment
21 specimen because that would confuse people and they would draw a
22 specimen and send it to the Repository.

23 From our point of view, certainly not to feed the
24 Repository, as Ms. Pahland said, but just logistically, we'd
25 prefer receiving things in big bulk from HIV testing contractors

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 who send us reliable data, rather than the glass tubes in wire
2 racks that we get from Air National Guard units, without data.
3 So, if we did away with all HIV force testing, we certainly would
4 have to come up with a creative way to do pre-deployment testing
5 in the services, with the same type of -- you know, looking at
6 the same issues the HIV program has looked at.

7 DR. OSTROFF: Dana, did you have a comment?

8 DR. BRADSHAW: Difficult issues, but I think I was
9 kind of thinking in the same line as Greg Gray about the cost-
10 effectiveness modeling and making sure that whatever lit review
11 that Rick is going to supply to the Board, that there are some
12 cost-effectiveness evaluations of screening and looking at
13 alternate methods of screening, if we're only looking at HIV,
14 Serum Repository obviously we're all grappling with this issue of
15 dual needs, but the HIV itself, doing risk-based screening and
16 the cost-effectiveness of that as opposed to just time interval
17 screening, you'll hear from the service reps this afternoon, but
18 there's things that are being done such as STD, people with STDs,
19 pregnant individuals, drug and alcohol rehab folks, and in the
20 Air Force we do the annual PHA and we ask questions about sexual
21 involvement. That could be another one where greater than 3 risk
22 sexual partners in the last year, or some other time interval,
23 you could look at frames like that. And hopefully there are some
24 things in the literature that might could address alternate
25 methods to make sure you have or pick up in the most efficient

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 manner the people that would be at-risk for becoming HIV-
2 positive. So, I would think about factoring that in as well.

3 And then the Serum Repository issues certainly
4 there's reasons to screen, but I know in the Air Force we have a
5 lot of frequent deployers, and interval again comes up as if you
6 only need serum, how often do you need to draw it if you bracket
7 a deployment. If you "deploy" three times in a year, do you need
8 three serums, or do you just need to bracket deployments and have
9 some baselines and followups?

10 DR. OSTROFF: Ben first, and then Ken.

11 COL. DINIEGA: Mark, you probably can answer this,
12 but I think that the data that you showed was a mixture of both
13 force testing -- and for the Board members, force testing is the
14 routine testing on your birth date, or whatever they use -- every
15 two years, five years -- and then there's clinical testing for
16 STDs and possible admissions, et cetera.

17 Are the cases, the new cases every year, are they
18 being detected through force testing, or clinical testing?

19 LtCOL. RIDDLE: That's a good question. I didn't
20 include a slide on that because we actually don't have very good
21 data. We do receive a field on each record that says what was
22 the reason for this test, and one of the reasons is force
23 testing, clearly one is sexually actually transmitted disease
24 clinics, one is a clinically indicated test, and then our biggest
25 category is everything else, which is "Other", and it's sort of a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 catch-all.

2 Just going from memory on the 5- or 6,000 HIV-
3 positive individuals that we have information on, like I said, I
4 don't really trust the data, but about a third came with saying
5 this was a force test, and about half of the people came with
6 Other, other tests for some other reason. There's about 35 or, I
7 don't know, maybe 25 different reasons that can be filled. So,
8 we're not sure what feeds that. So, we don't have real good
9 reliable data on that question.

10 DR. OSTROFF: Ken.

11 CAPT. SCHOR: Just a couple of quick comments. I
12 think when you look at HIV testing from an accession perspective,
13 you're really looking at data as an investment issue -- do we
14 want to invest in that individual and put money into that
15 training?

16 I really don't think -- and I think this may try
17 to answer Dr. Gardner's point. I'm not sure this is a readiness
18 issue, I think our Canadian and U.K. colleagues would suggest
19 that it probably isn't really a readiness issue.

20 I think that it is evermore a clinical issue in
21 terms of things like smallpox, and also a blood-borne pathogen
22 issue because forward deployed forces have no real way to test
23 blood-borne pathogen exposures. Interestingly, the dentist may
24 help solve that with salivary diagnostics for HIV testing. It's
25 just amazing. I think Navy dentistry is working on that. Cool.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Wouldn't that be great? But when you're in a ship on a big
2 amphib or something like that, or forward deployed surgical unit,
3 you don't know what that blood is. You have no way of testing
4 it. And especially if you're in a humanitarian assistance or
5 disaster recovery scenario in a high endemic area, that's a
6 fighting scenario.

7 So, I think that may reclassify some of the
8 considerations here, and gets to your point of do we test for
9 other things, too.

10 DR. OSTROFF: Well, let me just say -- I mean,
11 from the Board's perspective, we come at the issue from what
12 makes sense in terms of public health and what makes sense in
13 terms of the science, and that's largely based on the data that
14 you present to us regarding both the issue of why the testing is
15 being done, as well as what the data show in terms of -- I hate
16 to use the term sero-incidence -- but, by and large, that's what
17 we can take into consideration. We realize that there are many,
18 many other policy considerations which go into why things happen
19 the way they happen, and that's why I asked the question, are
20 people happy with what currently is going on because that has to
21 be a consideration as well.

22 I will point out that if you take the data that
23 Col. Rubertone presented, that even with that 12-month window,
24 you're still going to have some people that are going to end up
25 slipping through that window because you appear to have a sero-

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 incidence of about .2 or so per annum, at least in the Army. It
2 seems to be lower in some of the other services. But that would
3 mean that there would be 10 to 20 potentially that might slip
4 through, that become infected between the interval when they
5 could have received the test, which is as much as 12 months
6 earlier, and deployment. So, it's not a fail-safe system. And
7 as was pointed out, you could test people every day if you wanted
8 to, it's just what makes sense in terms of the reason that you're
9 doing the testing and what are you hoping to accomplish by doing
10 it. Even regarding the argument about some of the live vaccines,
11 if someone has sero-converted within the prior 12 months, the
12 likelihood that they're going to be far enough advanced in their
13 clinical course to develop progressive vaccinia, which is the
14 major thing that you're concerned about, is vanishingly low so
15 that that would be a prime driver and consideration in terms of
16 feeling uncomfortable giving them smallpox vaccine.

17 I mean, there are a lot of issues to discuss, and
18 I think that we'll be very eager to hear the presentations from
19 the various services about what the current policies are, and see
20 if we could bring some public health logic to the issue, and that
21 public health logic, I think as Greg pointed out, also has to do
22 with whether or not there might be opportunities for a cost
23 savings somewhere within all of this that satisfy the needs of
24 the services and also satisfies from a public health perspective.

25 Other comments before we go to lunch?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 (No response.)

2 If not, I'll turn it over to Rick.

3 LtCOL. RIDDLE: Let's go ahead -- and some people
4 have to leave this afternoon -- and get a picture of the Board
5 and the Preventive Medicine consultants for the Board, and we'll
6 do it just right out here in the lobby, in front of the fireplace
7 for the Thayer. So, if we could form up out there, we'll go
8 ahead and do that, get a Board picture, and then everybody is off
9 for lunch --

10 DR. OSTROFF: There's a beautiful view outside.

11 LtCOL. RIDDLE: We could do it outside.

12 DR. OSTROFF: Let's be back at 1:30.

13 (Whereupon, at 12:00 p.m., the luncheon recess was
14 taken.)

15

16

17

18

19

20

21

22

23

24

25

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

AFTERNOON SESSION

(1:45 p.m.)

DR. OSTROFF: Sorry about that. We took a little bit of extra time and plus we've lost a number of Board members who, in order to be able to get back to where they needed to be for commitments that they had in the morning, have departed. So, we have a smaller group, not to say a less auspicious group at all, but hopefully this will help us to quickly move through the afternoon agenda. So, why don't we get started with the first presentation from the services and, according to my list, that's the Army.

COL. GUNZENHAUSER: Thanks very much. Good afternoon on a beautiful day.

As I understood it, my main intention was to explain to the Board what the current policies are with Army HIV screening and, as simple as I think it may be, it may seem a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 little complex, but I'll try to add some comments at the end
2 maybe a little bit about the history of this and what some of the
3 additional reasons may have been why things were set up the way
4 they were. Next slide, please.

5 (Slide)

6 We have an Army Regulation, I think originally
7 published in the late '80s and it was updated in 1996, about HIV,
8 and there are a number of chapters in here, it's not a simple
9 delineation of what the testing frequencies are but, rather,
10 talks about policies and screening and a variety of other things
11 in the regulation, including community education and other things
12 that need to be done.

13 Within this policy -- and I'll go over these --
14 there are really three intervals that the Army deals with in
15 terms of screening frequency -- one of them is six months, one is
16 two years, and another is five years -- and I'll describe them
17 here, but they really are different policies regarding accession,
18 if you are on Active service, Reserves, if you go overseas, and
19 there are a couple other considerations that I'll go over. Next
20 slide, please.

21 (Slide)

22 What I've included here is really copies right out
23 of the Army Regulations so that you can see for yourself what it
24 says. For accession testing, there's a specific thing in here
25 for enlisted folks that this is completed at MEPS, but in here in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 the text you can see that if at the time they come on Active Duty
2 an individual hasn't had a test within six months, that it's
3 supposed to be done within their first 30 days, or 29 days while
4 they are there. And I think that the intent of this was concerns
5 that maybe people were infected between the time they were tested
6 and MEPS, if it's been a long lapse, and to assure that we're not
7 accessing people who are infected. And I've known of some cases
8 where these situations occurred, where there was a question of
9 whether it existed prior to service, and I presume this is not
10 only based on the interest of accessing somebody so they can have
11 a lifetime of service, but also there is an economic
12 consideration, you're accessing somebody that the medical cost
13 associated with it may be a concern. Next slide, please.

14 (Slide)

15 For Active Duty, really, our policy is biannually,
16 which means every two years. So, when someone goes through a
17 deployment processing site, the minimum requirement is they have
18 to have a test within two years to be considered deployable,
19 although depending upon the operation, if we know they are
20 deploying to a particular area where I guess it looks like
21 virtually all the policies are one year by default to really
22 deploy to those locations, unless it's just an Army operation,
23 it's going to have to be within a year. But the Army policy is
24 two years to be deployable.

25 Then within the Army, the National Guard and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Reserves, it says here every five years. Now, it used to be they
2 had the same policy as the Active side and it was every two
3 years, but prior to the 1996 revision of the regulation, the
4 Reserve Component came forward and they said from a cost point of
5 view this was not very effective, and so they put forward an
6 argument to revise it, and it was accepted. So, for the Reserve
7 Component, it was switched to every five years.

8 Nonetheless, if they come on Active Duty -- so, if
9 they are just drilling on the weekends and having a two-week
10 summer, or sometime during the year, type of drill, they don't
11 exceed 30 days, then every five years as part of their physical
12 examination is sufficient, but if they come on Active Duty for a
13 period of 30 days or longer -- and I think the reason I've heard
14 for this is because of something to do with medical benefits,
15 where I think if you are on Active Duty for 30 days or longer and
16 you have something that's discovered, then either while you are
17 on Active Duty or subsequently it may be attributed to your
18 Active service and, therefore, DOD would be responsible for all
19 the medical care.

20 So, again, this may be an economic decision such
21 as accessions -- got to have it within six months -- to show that
22 you're not infected.

23 I think for the Guard and Reserve, I know that if
24 you have HIV -- like in relation to the recent call-up -- you
25 can't be called up for service. I guess maybe there are certain

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 exceptions, but as a rule HIV, you wouldn't be called up forward
2 to support these operations. So, I presume that's why this policy
3 is in effect. Next slide, please.

4 (Slide)

5 This is about overseas assignments and, again,
6 it's a little bit confusing, but it says in here, the first thing
7 -- the bottom line is, if you are going overseas on a permanent
8 change-of-station, it's got to be within six months. And I think
9 that this was arrived at based concerns at the time about DOD
10 wanting to assure that we weren't sending folks overseas who were
11 infected. So they shortened the requirement for a long-term
12 assignment to six months. If you're going to be there for six
13 months or longer, you have to have an HIV test within six months
14 whereas, for a deployment of 179 days or less, it could be two
15 years. So, for many of our military operations, soldiers are
16 given orders that say TDY not to exceed 179 days going to some
17 location, they would only have to have a test within two years.
18 And the rest of it you can see there. Next slide, please.

19 (Slide)

20 And then the last slide that I had, one of the
21 issues that the Army had a problem with is that we would have --
22 and you can see from Col. Rubertone's data, there's been soldiers
23 on Active Duty since this began, and with the policy that an HIV-
24 infected soldier is non-deployable created some tremendous
25 difficulty for our line units whose mission was to deploy.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Basically, they were given a soldier, but could not deploy with
2 that individual.

3 And so this was a big issue when the regulation
4 was revised in the mid-'90s, and the compromise that was arrived
5 at was that a soldier who has HIV, once they are identified, they
6 complete that tour of duty in that unit, but they are no longer
7 assigned to a deployable unit. Similar to that, if an enlisted
8 soldier re-enlists, they have to have a negative test within six
9 months if they are going to re-enlist into a deployable unit,
10 which is a Table of Organization or Modified Table of
11 Organization, as listed first up here.

12 And then there were some other -- a couple of
13 other areas where they said if you are going to be assigned to
14 recruiting duty or certain types of special units, that, again,
15 they wanted a test to have been done at the time of re-enlistment
16 within six months. And so that's where those criteria came from.

17 So, that completes my slides. Again, it's really
18 six months at accession, two years for deployment, five years for
19 Reserves unless they are coming on for 30 days or longer, and
20 then if you're going overseas for more than two years, you have
21 to have a test within six months. It's a lot of rules and it may
22 sound confusing, but it's pretty well understood in the Army how
23 that is done.

24 A couple of other things I didn't include up here,
25 but in response to the AFEB's recommendation back in the late

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 '80s, if I recall the date, and this revision of the regulation,
2 we did include an adjunct screening program including all those
3 things that were listed before, such as hospitalizations for
4 Active Duty personnel, anyone presenting with an STD, and a
5 variety of other clinically indicated.

6 I notice that the AFEB recommendation, which I
7 hadn't read before, seemed to suggest that we should replace the
8 current testing with that, but it seems that what had happened
9 was it was simply rolled in and added on top of the existing
10 requirements.

11 And just to add to the list, I know that you're
12 thinking about medical indications and science issues that need
13 to be addressed in these recommendations. Some of the other
14 issues -- I think at least one of them listed was -- the concern
15 about medical exotic infections overseas, and that was a concern
16 when these policies were originally developed, and so I guess
17 that's why there is a shortened time interval for folks who are
18 going overseas as well.

19 And, also, I know there was a lot of debate -- and
20 I know there's plenty of medical literature discussion this --
21 but the issue of disease control, and some people thought back
22 then in the military that it was better to screen people and let
23 them know they had HIV infection -- at that time, there was
24 really no treatment -- some of you know a lot more about this
25 than I do. And even more recently with some effective therapies,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 some folks felt that doing the screening perhaps earlier was
2 beneficial, although, in general, doing it real frequently
3 probably won't be a great help for most individuals. But I just
4 wanted to add those three ideas to the list -- counseling to
5 change behavior and earlier access to medical care -- as issues
6 that might be of some importance.

7 That's all the comments that I had. I'd be glad
8 to take any questions.

9 DR. OSTROFF: Thank you, Colonel. Let me open it
10 up for questions. I do have one that probably is going to be the
11 same one that I'll ask after each presentation.

12 I know you weren't part of the policy
13 decisionmaking in 1996 when the current Army policy came into
14 being. Do you have any idea why they chose the two-year
15 interval? I mean, was, again, this an expediency issue? And I
16 was intrigued by the fact that they took cost considerations into
17 account when making decisions about the Reserves. Did they when
18 they were making decisions about Active Duty?

19 COL. GUNZENHAUSER: No. I think that the 1996
20 revision was to address concerns that people had raised as
21 opposed to a proactive review of all the policies and bring
22 science to question all of it. I think the change for the
23 Reserves was based -- I've seen the paperwork where the Reserves
24 made a very strong request for this to be changed, and they
25 provided some cost analysis associated with that, and it was

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 decided in favor of accepting that change. But I didn't see --
2 and maybe others know, I don't know if Col. Diniega or others are
3 aware -- but I don't see any paper trail that says there was the
4 same thinking applied across-the-board. I'm sure there was
5 informal discussion, but nothing I have in writing says that that
6 occurred at the time of the policy revision.

7 As far as the two years, I believe it was made on
8 judgment as opposed to any formal decisionmaking process.

9 LtCOL. RUBERTONE: At the same time that the
10 Reserves asked the question back in '94-'95 for that '96
11 revision, the Active Duty also looked at it, and the cost issue
12 was more significant for the Reserves because the contractor who
13 did the testing had to supply the blood drawers, the supplies,
14 the shipping costs, everything that the Active Duty sort of had
15 in their own infrastructure, that the Reserves didn't have when
16 they did their two-week drill. So, it was a much more expensive
17 undertaking for the Reserves and the National Guard, and
18 logistically a much more difficult one. They spent a fair amount
19 of their two-day weekend drilling every so often -- weekend a
20 month drill -- doing HIV testing. So, it was logistics and it
21 was the cost -- but at the same time, the lab consultant for the
22 Army also ran the Active Duty side, and looked at our data, or
23 the data that we had, and decided not to make any change for the
24 Army because I don't think the cost considerations were as
25 overwhelming.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 COL. GARDNER: Just one more point on the
2 Reserves, if you are a Reservist with eight years of service,
3 from the day you receive orders of 30 days or more, you are
4 eligible for Army disability. And so that's why they put the 30-
5 day limit, is to make sure they got tested negative before they
6 got 30-day orders because, if you test positive, you suddenly
7 become eligible for Army disability on the receipt of those
8 orders.

9 LtCOL. GIBSON: One point that goes along with
10 this issue of deployments for Reserves, or Active Duty service
11 for Reserves, current DOD policy by Dr. Winkenwerder's policy
12 letter is that all Reservists, if they are activated for 30 days
13 or more, have a pre-deployment sample collected on them
14 regardless of whether they have overseas assignment.

15 I wanted to add one other piece of information to
16 the mix that relates to blood testing at a remote site, et cetera
17 -- or blood donations at a remote site. It's my understanding
18 there is a rapid HIV test that is very, very close to FDA
19 approval, and it will probably be available in a very short
20 period of time -- 20-minute stand-alone test, don't have to send
21 it away to get results, et cetera. And, potentially, a
22 deployable -- could be put on ships to be done. So, it's at
23 least part of the mix in your decisionmaking process.

24 DR. HERBOLD: Jeff, can you tell me if an
25 individual is identified as being infected with HIV, are they

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 retested periodically, or are they taken out of the pool?

2 COL. GUNZENHAUSER: That's somewhat problematic.
3 In some situations, they are. We've really struggled with how to
4 identify them without violating privacy issues. So, for example,
5 in the CHCS systems, because they have universal access normally
6 to providers at many MTFs, they'll put in there "tested" or
7 something. It won't say "positive" or something. I can't speak
8 for all the MTFs, but many of them where I've been familiar with
9 it, they have different ways of trying to protect privacy.

10 And then on the other side, for triggering whether
11 or not they need a test, all that's fed is through the contractor
12 -- here's the date of the last test -- and that's going to show
13 up through the unit, through MEDPROs, or whatever other system
14 that's over two years old -- and then the question is, how do you
15 defer that individual? So, I know some soldiers will go back for
16 retesting. And so, frequently, at an MTF, you'll get positive,
17 you'll say it's already a known positive. We struggle with how
18 to do that and protect privacy.

19 DR. OSTROFF: Ben.

20 COL. DINIEGA: Roger, was that a screening test,
21 or a diagnostic test?

22 LtCOL. GIBSON: It's a rapid screening test. It
23 uses an ELISA, from what I understand, results within 20 minutes.
24 It's serum-based. They have the ability to do it either oral,
25 fluids-based, or serum-based. What's in front of the FDA for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 approval at the present time is a serum-based test, which plays
2 well into the Serum Repository issue. We will still be drawing
3 blood on these individuals, too.

4 COL. DINIEGA: Confirmatory.

5 LtCOL. GIBSON: Yes.

6 COL. GUNZENHAUSER: I think under the Army
7 contract, the requirement is to have the result back within seven
8 days, and normally they come quicker than that. Oftentimes, you
9 get them in two or three days, you get results, and I think the
10 cost is under \$5.00 per test, including the shipping materials
11 and all the testing and getting a result back.

12 DR. HERBOLD: Roger, do you have any data on what
13 the positive predictive value of that ELISA might be?

14 LtCOL. GIBSON: I don't have any at this time, no.
15 That's available from the company. And WRAIR has been deeply
16 involved with evaluating this rapid test for some time, so they
17 did the pilot work on it. So, that information is available, I
18 just don't have it.

19 MS. SMITH: I'm Edith Smith, from Navy Central
20 HIV. We actually deal with the confidentiality issue of doing
21 the second test by allowing the member to just go ahead and be
22 tested with their group. We don't make them separate out or say
23 they have a waiver or anything like that.

24 We do do two tests for confirmation, but once they
25 go through it, we know that they are known in our office and we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 just send the results on through.

2 DR. OSTROFF: Thank you, Jeff.

3 COL. GUNZENHAUSER: You're welcome, sir.

4 DR. OSTROFF: Jeff.

5 CAPT. YUND: Actually, we have Capt. Glen Schnepf,
6 from the Navy Central HIV Service, to present the Navy policies.

7 CAPT. SCHNEPF: Good afternoon. I'm Glen Schnepf,
8 and I'm also represented here by Ms. Edith Smith, you've just
9 heard. She's been 16 years with us at the Navy HIV Program for
10 Sero-Diagnostics. Ms. Jacqueline Sheffield couldn't be here
11 today because of an illness.

12 I have to say that the Navy is a little more
13 elaborate, and I have a position that's my assignment with BUMED,
14 Bureau of Medicine and Surgery. We are centrally funded and have
15 a dedicated budget as well as a dedicated staff for running this
16 program.

17 In addition, I'm an Infectious Disease Specialist,
18 and I run the HIV Clinic at National Naval Medical Center at
19 Bethesda. I've been involved with this for quite a few years.
20 Next slide, please.

21 (Slide)

22 When this question was posed to me, how frequently
23 should we test, I had to go back and ask the question, why are we
24 testing in the first place? And so I have to, as is typical in
25 the military, go back to the Instructions and find out why are we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 doing all this anyway.

2 SECNAV Instruction 5300.30C was signed off 14
3 March 1990. That is my current Instruction on how we run business
4 in the Navy for HIV testing. The first reason is readiness.
5 Obviously, paramount, being in the military -- and I put a few
6 points down just for my own speaking issues -- obviously,
7 maintaining the safety of the blood supply, if that is an issue;
8 maintaining troop readiness --

9 DR. OSTROFF: Can I interrupt? When is that
10 Instruction dated?

11 CAPT. SCHNEPF: 14 March 1990, it's the current
12 one for the Navy.

13 Maintaining troop readiness. It's apparent, from
14 the previous discussion, commanders really do want to know
15 whether their troops or sailors are HIV-positive or not. And, of
16 course, identifying unfitting conditions for worldwide
17 deployment. The Navy and Marine Corps require worldwide
18 deployable statuses. We don't have profiles. You either are
19 deployable or you are not. HIV is a special circumstance, in
20 that you are fit for full duty being sero-positive, but you
21 cannot deploy overseas.

22 Also, from a more clinical standpoint, is
23 detecting immunological deficiency. With the new guidelines from
24 the IAID, the recommendations came out in April of '01 for the
25 clinical management of HIV patients, recommended starting therapy

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 with triple or whatever combination of the HIV "cocktail" is, if
2 the CD4 count is less than 350 cells, or the viral load is
3 greater than 35,000 on a second-generation test. As you can
4 imagine and appreciate, one does not become infected and then ten
5 days later you suddenly have a CD4 count of 200. It takes
6 usually quite a while, from the bigger picture of things. I'm
7 not talking about acute sero-conversion reactions here.

8 Then, finally, for detecting immunological
9 deficiency is deciding on whether or not there is a disability,
10 and then processing that person for separation because of that
11 disability. And, currently, we're at about, in our HIV
12 population, 4 percent will go for disability per year, which
13 tells you 96 percent are not going for disability. Next slide,
14 please.

15 (Slide)

16 Some more reasons to test is, of course, paramount
17 to anyone who is around someone who is HIV-positive, is don't get
18 infected. Paramount is obviously when sexual partners, it would
19 be important to tell people that they are HIV-positive so that
20 they are not infecting other people. The population tends to be
21 high-risk, though it's not a very young population, as we noticed
22 in some of the data from Col. Rubertone.

23 Co-workers -- I didn't put it in here, but not
24 only the Walking Donor Blood Bank issue, but also with the Marine
25 Corps, they have a new program for hand-to-hand combat that can

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 be at times somewhat bloody, since it's meant to be relatively
2 realistic, and obviously HIV-positive personnel cannot
3 participate in that. So, that's an important separation out
4 there.

5 And, finally, from the patient's care standpoint,
6 whether the patient is HIV-positive or the provider is HIV-
7 positive, medical people in the Navy are tested every year, and
8 even though we're a relatively low-risk population for getting
9 and giving HIV.

10 Finally, which is very paramount in the
11 international arena, is complying with host nation requirements
12 and the Status of Forces Agreements, very important in that in
13 certain countries that the Navy deploys to, we have to have a
14 newly diagnosed HIV-positive person out of the country within 48
15 hours. That is sometimes a logistical difficulty and a nightmare
16 at times for the poor individual. Next slide, please.

17 (Slide)

18 So, looking at that as to why we're doing it, now
19 I decided, okay, how do we prevent people from coming in, and
20 what is the Navy's accession policy? Obviously, the people who
21 are trying to come into the service are tested via MEPS. That
22 will remove a certain population out. And then upon arrival at
23 either Great Lakes for the Navy and the MCRDs at San Diego or at
24 Parris Island, are tested upon arrival, usually within that first
25 week are tested, and then the results will be out. And if they

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 are positive, they are immediately separated with no benefits
2 given.

3 So, obviously, if the condition existed prior to
4 entry, they are not eligible for entry, and there are some
5 reasons for that. One is the potential for life-threatening
6 reactions -- we've already discussed this about live viruses at
7 basic training, though Yellow Fever is not a big issue, but
8 smallpox can be definitely a significant issue.

9 Not able to participate in any of the blood donor
10 activities, et cetera, you know all of this. One problem is that
11 you can't predict who is going to get sick more quickly. Just in
12 the last six months we picked up someone who had not had a test
13 in four years presenting with AIDS. That's a little unusual, but
14 not that rare of an occurrence. And, of course, to avoid medical
15 costs. As you appreciate even with some reduction in cost from
16 the pharmaceutical industry and our reduction in cost from the
17 bulk that we buy medications, you're still talking \$1500 minimum
18 just for the medications, as well as the cost of having
19 specialists taking care of them and their six-month visits to the
20 HIV Evaluation Treatment Units.

21 And, finally, you put in a lot of effort and
22 energy to train the individual and now they are gone after three
23 years on Active Duty, a bit of waste. Next slide, please.

24 (Slide)

25 So, in the SECNAV Instruction 5300, there are

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 multiple requirements, regrettably. It is not as simple as Dr.
2 Gunzenhauser's presentation, this is a little more complicated
3 for the Navy. This came really highlighted to me in regards to
4 compliance of are we being compliant with our own Instructions,
5 and as you will see, reading this down the list, it gets very
6 difficult to see if we're compliant.

7 First of all, there is an annual HIV testing
8 requirement for all Active Duty personnel who are overseas. This
9 is all Navy I'm talking about. Active Duty personnel in
10 deployable units, every year. All Active Duty Navy healthcare
11 providers are tested every year. And all Reserve personnel are
12 tested every year. And they are required to come in and get
13 their test every year.

14 In addition, there are more rules. A routinely
15 scheduled medical examinations. Whether it's a two-year exam,
16 three-year exam, or five-year exam, they get an HIV test with
17 that one. People who have PCS orders to a deployable unit will
18 get one within 12 months of their arrival. Anyone with PCS orders
19 to overseas, within 12 months has to have a negative HIV test.
20 And anyone who visits an STD clinic, alcohol or drug abuse
21 treatment or counseling visit, or prenatal care, all of those are
22 tested. Next slide, please.

23 (Slide)

24 This is just for information only. So you have
25 some vague idea of some denominator when I start talking about

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 different numbers, I'm going to show a series of graphs and
2 tables for numbers. This data is the latest of 30 June '02 for
3 the strength in the Active Duty service. Next slide, please.

4 (Slide)

5 This is for our initial testing data, and to
6 answer I believe it was Dr. Gray's question in regards to how
7 many were force-wide testing. For the Navy, it was 90 percent
8 force-wide and physical exam. The coding, as you know, as Col.
9 Rubertone mentioned, is about 25 different criteria. So, it's 90
10 percent for force testing and physical exams, 60 percent were
11 STDs, and 4 percent were Other -- clinical exams, prenatal
12 visits, alcohol testing. And this just gives you an idea of the
13 scope of the numbers that we do every year. We have a Navy
14 contract, and we are contracted to handle easily more than this
15 number every year. Next slide, please.

16 (Slide)

17 This is another pictograph of the same data that I
18 just presented to you, just lined out in a graph. Of course, as
19 all of these show Desert Storm/Desert Shield, that increase.
20 This data is not completed. Obviously, we are still in '02. We
21 think there's going to be a slight increase. We certainly had a
22 flurry of inquiries and activity with the Reservists being called
23 to duty in October and November, so I'm definitely anticipating
24 an increase in numbers. Next slide, please.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 For our current positive testing for up to and
2 through August of '02, we have 223,00 Active Duty have been
3 tested so far, of which we have a converters of 55 on Active Duty
4 for Navy, for Marines 105,000-over were tested and 5 of them
5 seroconverted positive. This is pretty constant with what has
6 happened no matter when you look at the data. Next slide,
7 please.

8 (Slide)

9 This slide highlights the point that our testing
10 is pretty complete. Even though there is no specific requirement
11 of how many people we have to test at any given period of time,
12 we are definitely well within or close to 100 percent each year,
13 and kind of adjust accordingly. And you can see here our
14 incidence for the numbers are roughly .2 per 1,000, which is
15 about 1/10th of what it is in the civilian community. So you
16 have a situation where the population is at lower risk than just
17 the general population. Next slide, please.

18 (Slide)

19 This is data that I took out of the MSMR, right
20 off of their publication, and just highlights the point of
21 testing every two years and the percent for whose been tested
22 within the last five years and ever gotten a test in the Navy.
23 As you appreciate with all those myriad of rules out there, that
24 there are people who will be four and five years with no HIV test
25 will then present. Next slide, please.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 (Slide)

2 So the question presented was, how often should we
3 be testing for HIV? My response would be that I do believe we
4 need guidelines, that the guidelines should be kept as simple as
5 possible. As you appreciate, my Air Force colleague has not
6 presented yet, but all the rules are different. They are
7 difficult to find out if one has been compliant. I recommend
8 something that is very easy to remember. Obviously, when you are
9 administrating a program of 1.4 million people every year, you
10 should keep it as simple to administrate and as easy to remember.
11

12 Compliance, we're always going to have data and
13 metrics -- how many are you testing, are you up to date, where
14 are you going with your data -- and so this would be easy to
15 monitor. It would be nice to not have to do this pre- and post-
16 deployment for the Navy. Capt. Stephanie Brodine (phonetic) put
17 out a very nice, elegant paper showing that, really, for the
18 Navy, the positives are not occurring on deployment overseas,
19 they are occurring at home, and that's been looked at several
20 other different ways. So, the problem is at home, not overseas,
21 so I'm a little personally not really thrilled about pre- and
22 post-deployments. I understand the reason for pre-deployment
23 screening, but post-deployment is like, boy, that's a lot of
24 waste of money for that one. So, that would be nice to remove
25 just the worry of the commanders and the physicians who are

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 working with commanders, of getting ready for troops and sailors
2 and Marines going overseas.

3 And, finally, we definitely have to meet the
4 Status of Forces Agreements, as well as international
5 requirements. We can't change their laws, that's their laws and
6 we're the guests in their country. And so my recommendation is
7 going to be that we have, at the minimum, an annual testing. And
8 I always think of having to get my teeth checked out once a year
9 on my birth month, and I think this would be a real simple
10 adjunct to the whole process of preventive medicine for our
11 troops.

12 I'd like Ms. Edith Smith to come up here and
13 discuss the cost issue, since that was raised. These things cost
14 money, obviously.

15 MS. SMITH: We have a contract with a company in
16 Minneapolis, Minnesota that right now we pay \$3.75. That includes
17 all the shipping, the supplies to collect the specimens, as well
18 as secure transmission electronically for our results back to our
19 29 medical centers, and it also includes the FedEx shipping of
20 hard copies back to Marines and other places that do not have
21 access to the electronic medium.

22 We have just awarded a new contract to the same
23 contractor, and the price only went up one penny for initial
24 ELISAs. We also get PCRs, Western Blots, all of our confirmation
25 testing through this contract as well, so they have all the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 certifications through FDA, and all the other things. Any other
2 questions?

3 COL. DINIEGA: The cost? The contract cost?

4 MS. SMITH: Right now is \$3.75 for initial ELISA.

5 COL. DINIEGA: No, the total cost of the contract?

6 MS. SMITH: I'm sorry. The total cost is about
7 \$2.75 million a year, and we test about 750,000 people.

8 DR. BERG: Does that \$3.75 include the confirming
9 test, Western Blot?

10 MS. SMITH: No, the \$2.7 million does, that
11 includes all the tests.

12 We're getting to the point where the Western Blot
13 becomes problematic for us, and so we're using PCR more and more,
14 and we have a good process with the current contract. We get
15 PCRs for \$66 a test.

16 CAPT. SCHOR: Do you have any idea how many of the
17 initial screening tests you're having to send for further
18 confirmation testing, and those sorts of numbers?

19 MS. SMITH: It's about .57 percent. It's less than
20 1 percent. What happens is we do a second set of ELISAs --
21 there's two of them. The initial ELISA is done single, then we
22 repeat in duplicate. If you get two out of three of those tests
23 positive, it goes on for confirmation testing. If the Western
24 Blot does not give us a strong pattern and it is suggested that
25 the person is seroconverting, we'll ask for a second sample or go

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 to PCR. But that's looked at on a case-by-case basis. And then
2 sometimes we have to do HTLV as well as HIV-2. We haven't found
3 an HIV-2 positive at this point.

4 DR. OSTROFF: I'll ask you the same question. Do
5 you have any idea in 1990 what criteria were used to establish
6 the annual testing policy?

7 CAPT. SCHNEPF: Specifically, no. I was just
8 reviewing all the different criteria for the different timing of
9 all the tests that we have. I think they were looking at -- and
10 I'm only speculating that they were looking at what was the
11 highest risk, with little information. I mean, in those days
12 there just was not a lot known about the whole disease process.
13 I think today we know a lot more. And I still haven't answered
14 the real question, the question as posed, do we really even need
15 to be doing testing at all, and I think, as a clinician, I think
16 absolutely. So, my bias is more as a clinician. The more data I
17 have, the more I know how to take care of the patient when I
18 need to. Could it be stretched out? Yes, of course it could.
19 But I think when you go to three and four years, that starts
20 getting a little more critical for the care of the patient. So,
21 I'm basing my response on the criteria for when do we initiate
22 therapy for patients, not what they used to know back in '89 and
23 '90 when that came out.

24 DR. OSTROFF: I'm wondering -- I mean, I'm sure we
25 could do the math ourselves, but if you looked at it from the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 perspective of average cost per positive, using the annual
2 screening in the Navy versus the biannual screening in the Army,
3 I'm wondering how different it would be.

4 CAPT. SCHNEPF: Right now, the way our contract is
5 written, we have more than enough ability to test annually. It's
6 widespread, but the majority, over 90 percent, are being tested
7 annually anyway, at least with one test.

8 DR. OSTROFF: No, I understand that, but I'm just
9 thinking in terms of how much you spend per positive test, and
10 I'm sure -- I mean, your numbers are higher than what the Army
11 has, and they are only doing it every two years. So, I assume
12 that your program generates considerably more costs for every
13 time you find someone who is positive than the Army's program
14 does.

15 CAPT. SCHNEPF: I don't know about the Army. I
16 can just say we have a contract and we have a budget that's
17 decided every year centrally. So, our costs are relatively
18 stable. And over the last five years, our numbers have been
19 relatively stable as to the number that we're picking up. So,
20 the last five-year data is about the same as it is now.

21 LtCOL. RUBERTONE: The last time this was
22 published, I think, in the Army was a cost of about \$5600 per
23 positive person identified, but that was in 1996 or '7, I
24 believe, that study was published. So, the rates were a little
25 bit higher. I think that was the number you're asking about --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 \$5600 per person identified as positive.

2 DR. OSTROFF: Greg.

3 DR. GRAY: Captain, from your clinical experience,
4 what proportion of HIV-infected individuals would progress within
5 five years, let's say, to a stage where you would evoke therapy,
6 multi-drug therapy, or be concerned about their combat readiness?

7 CAPT. SCHNEPF: If it's five years, the timing
8 difference from when they've been infected to when I get to
9 figure it out that they are positive, that would be relatively
10 high, about 60 percent of them at that point.

11 As I tell my new initial positives coming in --
12 because they are all terrified they are going to die the next
13 day, reassure them that, no, you're not going to die right away -
14 - is that about 90 percent of our new accessions don't even get
15 put on medications initially. And then it's over the next two
16 years that we start putting them on medication. And it just
17 depends where they're at on their curve as for their CD4 count,
18 what their own individual response is to that. And that,
19 regrettably, is not easy to predict or even predictable at all.
20 But I would say that by three years you may have to start making
21 intervention, so two years would be at the edge, but anything
22 further than that you need to start thinking about therapy at
23 that point.

24 DR. GRAY: Just an observation, if the Status of
25 Forces Agreement is a big barrier, if you will, it would seem to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 me that, from what he's told us, with having one-tenth the risk
2 of civilians, one might argue that we, in sending our deployed
3 personnel overseas to some of the sensitive countries, that we
4 are much safer than tourists who are not tested at all.

5 CAPT. SCHNEPF: I can't argue that point at all,
6 not at all. I mean, we really do have a low incidence in the
7 Navy and the military but, again, that is decided -- that's more
8 of a political issue, and I can't address international politics.

9 COL. GARDNER: Can you tell us, though, what the
10 Status of Forces Agreements' requirements are in terms of how
11 long but since a negative test?

12 CAPT. SCHNEPF: I don't know. It's individual for
13 their countries.

14 COL. GARDNER: Are any of them more than 12 months
15 or 24 months?

16 CAPT. SCHNEPF: Do you mean for having a test
17 before you come in?

18 COL. GARDNER: Yes.

19 CAPT. SCHNEPF: Within 12 months, for a negative
20 to come into their country. But when you're positive, then you
21 have to leave the country right away.

22 COL. GARDNER: By the way, if you take \$2.7
23 million and divide it by your 100 positives, you're at \$27,000
24 per positive, which is about what it costs.

25 DR. OSTROFF: And, also, most of your personnel

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 are on ships, right? I mean, it's not such an issue in terms of
2 the Status of Forces?

3 CAPT. SCHOR: They're in port.

4 DR. OSTROFF: Even for a day?

5 CAPT. SCHOR: They have the port guys come out --
6 I can't think of what their names are right now -- that you can't
7 tie up to a pier unless they check off things. It's a very
8 legalistic system. I can't think of the name of them right now.

9 VOICE: Pratique.

10 CAPT. SCHOR: That's right. They have to pass the
11 Pratique, and it's fairly -- I mean, they could actually check
12 your HIV logs now. It's a little more formal than perhaps flying
13 into an air base or that sort of thing, but going to different
14 ports is a fairly formal procedure.

15 DR. OSTROFF: Other questions?

16 (No response.)

17 Thank you. Kelly.

18 LtCOL. WOODWARD: Well, good afternoon again. I'm
19 again in the advantageous position of having all the issues
20 already been presented -- maybe not really -- but I'm going to
21 talk just really briefly about the Air Force policy and the Air
22 Force practice regarding HIV screening. I just want to make a
23 note that the two things are, quite honestly, a little bit
24 different -- policy versus practice.

25 (Slide)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 The Air Force regulation or instruction covering
2 HIV screening is what's called AFI 48-135. It's been updated,
3 with it's current date of August 2000, so it was updated fairly
4 recently. What you're going to see on this first of two slides
5 is that the Air Force force screening policy is to screen all
6 Active Duty and Reserve Component personnel every five years,
7 typically done at the time of their periodic physicals. There
8 are some more frequent requirements for flying personnel as a
9 stratification underneath the total force.

10 Other requirements that are listed in our Air
11 Force regulation that drive screening includes specific
12 occupational conditions such as healthcare workers -- let me skip
13 the next one for a minute -- pregnancy, STDs, incarceration, drug
14 and alcohol rehabilitation, and then what people have mentioned,
15 the host nation requirements, and then also PCS overseas.

16 The bullet there that says within 12 months before
17 deployment, I recognize now that it perhaps misrepresents that.
18 That is not in the Air Force instruction that we do an HIV test
19 within 12 months of deployment. Our policy is to follow the
20 policy that is put out otherwise by, say, the Joint Staff. And
21 so we do not have anywhere in our specific Air Force instruction,
22 service-specific instruction, that drives a deployment-related
23 HIV other than what's driven by the CINC requirements, the host
24 nation requirements, or the Joint Staff requirements.

25 And I would say at this point that that is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 somewhat problematic in a way when the Joint Staff Memo of
2 February 2002 states that HIV testing will be done in accordance
3 with the service policies, which means that we don't have a
4 deployment-related policy, however, we were sort of -- the catch
5 in there was, again, this issue of it was bundled to the Serum
6 Repository requirement, so, in fact, we sort of have a de facto
7 HIV screening requirement for deployments. So, we're a little
8 conflicted about that and we want to address that and anxiously
9 await your recommendation so that we can nail that down.

10 By regulation, all the sera are sent to our HIV
11 Testing Service at Brooks Air Force Base, Texas, for testing and
12 reporting. Next slide, please.

13 (Slide)

14 Now I want to talk about what really happens.
15 That was the requirement, now what actually happens. Well, first
16 of all, we have two Medical Centers that do their own testing.
17 They don't send it to the HIV Testing Service, they just send the
18 results and, for reasons I haven't totally understood yet, we
19 tolerate that.

20 (Laughter.)

21 More importantly, a couple of our commands have
22 found that in order to logistically manage deploying forces, they
23 actually have to test their personnel about every year. European
24 Command, U.S. Air Force Europe, is now testing people just about
25 every year. Air Mobility Command is testing flying personnel who

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 go in and out of the theater frequently, multiple times a year,
2 on deployment type activities, are testing them every year. So,
3 for operational reasons, we are, in some commands, testing
4 annually.

5 One of the big issues that I don't know whether
6 you all will be able to get into with your deliberations is this
7 issue of basic trainees or new accessions arriving, who may have
8 had a delay in entry from their MEPS screening, and our current
9 practice -- though, interestingly enough, is not actually written
10 in Air Force policy -- is that our new accessions whose MEPS
11 physical was more than six months prior to their reporting, are
12 retested for HIV. So, that is based on some experience over the
13 years that if periodically you identify someone positive who
14 converts between their MEPS physical and reporting to basic
15 training or officer training camps.

16 And then the last issue, of course, is one that
17 you already have heard a bit about, and that is that this HIV
18 testing for deployment is bundled with the serum sample for the
19 Repository and, as was stated earlier, it seems to have been done
20 originally out of logistical convenience for getting that serum
21 sample to the Repository. I believe, just so you all know, for
22 the Air Force, in talking with our HIV Testing Service and the
23 Brooks Lab at Brooks Air Force Base, they can easily process the
24 samples to the Serum Repository without doing the HIV test. If
25 you just call it that, they'll process it, they'll bundle them

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 all up, and they won't put glass tubes in little wire racks,
2 they'll actually do with some more modern technique. So we don't
3 have a dependency on that for convenience.

4 Now, I will go on to say, though, that if we have
5 a requirement for a serum sample for the Repository for
6 deployment indications and a requirement for an HIV test, we
7 certainly wouldn't hesitate to seize the opportunity to get both
8 samples in one needle-stick, but we would actually prefer if
9 there are two separate indications -- or separate indications for
10 those two tests, that we keep it that way so that we can keep our
11 policy straight as time goes on over years. So, it would be
12 quite helpful for us to know the reasons why we're doing these
13 various tests so that our policies evolve in lock-step with these
14 rationales.

15 And I guess, Dr. Ostroff, I know you'll ask the
16 question about why our policy of every five years, and it turns
17 out that the reason is that when we revised our policy in 2000 --
18 and I wasn't there, but Col. Bradshaw tells me this -- that there
19 is no public health recommendation to screen the general
20 population, however, we did believe there was some reason to
21 survey our population -- or it was reasonable to survey our
22 Active Duty population periodically and, therefore, we picked
23 every five years to do it in conjunction with the periodic
24 physical examination. So, it was purely because we needed some
25 interval, and we have this periodic physical, and the HIV test

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 was tagged to that. And that's all.

2 DR. OSTROFF: Thanks. Your policy sounds like
3 it's the most recently revised, if it was done in 2000. I
4 assume, also, people would -- I mean, if you have a five-year
5 interval, it's conceivable that you can be tested on entry and be
6 discharged without ever having any interval test. I assume that
7 they would test on discharge as well.

8 LtCOL. WOODWARD: Col. Riddle is shaking his head.
9 I guess I thought we actually -- I thought we did test people,
10 but everybody else is shaking their head no.

11 DR. OSTROFF: If there's no disability, how would
12 you be able to determine whether it was acquired during service?

13 LtCOL. WOODWARD: I was under the impression we
14 were, but everybody else is shaking their head no. I'll have to
15 clarify that. But we recognized that we had people coming in for
16 a single enlistment, and that we didn't need to test them
17 multiple times during an enlistment, but the issue about when
18 they separate is a different issue, yes, sir -- or an important
19 issue.

20 LtCOL. FENSOM: Does either your practice or your
21 policy make a difference between your non-flight crew air status
22 and others within the Air Force?

23 LtCOL. WOODWARD: Well, our policy for air crews
24 does drive more frequent testing, flying physicals. And so the
25 Reserve Component, for example, tests flyers every three years.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 And in practice, the sum total of our practice versus our policy
2 is that if you look at the numbers Dr. Rubertone presented, we
3 test just probably slightly less than half of our force every
4 year -- I'm sorry -- we do that many tests every year, and we're
5 still discussing whether that's unique individuals or actual
6 tests, but we are testing a large proportion of our Air Force
7 personnel each year, in practice, but it's not directly driven by
8 our force screening requirement.

9 DR. OSTROFF: If I remember the data that were
10 presented, the actual rates per 1,000 tests were, if anything,
11 lower in the Air Force than they were in the other services, and
12 yet you have a longer screening interval. Do you have any
13 potential explanation for that, and are you potentially missing
14 infected individuals and, also, there was the issue that was
15 raised by Capt. Schnepf about concerns about potentially having
16 adverse impact on healthcare for individuals if, indeed, they'd
17 been infected for that length of time before the illness or the
18 infection was recognized. Has that been an issue that you're
19 aware of within the Air Force system?

20 LtCOL. WOODWARD: The first part of the question
21 first is that I don't have an explanation for our low rates of
22 positive tests, and there is a chance we could be -- I mean, we
23 probably are missing incident cases each year, I believe, because
24 I don't think all of our tests are targeting high-risk people who
25 we might have a better positive predictive value.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 Regarding the second part of the clinical
2 implications, if you will, of our policy, not heard from our
3 infectious disease people or from our HIV-specific program
4 office, that that is an issue from their perspective, though I
5 haven't specifically asked them that question since I first
6 started looking at this issue, but I can, yes. They have not
7 pushed it to us.

8 DR. OSTROFF: Other questions?

9 COL. STAUNTON: Michael Staunton, U.K. The only
10 results I saw which would indicate any particular group was the
11 incidence amongst those, I think it was 30 to 34 years old,
12 seemed to be higher. The question which would come to my mind is
13 -- first of all, I have a concern about the specificity, and I
14 think that was answered during that cost question, as to the
15 number of tests which then carried out to ensure that you are
16 getting the correct results, and I think that's fine. But from a
17 health educational point of view, it seems to me that there's an
18 enormous investment here across the services, and it seems to me
19 that little has come out of that which could be used positively
20 to educate any specific groups. In other words, does this
21 identify either in terms of the occupation of individuals or,
22 indeed, whether they are exposed to operational or training
23 hazards or anything else -- is there any additional information
24 coming out of this enormous investment because it seems to me it
25 could be extremely useful to target groups for education, for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 health education.

2 DR. OSTROFF: I think that's a great point. I
3 don't think that the various services would likely find
4 acceptable an entirely risk-based approach to screening, but I do
5 think that your point is really well taken, that if you can do
6 some epidemiologic analysis and figure out what are the factors
7 associated with those individuals who are becoming infected, that
8 it might help very much in terms of developing risk reduction
9 messages, certainly, although that is not to say that the entire
10 force doesn't necessarily need those messages just because they
11 are not getting infected with HIV. But your point is very well
12 taken. There must be some -- I mean, as we heard previously,
13 it's not associated with deployments, but there must be some
14 information available about what the circumstances are.

15 DR. BERG: Bill Berg. I think that's a very good
16 suggestion. The Army actually had sort of a bit of experience
17 with it several years ago when they tried to make an educational
18 film on HIV risk factors, and they had actors doing it. And a
19 majority of the actors, as I recall, were African American
20 because they were trying to make the actors in the film reflect
21 the proportions of cases in the Army. And I'm not sure that ever
22 got approved. There was certainly a lot of controversy about it,
23 and a lot of objections to it, that it was stereotyping and
24 treating African Americans unfairly. So, certainly, you know,
25 risk-based prevention messages are good, but they have to be done

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 a little carefully sometimes.

2 LtCOL. RUBERTONE: I do think, though, that any
3 attempt to do risk-based screening other than possibly STD
4 clinics would be a logistical difficulty. I mean, if you
5 identify -- well, of course, 34-year-old black, single and
6 otherwise unmarried men -- logistically, the services are just
7 going to say just test everyone every couple of years. You can't
8 focus on any particular group.

9 COL. DINIEGA: And there may be legal implications
10 when you target groups based on race. You know, as I get older,
11 I tend to forget which phase of my career I had done what, and
12 things sort of get mixed up -- you know, part of Alzheimer's --
13 but let just make sure I have clear in my mind, Lynn -- the
14 question is on interval testing, which implies to me the phases
15 of testing is force testing. There is accession testing, there's
16 force testing, and the other category is the deployment-related
17 testing, and then there is clinical testing, and now the issue of
18 separation testing, do we do it or don't we, has come up. So,
19 I'm assuming the question relates to force testing interval, is
20 that correct, Lynn?

21 MS. PAHLAND: It is my understanding that we are
22 not asking the question about accession, there's already a very
23 clear policy on that. But once you're in the military, what
24 would be the appropriate interval, if any, during the time that
25 you are in the Active service.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 COL. DINIEGA: And then my other question, I
2 guess, is to myself and Mark and other people who have sort of
3 been -- and even John, who used to be the HIV guy at Health
4 Affairs at one time -- at the time the Air Force came up with the
5 proposal to switch to five-year testing, I remember a flurry of
6 activity, and for some reason I'm thinking there was a
7 presentation to the AFEB on changing that to every five years, or
8 there was a flurry of e-mails, or I was at some conference where
9 data was presented that looked at where the incidence cases were
10 coming from which, if I remember correctly, the data showed that
11 it was not coming from force testing, but it was coming from
12 clinical testing and other testing. And the other thing I sort
13 of remember is that a lot of the cases were not related to being
14 overseas or occurring as a result of deployment, that the comment
15 made by the Navy about most of the cases are obtained here in
16 CONUS is a correct statement. But I don't remember if it was in
17 front of the AFEB or in some other conference or meeting that
18 this was discussed.

19 DR. OSTROFF: Doesn't ring a bell with me.

20 DR. CATTANI: Jackie Cattani. I wonder if we
21 could ask our representatives from the Allied Forces, what is the
22 rationale or justification, and whether either of you feel like
23 there will be testing in the future, to comment on what your
24 experience in this area has been.

25 LtCOL. FENSOM: To be quite honest, I think, as I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 listened to the history, perhaps in the end cost is not a factor
2 for us because it's in a national healthcare system, so there's
3 no great concern about long-term cost.

4 The general feeling on the Canadian side recently
5 has been that we feel there is good military operational
6 rationale for both accession testing and pre-deployment testing,
7 and for some of our more HIV-laden missions like in Central
8 Africa, post-deployment certainly. Politically in Canada, it's
9 only very recently that Immigration, for example, has been able
10 to introduce mandatory testing for immigrants. That happened
11 last year. I think it's likely that we'll be looking at the
12 whole issue again, and we'll probably introduce accession
13 testing. I don't think we'll ever see regular interval
14 screening. Our rates, from what I'm hearing around the table
15 today, are about the same as yours, so I think it's a comparable
16 group in that way.

17 COL. STAUNTON: I think we are dealing in some
18 ways, I get the impression, with systems which work differently.

19 First of all, our considerations were based really on the ethics
20 of bringing in mandatory testing, which it was felt -- and I
21 think it's fairly to say mainly by physicians -- it was felt that
22 that would not be an acceptable avenue to go down, that it was
23 far more important to educate particularly our young people, and
24 then to have a system which would encourage them to come forward.

25 Now, I think that we base this, first of all, on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 the experience of going back some years -- historical experience
2 in terms of syphilis, particularly -- gonorrhea as well, but
3 syphilis -- and the importance of picking that up. Now, up to
4 probably about the early '60s, that was an offense for which a
5 soldier could be imprisoned for something like 28 days, with loss
6 of pay. So, therefore, soldiers were inclined to go elsewhere
7 for a diagnosis and treatment.

8 So, I think out of this -- this is my impression -
9 - that historically we did not feel that this sort of policy
10 worked very well. So, that, it seems -- and certainly my
11 experience as a physician has been -- that soldiers at risk are
12 very prepared to come forward. They know very well -- and we
13 document, for instance -- that they are guaranteed that whatever
14 goes on in that consultation and whatever the results are, that
15 until this becomes an issue whereby they will be downgraded so
16 that they will not go on operations, however, that they are
17 guaranteed, if you like, all of their rights, including pay,
18 including treatment, including being treated right. They will be
19 dismissed from service. So they will be seen right the way
20 through. So, the issues, I think, of their individual security,
21 which are very important, and the confidentiality, those are
22 actually guaranteed.

23 I think it has been our experience -- and I
24 certainly have not -- and I can only speak now from a personal
25 basis -- I have not come across any cases where anything has gone

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 wrong in those terms, in terms of confidentiality and in terms of
2 how individual soldiers and, indeed, therefore, if it applies,
3 their families have been treated. So, for us, that has worked
4 extraordinarily well.

5 I should add that all patients are seen -- in our
6 services, are seen by physicians. I put this in because I don't
7 know whether it makes a difference or not, but I think for the
8 sake of completion I feel I should mention it to you, that
9 because we don't have at this time -- we have been considering it
10 -- but we don't have, for instance, a Physician Assistant
11 program. We do not have any programs whereby any soldier would
12 need to come through some sort of triage system with any other
13 health professional before they get to the doctor. I just throw
14 this in for sake of completion, that it may make a difference in
15 our approach. So, we tend to have a great bond of trust between
16 the physician and the soldier, and very much the physician takes
17 the position -- and I know it happens here, too, by the way -- of
18 being the soldier's advocate, so there is that guarantee. And
19 that is aligned very, very strongly to this health education
20 program, and that was specifically, perhaps, why I said what
21 comes out of this, does it show us groups that we should target -
22 - and I don't mean in any way to stigmatize at all, I don't mean
23 that, I mean quite the opposite -- in a very positive way to help
24 people towards health education.

25 Now, where I have been particularly interested

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 today in listening is that I'm linking the potential bioterrorist
2 threat to our policy, and what I'm endeavoring to do and to think
3 through is whether we have to rethink aspects of our policy in
4 U.K., in light of the fact that we may -- and I personally think,
5 it hasn't come out as a policy -- that we will go on to a
6 vaccination program particularly for smallpox, perhaps for
7 anthrax. So, in light of that, in light of such potential
8 change, I obviously need to make our own medical -- our U.K.
9 medical departments aware of what thinking is going on here.
10 Now, I know that they are thinking about it, too, but we perhaps
11 have to move and perhaps change our policy if we are going to go
12 into a mass vaccination program.

13 So, does that answer that question?

14 DR. OSTROFF: One question I would have is -- I
15 mean, you both are required to adhere to the same Status of
16 Forces Agreements that we would have, I would presume. So, if
17 it's a British ship that's tying up to the same port, I would
18 assume that they would be asking the same questions about HIV
19 testing as they would for the U.S. Navy. Do you simply tell them
20 "We don't require it"?

21 LtCOL. FENSOM: I think the main country at issue
22 for you folks sounds to be Korea, which isn't a place that we
23 tend to go.

24 CAPT. YUND: I think I'd question your assumption
25 that they would have the same restrictions or have to go by the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 same rules that we go by in that the Status of Forces Agreements
2 are made on a country-by-country basis. We have a Status of
3 Forces Agreement with Thailand for our forces, and I don't think
4 that they would -- it's something that's negotiated, and I don't
5 think that it would necessarily be the same set of restrictions
6 or agreements for another country.

7 COL. STAUNTON: Our policy regarding testing, we
8 test for HIV, but it tends to be far more -- as I say, first of
9 all, because people will request it, but also -- perhaps I didn't
10 go into it enough -- but if the physician feels that this is --
11 for any reason, is something that -- a test which is necessary --
12 now, there's the obvious things if it's an STD -- but for other
13 reasons, too, coming out of some way -- you now, sub-Saharan
14 Africa -- and we have quite a few deployments there -- then there
15 is very widespread testing, but it's socially acceptable to the
16 soldiers to do so, particularly if they have been naughty boys
17 while they've been down there. They tend to --

18 DR. OSTROFF: Not British troops, I'm sure.

19 COL. STAUNTON: No, not British troops, as you
20 well know.

21 (Laughter.)

22 But they are very protesting in those
23 circumstances.

24 LtCOL. FENSOM: I would say that's the same in
25 Canada, although there's never any mandatory testing, but

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 certainly when we're bringing missions out of places like
2 Rowanda, people are strongly encouraged to be tested, and almost
3 all of them are.

4 With regard to Status of Forces, I'll give you one
5 example, and that's the U.S.-Canada Agreement specifies that any
6 Canadian troop coming into this country for longer than 30 days,
7 for training or exchange, must have an HIV test, and we do that.

8 I had to have one to come to this job.

9 COL. STAUNTON: I just want to make sure --
10 because Ken raised something -- whether I made it absolutely
11 clear, that the individual physician within a unit -- for
12 instance, our policy is that if any force greater than 60 members
13 is going into a country, or going anywhere, that a physician will
14 accompany. That is a policy.

15 Now, the physician actually has an enormous amount
16 of say, and responsibility, in terms of what he or she is going
17 to recommend -- and I have been in such a situation of saying I
18 want everybody tested from this group, and I would obviously have
19 to have particular reasons, and I'm very open -- and so would
20 others be -- very open, very clear about why this is to everybody
21 who is on that particular mission, and that happens. So, it's
22 both on an individual basis, but it can be on a unit basis. But
23 the physician is taking very much individual responsibility in
24 making those sort of decisions. And, personally, I have to say I
25 think that works very well.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 LtCOL. FENSOM: I would also say, in our forces I
2 think that physicians have a very, very low threshold for
3 testing, possibly because we don't have a routine testing policy.

4 DR. OSTROFF: Let me turn back to Col. Woodward.
5 Do you have any idea how much your program costs?

6 LtCOL. WOODWARD: No, sir, I don't. I don't know
7 if Col. Neville has that number.

8 COL. NEVILLE: About all I could say is it costs
9 in the ballpark of \$3.00 a test, for the screening test. That
10 includes indirect cost and so on. I could probably find out how
11 many are done. I might even have it on my Laptop here. Right.
12 That's the screening test. And the Western Blot is like \$51.06,
13 or something like that.

14 DR. OSTROFF: Have there been any discussions with
15 the upcoming policy on smallpox, about reconsideration to your
16 current screening policy?

17 LtCOL. WOODWARD: Yes, sir. We actually started
18 dissecting this question, I guess, about two or three months ago,
19 and actually talked a little bit about it amongst the GPPM-PG
20 committee, as well as raising the issue with Health Affairs, but
21 hearing that the question was coming to the Board, we were very
22 interested in what recommendations you all might have. But we
23 have actually been discussing both in regards to smallpox, but
24 just in the question of our screening policy and other
25 requirements, policy for requiring testing in general.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 DR. OSTROFF: Any other questions or comments
2 about the presentations because I think we're basically right on
3 schedule at this point in terms of taking a fairly brief break,
4 and then after the break, I think that there will be
5 deliberations of the subcommittees.

6 Now, one of the subcommittees, or two of the
7 subcommittees, basically, there aren't any significant issues
8 before those subcommittees. The only areas of discussion right
9 now are the recommendations that were written by -- yes, you
10 wrote those recommendations regarding the blood supply issues and
11 infectious agents that might be a risk for the blood supply. And
12 then there's obviously the discussion about this particular
13 question.

14 And so I'd like to suggest that since there aren't
15 other issues to bring before the other subcommittees, that the
16 remaining Board members basically just meet as a group to discuss
17 this particular issue, and we'll figure out some sort of way to
18 move this forward in relatively expedited fashion because I think
19 that we basically need to do that with the upcoming
20 implementation of the smallpox policy. And I must confess that
21 I'm a little surprised by how divergent the policies are amongst
22 the services, and I wasn't aware that they were this different,
23 and I can see why it's a relevant issue.

24 So, why don't we take about a ten-minute break,
25 and then come back at ten after.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1
2
3
4
5

(Whereupon, at 3:00 p.m., a short recess was taken, followed by the Executive Session which was not reported.)