

BEFORE THE
UNITED STATES DEPARTMENT OF DEFENSE

- - - - -x
In the Matter of: :
ARMED FORCES EPIDEMIOLOGICAL :
BOARD MEETING :
- - - - -x

The above-entitled matter came on the record,
pursuant to Notice, before DR. LEWIS KULLER, President,
at the U.S. Army Center for Health Promotion and
Preventive Medicine, Aberdeen Proving Ground, Maryland
21010-5422, in the Conference Center Building, on Friday,
October 13, 1995, at 8:10 a.m.

BOARD MEMBERS PRESENT:

- DR. LEWIS KULLER, President
- DR. MICHAEL ASCHER
- DR. JOHN BAGBY
- DR. CLAIRE BROOME
- DR. JAMES CHIN
- DR. GERALD FLETCHER
- DR. BARBARA HANSEN
- DR. DENNIS PERROTTA
- DR. CLADD STEVENS
- DR. MARTIN WOLFE

PARTICIPANTS:

B.G. NANCY ADAMS

CDR. DAVID ARDAY

DR. STEVEN JOSEPH

DR. JOHN MAZZUCHI

COL. FRANCIS O'DONNELL

LT. COL. MICHAEL PARKINSON

CAPT. DAVID TRUMP

PRESENTERS:

CAPT. DAVID TRUMP

LT.COL. MICHAEL PARKINSON

COL. FRANCIS O'DONNELL

COL. BRUCE JONES

DR. BARBARA HANSEN

COL. DONALD BURKE

MAJ. MARK RUBERTONE

DR. JON SMITH

DR. GEORGE LUDWIG

AUDIENCE PARTICIPANTS:

COL. ERNEST T. TAKAFUJI

COL. WILLIAM BANCROFT

- - -

A G E N D A

	<u>PAGE</u>
OPENING REMARKS	
DR. LEWIS KULLER	142
COL. FRANCIS O'DONNELL	142
PREVENTIVE MEDICINE OFFICER REPORTS	
CAPT. DAVID TRUMP	143
LT. COL. MICHAEL PARKINSON	148
COL. FRANCIS O'DONNELL	173
LCDR DAVID ARDAY	194
INJURY PREVENTION WORKING GROUP REPORT	
DR. BARBARA HANSEN	211
INTEGRATED INJURY CONTROL PLAN	
COL. BRUCE JONES	199
HIV PROGRAM IN ARMY	
COL. DONALD BURKE	226
ARMY MEDICAL SURVEILLANCE ACTIVITY	
MAJ. MARK RUBERTONE	255
UPDATE OF VEE OUTBREAK IN COLOMBIA	
DR. GEORGE LUDWIG	282
DR. JON SMITH	270

1 the Navy, Captain Trump.

2 CAPT. TRUMP: Good morning. Since our
3 meeting in July it's been a relatively short period
4 of time so I don't have a lot of detailed issues to
5 talk about. I did want to report that our Navy
6 Environmental and Preventive Medicine Units, our
7 Disease Vector Ecology and Control Units, continue,
8 quote, their routine operations, which has included
9 supporting joint exercises in Korea, continuing to
10 monitor the disease incidence and the intervention
11 program they have in place for pneumonia among the
12 Marines who are training out at Camp Pendleton in
13 California, providing support for a Naval
14 construction battalion, the SeaBees, who are
15 building a hospital in the country of Albania.
16 They've also been working with the Naval Hospital in
17 Great Lakes with the ongoing issues up there about
18 the VEE surveillance in our recruit population and
19 the disease screening intervention programs.

20 The one issue with Great Lakes at the last
21 meeting you had given us a recommendation on
22 varicella vaccine and it's potential for use. The
23 Great Lakes program is developing and hoping to
24 start serologic screening for varicella immunity and
25 then selectively to immunize those recruits who need

1 it with varicella vaccine. They anticipate starting
2 that on the first of January. And over the course
3 of the next year, we should be able to give you
4 updates on how that program is proceeding.

5 They're also, as part of that, looking at
6 the value of adding screening and also selective
7 immunization for measles, mumps and rubella to that
8 program.

9 One of the more interesting things that
10 really came up in the last two weeks came from a
11 phone call in the middle of the night to the
12 Preventive Medicine Unit that is in Sigonella,
13 Italy. And less than 12 hours later, they had an
14 industrial hygiene officer and a preventive medicine
15 physician on route to Qatar. There, there were
16 Marines who were involved in exercise in the Go
17 Desert, and for over two or three days -- about 20
18 Marine had been working pierside there and over a
19 two or three day period about 60 percent of them
20 started reporting symptoms, primarily respiratory
21 symptoms that were being attributed to pollutants in
22 the air from nearby steel and fertilizer production
23 plants.

24 The general in command really needed advice
25 on whether to proceed with the mission that they had

1 or whether to cancel it.

2 The team arrived, was able to work with the
3 Ministry of Health and industrial hygienists for the
4 country of Qatar. They did an analysis of bulk
5 samples of the dust and ash that was found there and
6 found no significant heavy metal contamination or
7 other immediate health threats. They did
8 environmental sampling and found negligible levels
9 of sulfur dioxide and other industrial hygiene and
10 personnel sampling results pending.

11 The initial epidemiologic study among the
12 Marines found that those who were at high risk who
13 were in that pierside area who were at high risk of
14 expected exposure were not at any increased risk of
15 respiratory disease or symptoms compared to Marines
16 who were working elsewhere.

17 This really is a very preliminary report.
18 They're working up the rest of the industrial
19 hygiene samples. But I think for us as a military
20 preventive medicine community it shows one of the
21 directions we need to go, which is that combination
22 of industrial hygiene, occupational health concerns,
23 epidemiologic studies out with the troops.

24 What has I think probably has been heard in
25 this group is our concerns about disease risks, the

1 infectious disease risks that are out there during
2 deployments, during operations. Obviously, there
3 are other risks out there. People are aware of
4 those risks, of the environmental concerns, the
5 industrial concerns, the exposures they may be
6 coming up with. And we're going to have to be able
7 to deal with those and deal with them quickly, as in
8 this case, getting a team out on site to provide
9 them with the information they needed.

10 The final thing I'd like to talk about was
11 what I think is probably one of our biggest success
12 stories over the Summer, was the efforts of a joint
13 team, which was Army, Air Force, Navy and Coast
14 Guard, who pulled together to generate the Armed
15 Forces Preventive Medicine Recommendations for 156
16 countries. It really is a success story.

17 It was a true collaboration of those folks
18 who are really dealing with these issues on a daily
19 basis who are providing recommendations to deploying
20 units, to individuals, on a daily basis. It really
21 is a joint document and succeeded to coming to
22 consensus on several issues.

23 And the product of this is going to be used
24 by the Armed Forces Medical Intelligence Center.
25 They've already developed a CD ROM version of their

1 Disease Environmental Assessment profiles for
2 countries around the world. The think that was
3 lacking was recommendations about how to prevent or
4 deal with those risks. And the issues that we faced
5 in the past are those of different services having
6 different recommendations, all with the same intent,
7 but we sort of went about making those
8 recommendations in different ways.

9 This group really was able to sit down,
10 work through these as a basic document and then
11 tailor them to all the countries in the region so
12 that we really have something that everyone felt
13 comfortable with can be part now of the CD ROM
14 product. And I really would like to thank the group
15 of 17 with Lieutenant Colonel Bob DeFraitas as the
16 coordinator, who really made that happen.

17 I think it is just indicative of what we're
18 doing already in working together in the joint
19 arena, which you'll hear a little bit more about in
20 the direction that we are going already and will
21 have to go as far as trying to minimize service
22 differences and really provide a joint product out
23 there no matter what we're doing. Whether it's
24 putting teams in the field to deal with disease
25 threats, whether it's supporting operations and

1 deployments, or in this case, whether it's putting
2 out a joint recommendation so that when we're
3 sending groups into the field, they're getting
4 something that makes sense, that they understand,
5 whether they are Army, Navy, Air Force, Coast Guard,
6 Marine, that the recommendations are the same. The
7 uniform doesn't change how we go about necessarily
8 preventing disease.

9 That's all I have. Are there any
10 questions?

11 DR. KULLER: Is this document going to be
12 available? Can members of the Board get a copy of
13 the document? Is the document printed or is it just
14 in the stage of development?

15 CAPT. TRUMP: There is a draft that went
16 out. I have a copy of that here. We can get it
17 photocopied.

18 DR. KULLER: And send it around to members
19 of the Board and let them take a look at it, at
20 least have a copy.

21 CAPT. TRUMP: Yes, sir.

22 DR. KULLER: Thank you. Very nice.

23 CAPT. TRUMP: Thank you.

24 LT. COL. PARKINSON: Good morning
25 everybody. You know, it's interesting how much

1 collaboration there is going on between the
2 services, such that when Colonel O'Donnell and
3 Captain Trump and I get together before these
4 meetings, we basically triage who's going to talk
5 about what because we have so much in common for
6 collaborating on.

7 Many of you in the audience, as you know,
8 are participating in these tri-service work groups,
9 and I can just tell you the intensity of those has
10 increased dramatically in the last six months to a
11 year and will continue to do so. So many of the
12 projects that Colonel O'Donnell will talk about
13 we've been deeply involved in, as the CD ROM
14 project, for example, that Dave was speaking about.

15 What I wanted to do is go through a couple
16 of things very quickly that represent what I
17 consider major initiatives directed almost
18 personally by the Air Force Surgeon General. As you
19 know, he has made prevention and evidence based
20 practice kind of the cornerstones of his tenure and
21 we have tried to move out very smartly with direct
22 engagement of our major epidemiologic assets in the
23 Air Force, which is Armstrong Laboratory at Brooks
24 Air Force Base and the Office for Prevention and
25 Health Services Assessment.

1 And I want to give you an update on a brand
2 new project that is going forward, as well as an
3 update on Putting Prevention into Practice and the
4 Biological Warfare Defense Working Group.

5 And I'll blitz through these very quickly
6 in a very little time, but I need you to understand
7 the scope of our effort.

8 First is that we would argue in the Air
9 Force that we have a very narrow and incorrect
10 prevention paradigm, and that is essentially that
11 when we talk to medical commanders, they're only
12 concerned if it's primary prevention. It seems to
13 be the only scope in which they think of prevention.

14 Secondly, they only look at prevention if
15 it saves medical care dollars as opposed to system
16 dollars which we should be concerned about.

17 And therefore, the vision that we have is
18 just bringing us up to speed with respect to the
19 private sector, and that is that secondary and
20 tertiary prevention is where the money is. And more
21 importantly, we have to include indirect costs and
22 opportunity costs in order to have a strategic
23 approach to the way we do prevention.

24 Now, how did we get here? Basically, DoD
25 in its financing sets up a false dichotomy between

1 the line and the DHP budget, the Defense Health
2 Program budget. What that leads to at the base
3 level is a lack of emphasis on disease prevention
4 and health promotion efforts and no notion of cost
5 effectiveness of our efforts.

6 There's no systematic way to calculate
7 indirect costs as regularly used in the private
8 sector to justify their health promotion disease
9 prevention programs and there's no economic pressure
10 on hospital commanders, medical staff or the system
11 as a whole to be economically efficient and to
12 promote cost saving strategies.

13 Secondly, DoD's own medical care system
14 that we're all engaged in is not yet managed care.
15 The three cornerstones of managed care are not yet
16 in place. We don't have true enrollment. We don't
17 really have true capitation yet. And therefore,
18 both of these things -- we have no ongoing process
19 to monitor and improve the quality of care.

20 So aside from those three things, we have
21 managed care in place. But this is not a criticism.
22 We are in the process of moving there. But a
23 system that basically is a \$16 billion animal that
24 takes care of eight million people doesn't do that
25 overnight.

1 We talked to our commanders. We've got to
2 give them the tools and incentives to basically give
3 them the state-of-the-art prevention ability.

4 Well, how could we get there? First of
5 all, we've got to realign economic incentives the
6 same way they do in the private sector and agree
7 that we can within law. And secondly, we've got to
8 build systems around smart people and incentivize
9 them so that we get the optimal type of behavior.
10 And it's this type of approach that we're trying to
11 undertake in the Air Force.

12 But the first thing we need is some type of
13 resource allocation method that uses the same units
14 of measurement; cost per year of life saved, work
15 days lost, worker's compensation avoided. And you
16 can see why I chose to pick this topic today because
17 it leads into what's going to be Colonel Jones, the
18 Injury Prevention Working Group. But we're trying
19 to develop an economic methodology to bring this all
20 together throughout the entire Air Force.

21 What we're trying to do is break down the
22 artificial funding stream barriers between line and
23 medical dollars and to raise to the very highest
24 levels of the Air Force that the Air Force Medical
25 Service is being underutilized in your efforts to

1 control and downsize all of DoD, not just the
2 medical service.

3 Well, the first thing we needed to do is
4 come up with what we call building health community
5 metrics, analyze our deficiencies and gaps, and
6 basically benchmark ourselves against Fortune 100
7 companies, which is basically what we are. And
8 finally, what we need is an economic model to be
9 constructed. And essentially, our Surgeon General
10 said, "And I need this two years ago."

11 So with that in mind, what we basically
12 started, we call it the skunk works,
13 epidemiologically based corporate resourcing model.
14 And this is what we're working on at the moment.
15 What population based investments and what internal
16 utilization management metrics in the Air Force
17 Medical Service do we have to change in order to get
18 return on investment for those dollars that we're
19 spending, particularly when the private sector has
20 been cutting medical care costs on the order of 5 to
21 7 percent a year. We're not there yet.

22 We need a lot of refinements to our medical
23 resource, and we call it business case analysis
24 right now. But we don't have any epidemiologic
25 factors in our resourcing scheme as it relates to

1 the Air Force. No knowledge of risk factor
2 prevalence. We have a lot of knowledge. We don't
3 apply it in the economic model. We don't use self
4 care the way we should; utilization management
5 review; and population based investments.

6 The second major product is a briefing by
7 the Surgeon General of the Chief of Staff of the Air
8 Force. I am -- hold me accountable for the health
9 of the Air Force community. And just like a
10 corporate medical director, it's not just for my
11 medical budget, it's for how my medical budget
12 maximizes the productivity of your line effort in
13 the Air Force.

14 So the second product is a briefing to the
15 Chief of Staff to basically say, sir, this is the
16 way I look at the health of your Air Force, not just
17 the health of the Air Force Medical Service, and
18 these are areas that basically we can do a better
19 job for you if you invest in some of the things we
20 want to do, just the way that line dollars from the
21 Chairman of IBM are mixed with medical dollars for
22 his corporate medical director. We don't even see
23 that as a potential source of funding, although in
24 some areas like occupational and environmental
25 health -- John's over here nodding his head -- that

1 happens kind of quietly.

2 So what we've got is four major categories
3 or metrics; productivity and economic, health
4 status, quality of life and health care system
5 efficiency, otherwise known as utilization
6 management. So with each one of these, we've
7 identified metrics; number and cost of lost duty
8 days, workmen's compensation and disability,
9 recruit/OTS training losses, for example.

10 Morbidity and mortality, traditional stuff,
11 behavioral risk factors, medical discharges under
12 health status.

13 Under quality of life, the assessment of
14 those things that are qualitative, the individuals'
15 perception of their own personal health status,
16 perception of life in the Air Force, are they happy
17 in what they do, are they happy in their job, those
18 types of things.

19 And finally, health care system metrics.
20 True utilization management: denominator-based
21 health care management, which for the first time
22 we're going to try to do in the Air Force;
23 preventable admissions; HEDIS indicators, things
24 that people are looking at in the civilian sector;
25 clinical preventive services for appropriate

1 utilization.

2 What we've done so far is we've had several
3 working groups in San Antonio to basically inventory
4 and collect the most recent Air Force data in each
5 one of these metric areas. Once we've done that,
6 what we will do -- we already have a contractor on
7 board. We're going to benchmark all of our metrics
8 in those four major metric areas against Fortune 100
9 companies or NCHS data or whatever is the most
10 representative and epidemiologically close match, if
11 you will, realizing that there's some problems here.

12 Then we're going to define basically after
13 we benchmark, we're going to define the gaps and
14 opportunities where we're really not getting good
15 return on investment and build an epidemiologic and
16 actuarial model that basically will become something
17 to inform our resourcing and basically brief the
18 chief of staff.

19 And as I said, the completion of this whole
20 project is slated now for February '96.

21 The second major thing is just to tell you
22 that we likewise put prevention into practice in our
23 clinical preventive services program. We see this
24 as the first true clinical practice guideline in the
25 Air Force Medical Service and within DoD. As you

1 know, we've been working very closely with the other
2 services to bring about a tri-service effort here.

3 We just held a conference in San Antonio of
4 our kick-off implementation conference. We brought
5 together over 200 providers and staff from every
6 single Air Force MTF worldwide. It was really quite
7 impressive. I've never been to a meeting quite like
8 this. But from the smallest facility to the largest
9 hospital, we had everybody represented. And for 2-
10 1/2 days, we basically had, with the high level
11 commitment of General Roadman, basically closing the
12 conference with a two hour hand-holding saying we
13 are dead serious about clinical preventive services.

14 The Texas Department of Health, Bill Huang,
15 came down. Basically, they've been doing this
16 around several of their primary care clinics in
17 Texas to talk about their experience. We had
18 piloted the program at Randolph Air Force Base in
19 San Antonio, not without some pain. I'll tell you
20 about that in a minute. And we spent a considerable
21 amount of time skill building in areas that are
22 traditional risk factors in DoD that we don't do
23 well on. Screening and counseling for alcohol
24 abuse, tobacco and also exercise prescription and
25 assessment; areas that we couldn't -- actually, we

1 need obviously full-fledged efforts in each of these
2 areas but we at least started it off.

3 When we tried to use this program at
4 Randolph Air Force Base, what did they tell us?
5 Well, clearly that an intact up-to-date, current,
6 accurate medical record is critical to a successful
7 program to know what preventive services people need
8 and what they've had. And not surprisingly, we
9 don't have good medical record discipline in DoD for
10 a lot of reasons, many of which are understandable.

11 But one of the things we have to do is get control
12 of our medical care system; get control of medical
13 records. Because without, there's no way that I can
14 basically hold my clinic accountable to the same
15 standard as Kaiser-Permanente down the street and
16 make sure that my two-year old immunization rates
17 look like they do around the rest of the country.

18 It's highly labor intensive. We have not
19 focused on ambulatory care as a quality focus within
20 DoD. Most of our efforts have been looking at in-
21 patient care and we're now moving to the out-patient
22 sector. It's a new type of thing.

23 Everybody has to be involved. If there's a
24 prevention person designated on the staff, it just
25 won't happen. It's a cultural change. And a phased

1 in approach is recommended. Why? Because it's such
2 a sea change. I mean, providers initially revolt at
3 this system, if you will. They know it's the right
4 thing to do but it demands such dramatic change that
5 they can't really do it at first. So we're
6 emphasizing the active duty members and those people
7 we enroll under Tri-Care Prime, which is the HMO
8 benefit, if you will.

9 We have been -- basically, Dr. Martin has
10 asked General Roadman for the Air Force to automate
11 the prevention model in CHCS. It basically would
12 take that left-hand side of the medical record that
13 has all that stuff in there that varies widely.
14 There's at least five or six different forms in the
15 services on problem sheets, preventive care forms,
16 some of which are very outdated. And basically,
17 what we want to do is put together an automation
18 model for that in CHCS. And basically, we've been
19 given the go-ahead to do that.

20 We've got \$24 million that's been earmarked
21 in the Air Force Medical Service budget with
22 directions going out to the field as to how to spend
23 that money, the types of things that are fair game
24 to do that. The health and wellness centers we
25 talked about before. We're finalizing program

1 guidance on that. It's kind of a one-stop health
2 promotion center on base.

3 The Surgeon General in late July said that
4 every single Air Force Medical MTF will have a
5 working prevention committee that will look across
6 all clinical and population based programs on base,
7 whether they're in or outside of the Air Force
8 Medical Service to coordinate those activities to
9 make sure that they're effectively targeted.

10 As we come down with metrics that are true
11 utilization management metrics that look at things
12 like preventive services, it's the prevention
13 committee that's going to make it happen.

14 As we get more and more into the clinical
15 area of appropriate use of PSA testing, preventable
16 emissions and asthma, it's going to be mechanisms
17 like this that will allow us to really do some
18 guideline implementation.

19 The final topic is the Biological Warfare
20 Defense Working Group. In the Air Force, as to some
21 degrees the other services, there's been an
22 unfortunate clumping, as far as I'm concerned, in
23 NBC, where we've got nuclear, biological and
24 chemical all lumped in there together in some type
25 of framework which is not necessarily a good fit.

1 In the area of biological warfare defense in the Air
2 Force, a lot of these resources and a lot of the
3 personnel have gone into the civil engineering
4 community with relatively little medical input.

5 And now as the intensity of the threat
6 increases for biologic warfare, we in the Air Force
7 realize we've got to reinject the medical community
8 into the BW world. And so Colonel Cropper has
9 pulled together, at the request of General Roadman,
10 a Biological Warfare Defense Working Group that had
11 its first meeting last week. It brings together
12 these disparate elements of pieces of BW in the Air
13 Force with a long-term charge to basically get in
14 training plans, get in air evacuation plans,
15 treatment plans. We really don't have operational
16 on-the-shelf doctrine or policies that relate to BW
17 for key things that are even Air Force -- not just
18 DoD, as far as the Air Force is concerned for DoD,
19 but also Air Force specific missions like ARABECK,
20 which is exclusively ours.

21 Quarantine. When is it appropriate to do
22 these things? Our potential support for the eboli
23 outbreak with CDC in Zaire brought all these to a
24 head. We had a presentation by presentation by
25 Major Don Noah, who is currently with the EIS

1 program of CDC. He's an Air Force Public Health
2 Officer. Ultimately, Major Noah briefed that to the
3 Chief of Staff of the Air Force concerning the fact
4 that there was relatively inadequate cooperation or
5 knowledge or awareness of what the military could
6 offer CDC in its effort to basically investigate
7 that outbreak. And we don't need to go into the
8 specifics of that because some of that is real and
9 some of it's not. But it got to the four-star level
10 in the Pentagon and essentially at that point the
11 Chief of Staff of the Air Force asked that the
12 briefing be raised even higher up to the SEC desk.

13 So I think that there are a lot of very hot
14 issue right now, both in peace time and the
15 operational side of the Air Force that quite frankly
16 all of us in the room in a blue suit have a very
17 hard time keeping up with because the pace of change
18 and the need for change is absolutely dramatic. So
19 it's exciting but at times frustrating.

20 Thank you.

21 DR. KULLER: Do you have enough data in
22 your database right now to be able to determine
23 whether the distribution of services across your
24 personnel, what the distribution looks like? In
25 other words, when you look at this in the civilian

1 sector, it turns out that a very small percentage of
2 the population uses up 80-90 percent of the
3 services. Is that the same? Is that true within
4 the military, within your Air Force program?

5 LT. COL. PARKINSON: What we -- you're
6 going to hear a little more later. What we find is
7 that -- yes. Just like all risk is not spread
8 evenly across the population, utilization is not
9 either. And certainly what we're finding is that in
10 the Air Force in the area of substance abuse,
11 stress, psychological factors, these are the folks
12 that represent a high risk group for utilization
13 that we need to target, maybe even more so than our
14 injury population.

15 So as we start down -- we've got some of
16 the folks in the audience here. As we start down
17 looking at our in-patient utilization, which is --
18 certainly we have much better data there, things,
19 stress related things come right up to the top of
20 the list.

21 I would just say that that's our whole idea
22 because basically putting our arm around those
23 people, those conditions that are historically known
24 to be high utilizers. We're going to be able to
25 know, for example, when we enroll people using these

1 instruments now, have you had a history of steroid
2 dependent asthma; have you been hospitalized. Any
3 single of these things are markers for high
4 utilizers and we can target those folks.

5 So we don't have the data yet that we need,
6 you know, to say it exactly but we know it's there.

7 DR. KULLER: Is there a goal to go back
8 then to actually the prior -- even records prior to
9 enlistment to try and see if you can identify
10 potential -- I mean, is the goal ultimately in pure
11 primary prevention almost from the military's
12 viewpoint to see if you can identify the potential
13 high risk individuals as far as utilization of
14 health services and cost and loss to productivity,
15 as you might say, as an industrial model prior to
16 even employment, you might say?

17 LT. COL. PARKINSON: Well, one of the areas
18 that Dr. Joseph didn't talk about yesterday in the
19 meeting with the Board that you might want to think
20 about in terms of a product -- he talked about
21 product review -- is DoD now has an accessions
22 medical working group. I know some of the folks in
23 the room are working on that. But as we talked
24 about the Persian Gulf Initiative, there's a
25 comprehensive review going on now of accession

1 medical standards. In the Persian Gulf side of the
2 world, we're certainly looking at the psycho social
3 stressers. We've asked among the preventive
4 medicine officers should there be some addition to
5 do some more screening along those type of efforts
6 at the accessions point because if it turns out to
7 be such a good predictor for who has these problems
8 downstream, perhaps we should look at that
9 proactively.

10 I'm not sure we link those two but it would
11 seem to me a worthwhile thing to look at. And maybe
12 the Board would even have a role because you're
13 certainly involved in the Persian Gulf aspects of it
14 and it might be a useful thing to look over some of
15 the efforts of the accession working group.

16 DR. KULLER: There's a lot of work, as you
17 probably know, in the asthma area, and it would be
18 interesting to link that with efforts to develop
19 predictive models. There's a very large NHLBI
20 collaborative study that's tried to look at this. I
21 only can say that you might help them because they
22 haven't done very well, so that you might be able to
23 generate some better data than they have.

24 LT. COL. PARKINSON: Well, asthma, as you
25 know in the Air Force -- I don't know about the data

1 in the other services, per se, but it's a major
2 concern right now with what we in the Air Force call
3 Code C status, which means that you're not worldwide
4 deployable. And there's been a lot of congressional
5 interest in why do you have these people if you
6 can't deploy them. And asthma is probably our
7 leading cause of reason for non-deployment.

8 So we need a lot more occupational work.
9 What degree of asthma is, quote, severe asthma?
10 What really is limiting to CONUS? I would say
11 that's an area that we need some focused clinical
12 work done in the military.

13 DR. KULLER: Thank you.

14 Dr. Ascher?

15 DR. ASCHER: The discussion previously
16 about the screening for the risk factors or pre-
17 morbid factors for stress reactions really can be
18 very positive if you don't make it an exclusion
19 criteria but make it something you recognize as the
20 training for stress reduction and stress management.

21 And all of the things associated with putting
22 people in these environments should be trained for.

23 We should learn behavior modification. We should
24 learn the therapies that can make people who may be
25 set up for this no longer be set up for this.

1 DR. CHIN: Dr. Chin. Mike, what did you
2 say about eboli and military capabilities?

3 LT. COL. PARKINSON: Well, just to give you
4 one example, one of the observations that Major Noah
5 made and we had -- Steve Ostroff came up and
6 basically briefed from CDC. Was there when we
7 talked to General Anderson and Roadman. And one of
8 the things that was a concern of the teams that went
9 in there was logistical support, communications,
10 access to accurate maps, all of which are things
11 that certainly DoD, that's our business. We do all
12 those types of things. And the discussion centered
13 around the factors are the working relationships
14 between Public Health Service, CDC and the Air Force
15 -- we're not talking about DoD. Does the Air Force
16 have, if you push the button to active Plan 1A, that
17 says we basically get the people into the hot zone
18 or we get them out of there and we have quarantine
19 procedures. We have our ARABECK noted and things
20 like that.

21 I know that Colonel Takafuji and we've had
22 discussions. Certainly USAMRED was on call. They
23 had the units ready to go if anybody came down with
24 something. But at the ground level, the people who
25 were there doing the investigation, they didn't have

1 the confidence that there was something out there.
2 And furthermore, when they needed a map, at that
3 point General Roadman said, "You needed a map?" He
4 said, "We'll have a map of all Zaire in two
5 minutes." And basically, it's a matter of working
6 relationships and knowing what's out there so that
7 we can do that.

8 And what General Anderson basically
9 committed to in a direct conversation with Ostroff
10 and the folks at CDC, "Let's work this. Let's go
11 through some active real time scenarios for the next
12 eboli outbreak that occurs somewhere."

13 And so myself and Colonel Cropper are
14 charged with actually getting together and saying,
15 okay, let's have a dry run. We do this all the time
16 for other types of exercises in the military. Why
17 wouldn't we do it for another eboli type outbreak.

18 So I think there's an opportunity here to
19 really just practice as we -- just train as we
20 hopefully are going to practice in the event one of
21 these comes out. Not that there is any major
22 deficiencies in this case. Transport of specimens
23 was a major concern. Things sat on the dock for two
24 weeks somewhere in Belgium or they couldn't get it
25 out of the country. Is there anything the DoD can

1 do to help facilitate those types of things so we
2 don't miss an opportunity for a disease that crops
3 up once every 15 years and specimens go bad because
4 the Air Force couldn't transport them and we didn't
5 have something in mind.

6 i'm being a little too simplistic here but
7 I don't think we have the working relationships in
8 place. We didn't for this one. And I think we need
9 to spend a little time thinking about it.

10 DR. ASCHER: The reason I asked is because
11 I'm sure USAMRED has all of those capabilities, just
12 that they have to be called.

13 LT. COL. PARKINSON: Right. And again,
14 this came on the heels of a field trip that
15 basically the SG staff took up to USAMRED and we
16 went around and did everything. I know they're
17 there, but again, how -- you know, it's the same
18 thing, getting it down to the operational level so
19 that people know how to access that.

20 If the people on the ground have fears that
21 they can't get their specimens out and that they
22 don't know where they're going in country and DoD
23 has those assets or resources and they're not there
24 on the ground -- there might be nice MOU's at a high
25 level but the people there don't know it, so how can

1 we change that. This was the theme with which we --
2 not that there's major deficiencies but that we
3 weren't operationalizing them, at least to the
4 people who were there in the field.

5 DR. CHIN: Just as a follow-up to this, I
6 think that we've been focusing a lot on sort of the
7 biologic defense in a foreign setting and I think
8 we're well aware that the potential at least for
9 these kinds of problems and use of biologic agents
10 might be in the United States. And I think it's not
11 too early to begin the dialogue with the state and
12 territorial epidemiologists and people on the ground
13 in terms of development of plans and contingency
14 plans for working with that.

15 I think the AFEB probably needs to play a
16 key role.

17 LT. COL. PARKINSON: I was talking to Dr.
18 Perrotta yesterday, and what I said, you know, I'm
19 not sure that, for example, the Air Force regularly
20 attends the Council on State and Territorial
21 Epidemiologist meetings. We've got to make sure
22 that all the services get to those meetings and
23 maybe DoD would like to raise this as an agenda item
24 for CSTE as to how we could work with them around BW
25 issues as it relates to domestic deployment. That's

1 an excellent way to get it on the table.

2 COL. TAKAFUJI: Colonel Takafuji. Mike,
3 just to follow-up on your comments about eboli
4 because I think there are some lessons learned in
5 that experience. There is definitely a need for the
6 capabilities of the Defense Department to be better
7 defined and better publicized. I think it's also
8 very important that the roles and missions of the
9 CDC be clearly recognized in terms of what their
10 responsibilities are. Because in the Zaire
11 situation, what we had there was an international
12 situation that really extends beyond the direct
13 responsibilities of CDC, per se.

14 We're getting into areas that have to do
15 with the independent authorities of these countries
16 to control what's happening within their boundaries.
17 It get into the turf of the World Health
18 Organization. And these are areas that simply are
19 extensions beyond what CDC traditionally does. And
20 that is to care for the American public with public
21 health issues pertinent to this country.

22 So I think that needs to be worked on and I
23 would recommend that in your further discussions and
24 explorations within the Air Force channels that you
25 approach this from a DoD perspective because JCS is

1 also very concerned about this issue.

2 One of the areas that we could explore
3 certainly is the capabilities within the Defense
4 Department across laboratories to support whatever
5 contingencies arise. And in fact, it's not just
6 research laboratories. It has to do with the
7 capabilities of the CHPPM, for example. They have
8 outstanding world class capability to respond to
9 environmental crises. All of these things need to
10 be put together and packaged and publicized much
11 better than the way we're doing it.

12 We are not marketeers. We're not trained
13 to be marketeers. And unfortunately, we suffer for
14 that when things like this happen and decisions have
15 to be made on short notice.

16 So the fact that the Air Force is concerned
17 about this I think is very pleasing, but what I
18 would suggest is that it be explored even wider.
19 This is something that the AFEB may want to take on
20 to help us in terms of publicizing our capability.

21 LT. COL. PARKINSON: I would absolutely
22 agree. I would say the model -- and General Burger
23 couldn't make it, but you'll hear more from Colonel
24 O'Donnell on a preventive medicine working group.

25 The model is you need an ops plan, just the

1 way when the flag goes up in a joint operation.
2 They pull out the plan and here you go and here's
3 the annex, and you just do it. And we need to do
4 that for an international infectious disease threat
5 of this type of nature, such that you could have the
6 right type of response using the right type of
7 resources.

8 I think that would be a wonderful -- again,
9 AFEB oversight with obviously the three services
10 working together, maybe even through the JCS to do
11 it.

12 DR. KULLER: That was one of our
13 recommendations yesterday, as I'm sure you know, to
14 do exactly that. So I hope that will move forward.

15 Thank you very much.

16 Colonel O'Donnell.

17 COL. O'DONNELL: Good morning.

18 In the interest of time, I'll try and do
19 this as quickly as I can. A few summary items.

20 Within the Army inventory right now we have
21 approximately 94 physicians who are fully trained in
22 preventive or occupational medicine. And of those,
23 about 82 of them are actually earning their livings
24 currently in the fields in a broad way of describing
25 preventive and occupational medicine.

1 And I say that including an assignment such
2 as we are about to assign an officer to the On-site
3 Inspection Agency who will attempt to coordinate a
4 variety of items on behalf of that agency with a lot
5 of the other players who have interests in the
6 health related aspects of what that agency does as
7 it works at implementing some of these international
8 treaties on disarmament.

9 We have two physicians who are dedicated to
10 the Persian Gulf business in the sense that one is
11 working with the comprehensive clinical evaluation
12 program management team sort of massaging the data
13 that's coming in on the veterans who are being
14 evaluated and we have one other physician recently
15 assigned to the team, a special investigative team,
16 whose mission is to essentially evaluate if you will
17 anecdotes about potential clues to the etiology of
18 Persian Gulf illness. And it's a quest to leave no
19 stone unturned. And then secondly, to participate
20 in the evaluation of the declassified materials from
21 the Persian Gulf conflict. I've heard estimates of
22 27 million pages of documents that have to be
23 declassified and that individually will at least
24 provide some oversight to the medical review of
25 those documents.

1 And then one other assignment I'll mention
2 is we currently have a physician assigned on
3 temporary duty down in Haiti with the taskforce down
4 there, and that individual would be rotating back
5 and should be replaced by another Army preventive
6 medicine officer.

7 With respect to the pipeline into the
8 specialty, we -- as you may be aware, we have three
9 preventive medicine or occupational medicine
10 residencies within the Army. One of them is the
11 occupational medicine residency right here at CHPPM.

12 There is a residency at the Walter Reed Army
13 Institute of Research in general preventive
14 medicine, and another one of those at the Madigan
15 Army Medical Center in Ft. Lewis.

16 Currently, we expect to graduate in 1996
17 eight individuals who will be come in out of those
18 three programs. Exiting in 1997 will be six
19 graduates and we're hopeful to be able to select
20 this Winter candidates for nine physicians who will
21 finish in 1998.

22 One other thing I want to mention with
23 respect to events in the Army. Just last month the
24 annual Preventive Medicine Officers Symposium took
25 place in Charlotte, North Carolina. And I won't

1 belabor the point but the lead role in terms of
2 sponsoring that conference was CHPPM and they did a
3 great job in terms of putting together a program, as
4 well as the administrative aspects of it. And that
5 was productive of about 25 CME units for the
6 attendees. And we had a fair representation of
7 the other services who were able to attend as well.
8 That's an annual event and it went very well this
9 year.

10 On behalf of the two previous speakers, I
11 wanted to make two comments about some joint work
12 that has been ongoing in the area of what we have
13 variously labeled several things, but it sort of goes
14 under the umbrella term of medical surveillance, a
15 topic of great interest not only to the Board but
16 also to the folks within the services who benefit
17 from the Board's deliberations.

18 And I wanted to let you know that for over
19 a year this has been a concerted area of interest on
20 behalf of both Health Affairs, as well as the
21 services. And what's going on now is a byproduct of
22 what some of you may be familiar as this 12 point
23 set of recommendations that Colonel Erdman had
24 helped draft on behalf of this initiative. And that
25 concept has evolved and we're in the process now to

1 try to come out on the street with both a DoD
2 directive and a DoD instruction which will be in
3 essence instructions to the services, as well as
4 other components of DoD on how to get this thing
5 going.

6 Just want to read to you a few extracts
7 from these draft documents to kind of give you an
8 idea of the approach.

9 In essence, this starts out with saying
10 essentially that it would be policy in DoD for the
11 military departments to conduct joint preventive
12 medicine support of all military operations.
13 Obviously, joint support of joint operations. But
14 this would include comprehensive medical
15 surveillance. And medical surveillance is sort of
16 the linchpin around which we're trying to build sort
17 of a broader approach to not only collecting
18 information but also beefing up actual preventive
19 medicine activities.

20 But one thing we've tried to put into this
21 whole concept is that surveillance activities shall
22 be in effect continuously for each individual
23 service member throughout their entire period of
24 military service. And we'd like that to be in a
25 manner that there is at least a core that is

1 consistent across the military services.

2 And in addition, we'd like a system to be
3 sensitive enough so that it will be able to assess
4 the effects of deployment on the health service
5 members. And finally, that if there are
6 identifiable and special exposures for individual
7 service members, that those events will be
8 documentable throughout the course of his military
9 career.

10 A couple of other points. One of the goals
11 of the DoD field system or process which will
12 essentially allow automated capture of diagnoses,
13 treatment, disposition, as well as obviously
14 identifying information. There will be a
15 centralized repository for all such data. The
16 database will be accessible to appropriate parties
17 for analysis and the compatibility of this
18 continuous database with if you will surrogate data
19 collection systems that may be applicable only
20 during deployments or similar operations. And we
21 also feel the system should be able to link not only
22 medical outcome information in the databases, be
23 able to link that to both environmental and
24 occupational exposures.

25 Now I've just described a few sentences

1 which is a big piece to bite off, but in essence
2 what we're trying to do is institutionalize, if you
3 will, what the goals are of this initiative.

4 Just a couple of other points. We're
5 trying to be very specific in the sense that we
6 believe an automated medical record is probably a
7 piece of this business on down the road. We would
8 hope that this system would simultaneously enable
9 capture the patient encounter process but
10 simultaneously feed the database for archiving and
11 analysis on collected data.

12 We'd like to think that transmission of the
13 collected database across geographic boundaries and
14 political boundaries would be in place. Right now
15 we really don't have that. We'd like to think that
16 this would be applicable in a deployed state or in
17 the overseas state so that the byproducts of being
18 able to capture and analyze data would be
19 immediately or almost immediately available to the
20 taskforce surgeon and in turn to the taskforce
21 commander to be able to give real time feedback to
22 the commander in terms of the health of the force
23 and those elements of the medical threat which we
24 think the commander needs to be attentive to or
25 which need his attention to change.

1 And there's a comment made in there that we
2 think the geographical information system or
3 something along the lines of what you've seen would
4 be a compatible part of this kind of system. We
5 think it ought to be tied to at least company sized
6 units in order to deal with the geographic aspects
7 of this initiative.

8 And one other point is that the emphasis
9 made on the services should participate in the
10 maintenance of serum banks which conceivably might
11 be of some value in terms of assessing after the
12 fact what may have happened. We're not suggesting
13 there ought to be de novo serum banks established
14 for this purpose but the HIV testing program within
15 at least two of the services essentially already
16 results in the storage of serum specimens, if you
17 will, over time. And we're just trying to
18 reemphasize that.

19 Another part of this document is to
20 reemphasize what Captain Trump was talking about
21 earlier. Essentially the attempt to systematize this
22 in a way that countermeasures for the deployed state
23 are continuously updated and revised and linked to
24 the DEARS System coming out of AFMIC and through
25 technology such as CD ROM or electronic bulletin

1 boards. These would be available particularly
2 during the planning process for operations.

3 And lastly, one thing I want to mention is
4 that the draft instruction would call for the
5 establishment of what for the moment is being called
6 a Joint Preventive Medicine Policy Group, which in
7 essence would be composed of PM representatives from
8 each of the military departments and the joint
9 staff, Health Affairs, and anybody else who seems
10 appropriate. And that includes representatives
11 probably from the three major, if you will,
12 functional cells in preventive medicine; CHPPM, for
13 example, and Naval Environmental Health Center and
14 the Air Force Armstrong Laboratory, perhaps the
15 AFEB, Defense Pest Management Board and the Unified
16 Commands, things like Central Command, for really
17 the customers, particularly in the one that we're
18 talking about, deployment situations.

19 So that's a very quick overview of that
20 initiative which has consumed a lot of time on
21 behalf of myself and the other two folks who have
22 been up here this morning.

23 The last thing I want to mention pertains
24 to the subject of adenovirus vaccine. I'll just
25 give you an update on that. The Board considered

1 that issue two meetings ago and basically threw its
2 weight behind the value of the adenovirus vaccine.

3 What I'm going to tell you now is basically
4 nothing is ever easy. As you know, Wyeth is the
5 manufacturer of the adenovirus vaccine and what they
6 have essentially forecast is that their last
7 production lot out of their current facility will
8 come out in 1996. Then they're going to demolish
9 their plant there. They are willing to continue to
10 supply vaccines to the Department of Defense but
11 they need to build a new plant. They're essentially
12 asking the DoD help underwrite this process, and the
13 way to do that is to up the price for the vaccine.

14 And the price will go from approximately --
15 Wyeth's price will go from approximately 60 cents a
16 tablet to \$4.90 a tablet in order to do this. We
17 believe that the -- and then on top of that, our own
18 Defense Personnel Support Center, which is sort of
19 our supply conduit, has it's own surcharge which is
20 going to add on top of this. And at least for FY
21 1996, that surcharge is 44 percent, which is
22 probably a little bit higher than Rite-Aide Pharmacy
23 would charge, but anyhow, those are some problems.

24 And because of at least on the face of it a
25 tremendous expense which will be associated with

1 continuing to use adenovirus vaccine, although we
2 all in our hearts feel this is a valuable thing that
3 needs to be continued, the services have gone
4 through sort of a cost benefit assessment, if you
5 will, and the Navy has done one where they've
6 essentially reviewed their respiratory disease
7 experience, particularly earlier this year when they
8 had a brief period where some of their basic
9 trainees were not provided the vaccine. They looked
10 at all respiratory disease collectively, not
11 separating adenovirus, but there was a tremendous
12 upswing of acute respiratory disease amongst their
13 basic trainees during this brief period and they
14 essentially went through the process whereby making
15 some estimates and assumptions about what role
16 adenovirus may have played in this, they essentially
17 said it really is well worthwhile to continue to use
18 adenovirus vaccine in the Navy.

19 Major Roberto Nang from the CHPPM here
20 actually went -- looked at the Army situation, took
21 a slightly different approach. I might add that the
22 Navy's approach basically was the cost associated
23 with -- the savings to be achieved by a vaccine had
24 to do with savings in terms of lost training time of
25 the basic trainees. Major Nang from the CHPPM,

1 looking at it from the Army perspective, looked at
2 it two ways. The main way he looked at it was in
3 terms of savings of medical costs, just the cost of
4 hospitalization and the assumption of one out-
5 patient visit for each case of disease, as well as
6 looked at it in the way of total costs that could be
7 avoided.

8 And in essence, his analysis, even
9 factoring in the major boost in price and the
10 surcharge to be added by DPSC, essentially his
11 assessment would suggest that we would save money
12 for the Army community at the current rate of basic
13 training if we simply prevented -- in terms of
14 savings of medical costs, we only had to prevent 423
15 cases and basically it would be a wash. And if we
16 in factored in indirect costs, which include things
17 like training costs, we only had to prevent 368
18 cases per year to make this basically an even score.

19 Of course, any more cases than that would be
20 definitely, we'd be up.

21 It brings up the point that some of these
22 costs, however, particularly some of the indirect
23 costs and training costs that might be saved, those
24 are not Defense Health Program dollars, kind of the
25 problem the previous speaker alluded to. But we

1 really feel that based upon these assessments, as
2 well as our historical perspectives on this issue,
3 that the adenovirus vaccine is definitely a go and
4 we would continue to support it. I don't think it's
5 time for the AFEB to come on -- to weigh in on this
6 again, but it may be in the future.

7 The second complication with respect to
8 adenovirus is to bring up the speed. Major Nang,
9 who's been in touch with the folks in the logistics
10 channels, informs me that not only is Wyeth going to
11 have to tear down their factory and build a new one
12 but, because it takes time to build factories,
13 essentially we're facing potentially a two year gap
14 in the availability of adenovirus vaccine for the
15 service.

16 Now that's just a crude estimate well in
17 advance of that coming to bear. But that's a
18 worrisome aspect of this whole business. And
19 although theoretically we could say, well, maybe
20 we'll be a little bit more careful in how we dole
21 out the available stocks of the adenovirus vaccine
22 and we are getting -- expecting one more delivery
23 next year, nevertheless those things have a shelf
24 life of about one year and they'll all expire in
25 1997 and we really don't think the production line

1 will be up and delivering approved vaccine until
2 1999.

3 So that's kind of what it looks like the
4 future brings in terms of the adenovirus vaccine.

5 That's all I wanted to mention. Does
6 anybody have any questions?

7 DR. KULLER: Can I ask a question about the
8 adenovirus? There was a paper out -- I guess it was
9 either in JAMA or the New England Journal very
10 recently which was kind of surprising, which showed
11 that even in young adults the cost benefit in the
12 civilian sector of influenza vaccine was positive,
13 which somewhat surprised me, somebody who works with
14 influenza in older individuals.

15 Has anybody looked at the same situation
16 with adeno vaccine? In other words, can you sell
17 Wyeth the idea that there might be, given the
18 results of the influenza study, that there might be
19 a similar market for adenovirus, the same kind of a
20 model, in the civilian sector in terms of reducing
21 occupationally related loss of work days and things
22 of this sort so that they both keep the price down
23 and perhaps stimulate their interest in building the
24 factory a little faster?

25 COL. O'DONNELL: I think Colonel Bancroft

1 may be coming to my rescue here, but my recollection
2 when Colonel Gados address this issue back in the
3 Spring was that there's never really been any
4 documentation that adenovirus, at least the two
5 strains with which we're concerned which are in the
6 vaccine, have ever been a significant problem in the
7 civilian sector. And that may be an exaggeration
8 and I may have oversimplified it. But it was my
9 understanding that there really is no market in the
10 civilian sector.

11 But Colonel Bancroft, would you --

12 COL. BANCROFT: Colonel Bancroft, U.S. Army
13 Medical Research Material Command.

14 This is where I came in when I pinned on
15 captain's bars. When we were doing studies of
16 adenovirus epidemics on basic training posts, we
17 found that the incoming recruits had a prevalence of
18 adeno-4 and seven antibodies ranging from 10 to 20
19 to 40 percent and indicating that there was some
20 transmission of adeno-4 and 7 in the recruiting
21 community in young adults but not a great deal. And
22 these were the predominant causes of acute
23 respiratory disease on post.

24 Occasionally we'd see adeno-21 and
25 occasionally, once in a while, rarely, adeno-14.

1 But the disease was pretty much eliminated when we
2 introduced bivalent immunization with type 4 and 7.

3 There's a lot of adenoviruses out there in
4 the civilian community. At that time it was decided
5 that there was probably very little use of it in the
6 civilian community. We wouldn't reduce the
7 respiratory rate by using vaccines for just two
8 types of adenoviruses on a widespread basis, except
9 on a military post where susceptibles were coming
10 together and living in crowded conditions.

11 I don't know that that would have changed
12 or would be any different now than it was then when
13 there was a lot of transmission on post. I think
14 we're going to go through an experiment in nature
15 here if we have a gap of a year or two and have no
16 vaccine.

17 Under the changes in the training
18 procedures and the housing of recruits now and all,
19 it will be interesting to see whether adenovirus
20 comes back. And it may not come back immediately.
21 It may take a year or so before the transmission
22 gets reestablished, but I bet it will come back.

23 DR. KULLER: Dr. Chin.

24 DR. CHIN: My first gainful employment was
25 looking at adenovirus and influenza among military

1 recruits at Fort Ord. And the literature at that
2 time, and I think it still holds is that adenovirus
3 is really recruits' disease. We definitely had
4 major problems in U.S. military. And if you look
5 throughout the world, I think there are some
6 outbreaks among Japanese recruits and other military
7 recruit populations. But when we looked for it in
8 the civilian population in terms of any type of
9 outbreak phenomenon or any significant prevalence,
10 no. It was sporadic in the civilian population. So
11 there's no market unless the epidemiology has
12 changed, and I doubt it.

13 DR. KULLER: What happens with college
14 students when you bring together large numbers of
15 students going to college? Why don't you see it
16 there?

17 DR. CHIN: There may have been at least one
18 or two reports but there's never been any well
19 documented sustained sort of periodic adenovirus
20 outbreaks in college.

21 COL. TAKAFUJI: Colonel Takafuji again. We
22 just simply don't know. You would think that in any
23 type of crowded situation, especially in enclosed
24 spaces as college dorms are, as many of you are very
25 familiar with, and people are very crowded together

1 and sharing very common areas, you would expect to
2 see more disease. It's incredible. And I think Dr.
3 Chin would agree that we've come a long way with
4 adenovirus and we still don't basically understand a
5 lot about its transmission potential and why it hits
6 recruits particularly hard.

7 What was the driving factor, in fact, with
8 the vaccine development for adenovirus was the fact
9 that we had recruits not only that were getting
10 infected but they were dying from fulminant
11 pneumonitis that was really very tragic.

12 So there is something peculiar about
13 adenoviruses and military populations and there have
14 been indeed outbreaks in European forces with
15 strains even that -- in fact, adeno-21, for example,
16 caused a problem in some European forces.

17 So it's something that if there's any
18 lessons learned over time it's the fact that, number
19 one, there must be a continuing program with the use
20 of adenovirus vaccines, but with some idea that if
21 it would be used where the need is identified as the
22 greatest. The Air Force, for example, does not have
23 as big a problem in San Antonio as we do in other
24 places. We really don't understand quite why but
25 that's a fact.

1 But the second thing is that there must be
2 a continuing ARD, acute respiratory disease
3 surveillance program. It must be very active and
4 proactive. And clearly, not sacrifice with the
5 cutbacks going on.

6 COL. O'DONNELL: I just would throw in -- I
7 think we mentioned this at the previous meeting but
8 during this hiatus earlier this year there was an
9 outbreak of adenovirus disease at Fort Jackson, a
10 basic training company, amongst a cohort of trainees
11 who had not been able to be vaccinated. And we
12 documented with positive -- I forget whether it was
13 4 or 7, but at major -- I think in one company the
14 rate was like 10 per 100, 11 percent of the company.

15 So if that's any harbinger of what might be
16 the case in the future, I'll bet five bucks if we
17 run out of vaccine we're going to have problems, as
18 we did in the pre-vaccine era.

19 DR. CHIN: I think that some of the studies
20 indicated that spacing and housing -- I think the
21 Air Force is what? Four to a room? But in the Navy
22 and in the Army the barracks are such that you
23 really get sort of exposure of 20-50 people. Those
24 are not the kinds of situations you see in college
25 dormitories and Air Force dormitories. That may be

1 another way of approaching it; get better barracks.

2 COL. O'DONNELL: Vaccine is cheaper.

3 DR. KULLER: Dr. Ascher.

4 DR. ASCHER: You've shown in recent years,
5 you and your colleagues, a number of interesting
6 exercises regarding the changing role of the
7 military with Haiti and Guantanamo and other things.

8 I'm wondering if you have any sort of views of what
9 may happen in the Bosnia situation with regard to
10 preventive medicine. Any surprises? And
11 particularly, as the humanitarian side starts to
12 unravel.

13 COL. O'DONNELL: There's probably somebody
14 in this room who could give you a more introspective
15 answer on that than I. I have not been involved in
16 any contingency planning for Bosnia.

17 Anybody else? Colonel Takafuji, are you
18 ripe for this one?

19 COL. TAKAFUJI: Well, I think there can be
20 some general statements made, regardless of whether
21 it's Bosnia or whether it's Haiti or any other
22 scenario. Whenever you send immunologically naive
23 troops into an area where there's endemic disease
24 and they're under stresses having to do with
25 sanitation and other conditions, are we going to see

1 disease? Yes. We're going to see some problems.

2 With the Bosnia scenario, there's also some
3 peculiar diseases that are in that part of the
4 world. Lessons from history clearly indicate that
5 some of these diseases are old world plagues that
6 cause major outbreaks over the years. So can we
7 have situations like that? Absolutely. And we're
8 looking at that. And as troops prepare to deploy to
9 Bosnia, that certainly is in the scenario.

10 For example, disease that we ordinarily
11 wouldn't think of, like Crimean-Congo hemorrhagic
12 fever. This can be a very serious problem for us if
13 you have casualties showing up at our front door of
14 our hospitals and our physicians are not clearly
15 recognizing this type of infection coming in the
16 door. You could have -- transmission that goes
17 ripping through the hospital.

18 So we're very much aware of these. We're
19 concerned about it. And I think we're probably as
20 somewhat prepared to deal with them as we can
21 possibly be right now.

22 DR. WOLFE: Dr. Wolfe. Are you planning to
23 use the tick borne encephalitis vaccine?

24 COL. TAKAFUJI: That's a decision that the
25 preventive medicine officers are going to have to

1 recommend, but really it's going to be an ultimate
2 decision of the unit surgeons. In this case it
3 would be the taskforce surgeons that would have to
4 make that determination based on risk.

5 Obviously, there are considerations with
6 tick TB that has to do with seasonality of disease.

7 If you're going to deploy at a time when ticks
8 aren't out, then the risk is of course considerably
9 less than when they are out. So, there are many
10 factors that come into play, but it has to do with
11 the requirements and the risk factors associated
12 with likelihood of transmission.

13 But we're ready if there needs to be a TB
14 used, we will use it. We've used it for inspectors,
15 for example, who have gone into parts of Russia
16 during inspections. Part of this refers to some of
17 the things that Colonel O'Donnell alluded to earlier
18 with the On-Site Inspection Agency, OSIA. They sent
19 inspectors into those areas and they received TB
20 vaccine because they were out when the ticks were
21 out.

22 DR. KULLER: Thank you very much.

23 We'll turn to Colonel Ardy, Coast Guard.

24 LCDR. ARDAY: Commander.

25 DR. KULLER: Commander.

1 LCDR. ARDAY: I lost my great segue because
2 we were talking about adenovirus vaccine and I'm a
3 walking case of adenovirus at the moment. I have a
4 toddler in day care and we ought to do a study on
5 what gets spread from day care facilities, including
6 DoD ones, which is where our toddler is, to all
7 their parents. I think I've had every rhino virus.
8 I've even had some Coxsackie virus infections, with
9 the characteristic lesions transmitted from my
10 toddler in the last year.

11 Well, I have only one topic to discuss this
12 morning and that's -- I'd like to update you on what
13 I talked about a little bit in July, PCBs on Coast
14 Guard vessels.

15 Last Spring, several bulk weight samples
16 were taken from Coast Guard vessels which had been
17 decommissioned and were at our Baltimore shipyard
18 for disposal. The bulk samples revealed high levels
19 of PCB, mostly associated with Chromolock tape.
20 Chromolock is a commercial name, I believe, which
21 was used in almost all of our vessels constructed
22 during the '60s and '70s. It was very common.

23 The Chromolock tape is a felt type material
24 impregnated with PCBs and it's used to prevent
25 dielectric corrosion where you had two different

1 types of metals joining. It was very common in ship
2 construction when you have multiple different
3 metals.

4 Construction techniques have changed quite
5 a bit since then and some Chromolock was up to 75
6 percent PCBs by weight, which is mostly aero-chlor
7 1268, although we found a whole bunch of other ones
8 in these ships.

9 The other major source of PCB contamination
10 in these vessels was insulating material used in
11 electric cabling.

12 On August 1st, NIOSH assisted the Coast
13 Guard in conducting a follow-up survey of contact
14 surfaces and crew living and working areas on three
15 similar vessels which had recently arrived in the
16 yard, two 82 foot cutters and one 65 foot harbor tug
17 which had been decommissioned and were there for
18 destruction or preparation for sale. Twenty-eight
19 surface wipe samples were taken from living and work
20 spaces for this study.

21 This table illustrates the range of values
22 obtained in those 28 samples. Nine samples were
23 negative. Three samples found trace amounts below
24 quantifiable levels. Ten samples had levels less
25 than 100 micrograms per meter square, and the

1 remaining six samples had levels higher than 100
2 micrograms per meter square.

3 These are just some of the samples showing
4 the types of surfaces that were sampled and the
5 types of levels that were observed.

6 Now, all of these samples -- the good news
7 is that all of these surface wipe samples are below
8 the EPA spill-cleanup criteria of 1,000 micrograms
9 per meter square. That criteria is based on an
10 estimated risk of one case of cancer per 100,000 to
11 one million persons exposed to surfaces at that
12 level. From what we know about PCBs, that's pretty
13 much a swag because there really isn't any good
14 human data on any cancer cases. That's based on
15 some animal models.

16 However, the Chromolock and other
17 impregnated materials require proper removal and
18 disposal before the ships can be scrapped and
19 current plans are to use high temperature
20 incineration which is probably the best method of
21 disposal. You can also landfill it, but under EPA
22 regulations, you would still be responsible forever
23 into the future if the landfill decided to leak, so
24 we're going to, as I said, incinerate it at high
25 temperatures. Anything greater than 100 parts per

1 million of PCB is going to be incinerated.

2 It's also felt to be prudent to clean up
3 the eating areas to what is considered to be the
4 background level of PCBs in the environment, which
5 is 50 to 100 micrograms per meter square of surface
6 area.

7 Now what we're presently doing with this is
8 we're taking surface wipe samples on active ships to
9 get a better feel for what level of contamination is
10 present in crew working and living areas. And a
11 taskforce has been formed to discuss the options and
12 make recommendations on remediation procedures. So
13 that's where the situation stands at the moment.

14 And that's really all I have. There hasn't
15 been too much going on in the last three months.

16 DR. KULLER: Any questions?

17 (No response.)

18 LCDR. ARDAY: Thank you.

19 DR. KULLER: Thank you very much.

20 We're going to move now to the Injury
21 Prevention Working Group Report, and I'm going to
22 ask Dr. Hansen to lead off.

23 DR. HANSEN: Colonel Jones is going to lead
24 off with a little introduction.

25 DR. KULLER: Okay. Fine.

1 COL. JONES: I'm honored to be able to
2 present this concept to you, Mr. Chairman, Board
3 members and General Adams.

4 The concept that I will talk about is for
5 an integrated approach to Army injury control, but
6 this might just as well be a concept for any of the
7 services. And in fact, for more than just injuries,
8 any preventable disease or medical condition.

9 I think that it serves as a good lead into
10 the presentation of the AFEB Injury Work Group
11 Report that Dr. Hansen will give you next.

12 This concept was developed at the request
13 of the Army Deputy Chief of Staff for Personnel and
14 has been presented to the Army Health Promotion
15 Council.

16 Before I get into the meat of this, I'd
17 like to acknowledge the contributions that several
18 organizations have had to the thinking that went
19 into this. Foremost is the Army Safety Center, but
20 also my participation on the National Center for
21 Injury Prevention and Control Oversight Committee
22 has contributed a great deal to the thinking that
23 has gone into this, as well as thinking from the
24 National Highway Traffic Safety Administration.

25 The purpose of this is to provide you with

1 some background on injuries in the Army and the
2 concept for comprehensive and integrated approach to
3 Army injury control.

4 Why the focus on injuries? You've seen
5 much of this, but the basic reason in the Army is
6 that it's the leading cause of death, disability,
7 hospitalization and out-patient visits, and is also
8 the leading cause of soldier non-effective days. It
9 already has tri-service interest, as we know here.

10 The approach that I will outline is
11 basically the public health approach, which
12 addresses the five questions that you see here. We
13 need information on how big the problem is and how
14 severe the problem is in order to prioritize scarce
15 resources. We also need to know the causes of the
16 problem. We need information on causes in order to
17 be able to develop strategies to prevent injuries.

18 Once we have strategies, we need to know
19 which prevention strategies actually work. But
20 that's not enough. We also need to know who need to
21 know and what do they need to know. We need to get
22 the information out to them. And once the programs
23 are in place, we need to monitor them to see that
24 they are effective and that they continue to be
25 effective and to monitor for newly emerging hazards.

1 So what is the magnitude of the problem
2 with injuries in the Army? How big is that problem?

3 If we look at deaths, you can see that the
4 biggest slice of the pie is accidental injuries,
5 about 50 percent of the total, and that violent
6 injuries make up about another 25 to 30 percent. So
7 80 percent of the fatalities in the Army are due to
8 injuries of some kind or another.

9 If we look at disabilities, you can see
10 here that the top five causes of disability are
11 either injuries or injury related conditions. There
12 should be handout coming around to you also that has
13 these slides on it. Okay. Great.

14 If we look at this from another
15 perspective, hospitalizations, we can see here that
16 looking at all hospitalizations for the year 1993,
17 muscular-skeletal conditions and injuries accounted
18 for 34 percent of total hospitalizations. However,
19 there's probably a better indicator of the impact
20 that injuries have on readiness, and that is soldier
21 non-effective days.

22 This is, again, hospital data. In 1993
23 there were roughly 840,000 man days on the hospital
24 roles. Those are days either in a hospital bed or
25 on convalescent leave. Over 350,000 of those were

1 due to injuries, 41 percent of the total.

2 So far, what we've looked at is just the
3 tip of the iceberg, though. Perhaps the biggest
4 impact of injuries on readiness are those seen on an
5 out-patient basis, as they include things like
6 fractures, stress fractures, sprained ankles, which
7 can cause many days, weeks or months of limited duty
8 and don't make it into the current record systems.

9 In this particular infantry unit, the rate
10 of sick call visits for injuries a month was 19 per
11 100 man months. They accounted for 61 percent of
12 the total sick days or sick call visits. If we look
13 at rates of limited duty, it was over 100 man days
14 per 100 man months, 91 percent of the days of
15 limited duty. We have similar data on five or six
16 other infantry and special forces units.

17 We can use information such as you have
18 just seen to construct, if you will, an injury
19 pyramid. And what we see here is the ratios of
20 disabilities, hospitalizations and injury sick call
21 visits on the right-hand side to deaths. For every
22 death in 1994 we can estimate that there were 15
23 disability cases, 60 hospitalizations and over 1100
24 sick call visits.

25 Now, the base of this pyramid is important

1 for two reasons. One is that the number of sick
2 call visits in the Army for injuries is very large.
3 Conservative estimate is 400,000 visits a year.
4 The other point is that this is the area where we
5 have the least precise information. In fact, there
6 are no routinely automated systems to capture
7 diagnoses in this area. It's also associated with
8 many man days of lost duty time. We can estimate a
9 million to two million man days on profile per year.

10 From what you have just seen, we know that
11 the problem in the Army is big. I can tell you from
12 experience and you'll see in the report that the
13 problem is also big in the other services. But just
14 knowing that the problem is big is not enough. What
15 causes the problem?

16 We have abundant information sources of
17 very high quality that this is data from the Army
18 Safety Center in 1994, and what we see here are
19 causes of reports to that reporting system. And
20 what we see, on the right-hand side over there, the
21 biggest slice of the pie is due to private operated
22 vehicle accidents at 17 percent. The second leading
23 cause is sports, followed by combat soldiering. A
24 good source of information.

25 We also have hospitalization records where

1 injury causes are coded and this is the foundation
2 for future prevention. And what we see here from
3 the hospital records are the percent of causes of
4 injury hospitalizations due to different types of
5 causes. The biggest specific cause in 1993 was
6 sports, followed by motor vehicle accidents, falls
7 and jumps and poisoning, by both injection and
8 inhalation and other causes, as you see there.

9 If we're going to prevent injuries we need
10 to know more than just the causes. We need to know
11 what works to prevent injuries.

12 One of the things that we know works are
13 programs to prevent both private and militarily
14 operated vehicle accidents. If you look at the
15 bottom line, you can see that the rates for military
16 vehicle accidents have gone down steadily since 1980
17 with the exception of 1991, which included the data
18 from Operation Desert Shield/Desert Storm.

19 Other than that, the trend is down. And
20 you can see that for privately operated vehicles
21 we've had a stunning success with rates going down -
22 - fatality rates going down from about 40 per
23 100,000 to 20 per 100,000 over this 15- year period.
24 And I can tell you from direct knowledge that there
25 is a trickle down effect of these programs to

1 prevent fatalities because there's an even greater
2 reduction in hospitalizations from motor vehicle
3 accidents.

4 We also have information on some specific
5 prevention strategies. This was a study that was
6 done at the Airborne School in 1992, among almost
7 800 jumpers who conducted 4,000 jumps. What we did
8 was randomly assign them to wear a brace, an ankle
9 brace, an off-the-shelf ankle brace, and a non-brace
10 group. In this controlled study, we found that
11 there was an 85 percent reduction in ankle sprains,
12 the leading cause of tactical parachuting injuries
13 in the brace group.

14 So we know that we can devise and test
15 effective strategies. Simply having specific
16 strategies is not enough however.

17 What I'd like to do now as really the meat
18 of this is look at the requirements for an improved
19 injury control program for the Army, and I think
20 also the other services. What we need is to
21 integrate and coordinate our systems, especially the
22 information systems. We need to establish community
23 partners throughout the military community. We need
24 to use the information that we have that's already
25 existing in databases that are automated to target

1 the biggest problems based on that data and to
2 prioritize our prevention and research efforts with
3 that information.

4 We need to use as much as possible off-the-
5 shelf solutions such as the ankle brace and we need
6 to monitor program effectiveness at all levels.

7 The components of the comprehensive injury
8 control system, or the elements, are those that you
9 see here: primary prevention on the left, acute care
10 systems on the bottom and rehabilitation systems as
11 you see here. But the central focus of all this and
12 what is new is the focus on information that at this
13 time is not generally used. We need to use that
14 data, analyze it. We need to take it from
15 surveillance, research and monitoring sources and
16 apply it to all the elements of the program.

17 Now, what are the purposes of those various
18 systems in the military? Well, primary prevention.

19 The focus is prevention of the occurrence of events
20 in the first place, to reduce their incidence, and
21 act as a force multiplier. In the acute care
22 system, secondary prevention, we would focus on
23 early recognition, early treatment, with the idea of
24 minimizing the severity of injuries. The rehab or
25 tertiary prevention system seeks to optimize

1 function and early return to duty and thereby
2 minimize long-term disability.

3 We need to do this through partnerships.
4 Any one organization or any one element of an
5 organization cannot do it all together. We need to
6 work in synergy together. We need to communicate
7 better.

8 The partners for each element of the system
9 and perhaps each problem, will be different. In the
10 primary prevention system in the Army, the Safety
11 Centers, would take the lead, followed by
12 commanders, supervisors and NCOs. We need to get at
13 the soldiers through the military schools and
14 there's clearly a role for preventive and
15 occupational medicine, other health care providers.
16 Data systems, of course, are important.

17 Now in the acute care system in the
18 secondary prevention system, medical caretakers
19 provide the care, but they aren't the leaders in the
20 prevention aspect of this. Soldiers would be the
21 first ones to recognize an impending injury. That,
22 or their immediate supervisors, NCOs and commanders.

23 And it's important that they understand the
24 problems that are out there and what's important to
25 recognize to get that care early or even to prevent

1 the need for care.

2 In the tertiary prevention system, medical
3 care providers, of course, would have the lead. But
4 commanders and soldiers need to understand the need
5 for compliance if they're going to return to full
6 duty with minimal or no residual disability.

7 Again, I would remind you we have
8 information systems available. We need to use those
9 systems to prioritize the allocations of resources
10 for prevention and research to where the problem has
11 the biggest impact on readiness.

12 Again, we need to use existing solutions,
13 off-the-shelf solutions, if you will, to attack
14 known causes and risks of injuries through multiple
15 strategies, including behavior modifications, safer
16 procedures and equipment and environmental
17 monitoring and safety.

18 Again, I get back to monitoring. We know
19 from Army data such as you see here that the rates
20 of accidental fatalities have been going down. You
21 see data here for the decade of the '80s, the
22 decrease is even more dramatic than this. It's gone
23 down in the Army from about 75 per 100,000 to now
24 about 40 per 100,000 of fatalities due to accidents
25 annually, while other causes, homicides, suicides

1 and disease have really remained pretty much stable
2 over that period of time.

3 This is just one system. It's the only one
4 that's routinely reported. We need to integrate
5 monitoring systems for disabilities, out-patient
6 visits, in-patient visits, as well as the deaths.

7 What are the benefits of such an approach?

8 I think that they're fairly obvious. By linking
9 the components of the system we have the synergy
10 through those partnerships that expand our effective
11 resources, broaden the scope of the efforts that we
12 can make and I think facilitate the execution and
13 efficient uses of resources.

14 So what's the vision? The vision of this
15 approach would be to drive down the size of the
16 entire curve, not just the right-hand portion where
17 we have generally focused on fatalities and severe
18 injuries, but across the entire spectrum of cost and
19 manpower losses.

20 The vision would be to protect our war
21 fighting forces and conserve resources, while
22 optimizing the performance of soldiers and other
23 service members. We can do this more effectively by
24 prioritizing our efforts, based on the magnitude and
25 severity of problems, and also the availability of

1 potential solutions.

2 The requirements for success or
3 accomplishment of that vision requires commitment of
4 Army leadership -- and I would submit to you DoD and
5 other service leadership -- understanding by
6 soldiers and other service members, DoD wide
7 education, participation and continued evaluation.

8 I think that this concept is apropos to the
9 report that the Board members have in front of them.

10 One of the main thrusts of this report is to
11 provide a foundation for acquiring the support of
12 military medical leadership first and the
13 information that can be used to garner the support
14 of military leadership in general.

15 What is new about this concept I think and
16 central to it is the recommendation to make more
17 adequate use of the rich medical information sources
18 that we have to prioritize both research and
19 programs.

20 The other part of this that is really new,
21 although it makes good sense and you sort of say,
22 well, why didn't we think of this earlier, is the
23 focus on the entire spectrum to capture the injuries
24 that have the biggest impact on the readiness of our
25 military services.

1 And with that, I'll turn the presentation
2 over to Dr. Hansen.

3 DR. HANSEN: Thank you very much, Colonel
4 Jones.

5 I think all of you can see from the
6 enthusiasm of the preceding speaker why this work
7 group was so successful, at least in my view.

8 You have I think in your hands -- at least
9 the Board has and the rest of you will soon have --
10 a copy of the near final draft of the injury work
11 group. I'm not going to try to read through the
12 conclusions or explain all the conclusions, but I
13 thought it might be useful since some of you will
14 not read every page of it and every word of it. I
15 just pulled out just a few of what I personally see
16 as some of highlights among the conclusions of this
17 report, some of the implications for this Board and
18 for its future deliberations.

19 I think that the executive summary provides
20 perhaps the best capsulation of this report,
21 specifying some of the key conclusions that we
22 found. We organized this report specifically around
23 databases because the first question to be asked was
24 how good is the surveillance; how well can we
25 determine what's causing all these injuries that

1 Colonel Jones has highlighted. Do we know what
2 the injuries are and then can we develop preventive
3 strategies.

4 Some of the group were ready to leap to
5 specific research projects on prevention, but it was
6 clear that the database needs to be refined and
7 improved in order to direct those preventive efforts
8 more effectively.

9 Some of the key findings that we discovered
10 or identified in these data. First, the disability
11 compensation. It's hard to imagine but it's \$1.5
12 billion a year in compensation for disabilities,
13 most of which are injury. Not all of which but most
14 of which are injury caused.

15 So in terms of economics, it's clear to us
16 that the military has a tremendous potential area
17 for reducing costs and that is obviously reduction
18 in severe injuries.

19 Back and knee injuries clearly constituted
20 the largest portion of those injuries and certainly
21 the changing death rates and accident rates that
22 Colonel Jones showed you was in large measure due to
23 the change in use of seatbelts.

24 Well, that's one example but certainly not
25 the only one of ways in which injury reduction can

1 have a major impact on the military health system,
2 as well as military readiness.

3 We found that there were many databases
4 available to examine questions about injury but that
5 very few of them were complete enough and very few
6 of them were actually being used for injury
7 surveillance.

8 We looked at specifically some
9 improvements, and I'll go through a couple of those
10 areas. We looked at some improvements that we felt
11 were needed in the surveillance system, based on
12 what I would consider a first review of those
13 databases. Not the kind of intensive review that I
14 would hope would be the sequel to this present
15 effort.

16 One of the things that we have suggested is
17 that at the very minimum we collect what is called
18 the minimum basic dataset for unintentional
19 injuries, which has been recommended by the
20 international collaborative effort on injury
21 statistics and was just recently published. It
22 seems that if we mesh the military data to
23 international standards, that that will be useful in
24 the long-run for being able to look at the military
25 specific differences.

1 There is concern in a number of the
2 databases about whether the coding is sufficient
3 consistent and adequate to really be used for injury
4 surveillance. And certainly we found a number of
5 areas where we thought the coding could be or should
6 be improved, particularly in the muscular-skeletal
7 injury area.

8 One suggestion was to produce a free text
9 field in the database so that we can capture more
10 detail about the actual causes of injury.

11 One of the major recommendations of the
12 group is to convene a tri-services workshop which I
13 was surprised Colonel Jones didn't focus on since
14 it's one of his biggest commitments. And that is to
15 bring together the DoD work group that has been
16 working on this same area of injury analysis and the
17 AFEB Board and working group to define some of the
18 next steps that are needed and perhaps to begin to
19 marshal resources.

20 The second area besides the surveillance
21 part that we looked at were recommendations for
22 specific research areas. We felt that there was
23 very little in the way of systematic research going
24 on in the area of injury prevention and that the
25 potential for positive effects in the military is

1 very large. And thus, that specific research,
2 targeted research, should be increased.

3 You saw the one report of the use of the
4 brace. It appears there's sequels to that study as
5 well as other empirical studies of other possible
6 injury prevention are greatly needed.

7 The area of research into the relationship
8 between military training, physical fitness,
9 performance and injuries is one that actually helped
10 to trigger this work group in the first place. It
11 was the report of the extraordinary level of
12 training injury and I remember to this day the
13 extraordinary number of females that were injured in
14 training, but also males as well.

15 It seems to us that this area of training
16 methods and injuries related to training is ripe for
17 more systematic experimental manipulation to develop
18 methods of improving fitness, holding to military
19 standards while reducing the injury.

20 The training injuries were certainly at an
21 extraordinarily high level.

22 The third area that we addressed is the
23 development of injury prevention programs. Some
24 areas of injury prevention probably don't need a
25 systematic research effort but rather the

1 development of implementation strategies to reduce
2 what we already know about injury and to teach
3 people, educate people and perhaps change their
4 behaviors.

5 Particular emphasis in that area where we
6 can already perhaps initiate prevention efforts
7 should be in the area of training that I mentioned;
8 in the area of sports injuries which are very
9 common. We haven't good comparative data to the
10 nonmilitary population but certainly sports injuries
11 are common within the military. And the area of
12 falls, which surprisingly sorted out both in the
13 death data and in the injury data.

14 Right now there's very little data about
15 why falls in the military are producing significant
16 death rates. Something like 1 percent of all deaths
17 are due to falls -- and that's not parachute
18 jumping, by the way -- and why a large number of
19 injuries themselves require hospitalization are due
20 to falls.

21 We looked particularly at causes of death
22 in the second chapter -- the first chapter is just
23 the introduction -- and used the death database
24 which is fairly comprehensive in terms of deaths,
25 per se, but is not very good about the specific or

1 proximate cause in general. If you are looking at
2 your book you might want to look at Table A1.

3 Vehicle accidents clearly exceeded all
4 other specific causes, but falls, for example,
5 caused seven deaths in the Army. If you look at
6 Table A2, you'll see some of the problems of
7 comparing data across the military. And this is a
8 theme throughout our report, the importance of
9 improving the ability to compare across the services
10 and to collect similar data.

11 So you'll see that the Air Force data are
12 broken down differently than the Army data for
13 causes of death. And if you go to the following
14 page or two, you'll see that the Navy has its own
15 breakdown and the Marines has yet a fourth
16 breakdown. And it would certainly help in terms of
17 future analyses of these data if analytical
18 approaches could be made more consonant.

19 We next looked at disabilities caused by
20 injury and we found some very interesting
21 differences again between the services. For
22 example, the Air Force Physical Disability Division
23 maintains a database on their disability files.
24 However, there's no record of race, sex or age of
25 the injured individuals, which take three of the

1 major variables right out of the equation.

2 The Navy has a computerized database and
3 the Army does not have one at this point, so it's
4 clear that there are some inter-service issues here
5 that need to be improved.

6 There was a tri-service disability
7 information system proposed and a work group set up
8 in December of 1993. I can only assume that Colonel
9 Jones was not put in charge of that work group
10 because there's been no output from that work group
11 yet as far as I'm able to discern. So it seems that
12 that work group needs some artificial respiration if
13 indeed it's still around.

14 Looking at the causes of disability on page
15 5 of that chapter, certainly lumbo-sacral strain,
16 knee impairments, traumatic causes of arthritis and
17 back fractures are very frequently observed in the
18 disability data.

19 The next area we looked at were hospital
20 admissions. And of course the hospital admission
21 database is a little better in the sense of being
22 able to tell more about the nature of injuries. The
23 data from Desert Storm, for example, suggest that
24 accidents and other acute injuries in muscular-
25 skeletal conditions accounted for 43 percent of all

1 the hospitalizations during the Desert Storm
2 deployment. More than 10 percent of all
3 hospitalization are injury related in any case, not
4 just in a combat situation.

5 Again, the causes need to be looked at more
6 carefully and the hospitalization data can help at
7 least where there's severe injuries. We identified
8 in that chapter a section on strengths and
9 limitations of the current databases, hopefully to
10 stimulate further improvements in the existing
11 computerized databases from the hospitalization
12 data.

13 Next we looked at the out-patient care data
14 to see what those databases looked like and what
15 they might tell us about injury. There is no service
16 wide surveillance available, particularly if you
17 look, for example, at muscular-skeletal injuries.

18 There have been almost no intervention
19 trials, so that's an area that certainly needs work.

20 And most out-patient care is not computerized at
21 this point. There is a record, an out-patient
22 record being Beta tested at this point, and I would
23 urge that the Board get involved in looking at the
24 questions that will or will not be addressable if
25 this new out-patient record system is adopted.

1 It's clear that the time to think about
2 the answers to the questions is before the questions
3 are asked and that's before the out-patient record
4 gets finally adopted. We certainly anticipate a
5 growth in the computerization of out-patient
6 records, and the more that growth is attuned to
7 being able to use the data later to solve problems,
8 the better.

9 One of the problems, of course, with out-
10 patient data records is that their first priority is
11 the clinical management of the particular patient.
12 And often, those involved in designing such a
13 purpose may not be thinking about the alternative
14 purposes of overall surveillance and future use of
15 those records.

16 Finally, we have a chapter looking
17 specifically at combat situations and we looked at
18 the non-battle injuries that are appearing in those
19 combat databases. I think it was interesting that
20 in the Operation Desert Shield and Desert Storm, for
21 the single year August 1, '90 to July 31, '91,
22 unintentional trauma or accidents produced 81
23 percent of the non-battle deaths in the Operation
24 Desert Storm, so it's clearly also a combat issue.

25 If we look at the hospitalizations, the top

1 causes of hospitalization in Operation Desert Shield
2 were fractures, sprains, strains, other injuries,
3 dislocations, lacerations. So again, injury is
4 clearly a big problem.

5 We think the Board's attention on a
6 continuing basis will be useful, and we'd like to
7 urge specific actions to bring together the services
8 and to
9 begin to improve the database and to address more
10 specifically the causes of injuries so that
11 effective prevention strategies can be developed.

12 I'd be happy to take any questions or
13 receive any comments from the Board or anyone else.

14 DR. KULLER: The plan, Dr. Hansen, to
15 continue this, could you briefly give us a briefing,
16 or Dr. Jones, of what the plan is for continuity of
17 documenting.

18 DR. HANSEN: Colonel Jones, do you want to
19 address the plans for the workshop that you're in
20 the process of developing at this time?

21 COL. JONES: I think that that's the key
22 recommendation in this. There are other
23 recommendations that we'd provide to you for your
24 perusal and prioritization, but in my mind, that's
25 the key one. And I would hope that that could take

1 place sometime in the next six months. I think
2 that's the critical link. We need to link.

3 The other DoD work group has been very
4 active because without the other work group this
5 report would not have been possible. They have
6 compiled the data that generated this. The focus of
7 that work group is on completing an inventory of all
8 of these databases and there are some missing links
9 that we're still working on.

10 The AFEB Injury Work Group decided -- my
11 initial plan was to have this report follow the
12 other one, but it seems like parallel production
13 would be better so that we would have the arrival of
14 the two main links. And the link would be to have
15 the DoD Injury Work Group and this AFEB Work Group
16 and at least the Safety Centers meet to decide how
17 to link the databases and get that information out
18 to the safety organizations of the three services,
19 and thereby the commanders, who can really use this.

20 So, that I would see as our key
21 recommendation is to begin that building of
22 partnerships.

23 DR. HANSEN: I think the other thing I
24 would add is that we had a lot of contributions from
25 lay consultant members of the work group and most of

1 them indicated a willingness to continue to serve
2 the AFEB should there be a desire for those lay
3 people to come. I shouldn't call them lay, but non-
4 military personnel to continue to consult and help
5 with the development of the next set of strategies.

6 COL. JONES: I think another recommendation
7 that isn't clear in this would be that the medical
8 departments of the services and DoD Health Affairs
9 really need to define what we feel our role in this
10 is. Clearly these medical databases which are
11 currently unused for this purpose need to be
12 developed, not just for injury control but for
13 disease control in general. So that would be
14 another part of this.

15 Before we continue, I'd like to correct a
16 misconception here. When you compile a report of
17 this magnitude and you have multiple editors and
18 participants, frequently small errors make big
19 differences. I'll call your attention to the first
20 page of chapter 2. The next to the last paragraph
21 there's a sentence there that Barbara's highlighted
22 for me, and it reads: The Army at this time does
23 not maintain a computerized listing of decisions
24 reached by the Physical Disability Agency.

25 That should read "does maintain" a

1 computerized listing of decisions of the Physical
2 Disability Agency. But, does not maintain a medical
3 evaluation board database.

4 The Physical Evaluation Boards are
5 predicated on medical evaluations, which could be
6 coded with ICD 9 codes. So that's a critical thing.
7 And if you would make those corrections. I would
8 hate for that to escape and get back to the Physical
9 Disability Agencies because it's really an editing
10 error and it highlights how careful you have to be
11 in this whole process, iterative process.

12 DR. KULLER: I'd just like to make one
13 other pitch or comments. And that is, as you
14 probably know, and I mentioned it yesterday to some
15 of you, that there is about -- I don't know -- \$10
16 [million] or so in the Department of Defense Women's
17 Programs, which is about to be made available. And
18 I strongly suggest that some effort be made to apply
19 this efficiently in some of these issues related to
20 injuries.

21 I don't know whether the group has given
22 any thought to that, but I think it's really up to
23 the people who are involved in these programs
24 whether that money is going to be wisely used or
25 whether it's going to disappear in a big bird into

1 the sky and never be seen again, at least for any
2 useful purposes.

3 So I hope maybe you give -- some of the
4 people give some thought to that idea or utility.
5 There is a fair amount of money that's been set
6 aside with the opportunity of doing some useful work
7 in these areas.

8 COL. JONES: I think that's very prescient.
9 And in fact, the joint program review has
10 considered that for the Women's Health Defense --
11 Women's Health Program. And perhaps Major Rubertone
12 could make a brief comment on that when he gives his
13 presentation because he's been more actively
14 involved in that part of that effort.

15 DR. HANSEN: Okay. Well, this is my last
16 time at this podium and I would like to take moment
17 to thank Lou for his leadership of the Board and
18 both the Board members and the prevention officers
19 for an extraordinary tutoring in military medicine
20 over the last four or five years. I've enjoyed the
21 experience very much and I wish the Board and the
22 officers well.

23 DR. KULLER: Okay. We're going to talk now
24 briefly about the HIV program in the Army.

25 Colonel Burke.

1 COL. BURKE: My presentation is based on
2 slides so it's going to be a little awkward if we
3 don't have them yet.

4 Well, why don't we start with questions.

5 (Laughter.)

6 The purpose for the presentation today is I
7 thought I'd review the global molecular epidemiology
8 of HIV and that rather than focus on the domestic
9 problem, I thought that it would be worth the
10 Board's time to review what we know about the global
11 spread of the HIV epidemic and particularly what
12 countries are being affected, the types of viruses
13 and what impact it's having on what we know about
14 some of the UN peacekeeping operations in some of
15 the countries.

16 I don't see any activity up there at all,
17 so --

18 DR. KULLER: Why don't we basically take
19 about no more than a 10 minute break because we're
20 way behind. People -- some of us, have to leave
21 fairly early. And then we'll start out with the HIV
22 and go through.

23 So let's make sure we're back by 10 after
24 because that's when we're starting hopefully with
25 the projector.

1 (Whereupon, a brief recess was taken.)

2 DR. KULLER: Colonel Burke, let's go.

3 COL. BURKE: Okay. Let's go.

4 Today I'll speak to you about the molecular
5 epidemiology of HIV worldwide. The components of
6 the talk will be on genetic variation, the tools
7 that we use, the dispersal patterns of HIV as
8 they're occurring, what we know about the antigenic
9 diversity of different types and some late
10 information on viruses that are recombinant forms.

11 The convention model of HIV spread
12 worldwide is that the virus emerged from primates
13 into humans sometimes 50 years ago or so. That is
14 spread within Africa and then subsequently it's been
15 spreading worldwide.

16 To study the HIV strains, we collected
17 viruses from around the world through a large number
18 of collaborators and genetically analyzed those
19 viruses first through a screening method, a
20 screening PCR, and then through sequencing of
21 different genes in the virus.

22 Our strategy was largely based on taking
23 the genes that encoded for the central part of the
24 virus, the GAG gene, and genetically analyzing those
25 viruses by sequence. And then for interesting

1 viruses, to sequence the envelope gene. Most other
2 groups in the world just went straight to the
3 envelope gene and sequenced that part of the virus.

4 When you do this with the GAG gene, the
5 different viruses can be put into a taxonomic or
6 phylogenetic trees, each of which of the branches is
7 given a letter name, A, B, C, D, E, F, G, H, and
8 that all of the viruses from North American are in
9 this group. The viruses from other parts of the
10 world are in different groups, and I'll give you the
11 geographic distributions in a moment.

12 The numbers here are the reproducibility of
13 those on a sample, a bootstrapping technique, as to
14 which viruses to cluster together, and so that
15 there's a very high reproducibility of this
16 depending on your sampling.

17 Another way of thinking of this genetic
18 distribution is that there are a number of different
19 viruses, all of which are essentially equally
20 distant from each other. There's not a clear
21 branching relationship with a progenitor virus that
22 is the parent of all AIDS viruses, a so-called
23 starburst by the genetic distribution.

24 But when we compared the phylogeny based on
25 the envelope gene compared to the GAG gene, if the

1 viruses are all descended similarly, then they
2 should have a similar distribution of trees. So
3 what we've done here is simply to color code the
4 envelope gene phylogenetic tree and then to compare
5 that to the GAG gene phylogenetic tree. And most of
6 the viruses are in exactly the same grouping.

7 However, you'll see that some of the
8 viruses, like the E viruses, all of these viruses,
9 although they form one separate group on the
10 envelope gene analysis, fall into the A gene group
11 for the GAG gene analysis and some of the D viruses
12 also have AID GAG genes. This I'll come back to as
13 being I think very significant in that there are
14 recombinant viruses that have been evolving over the
15 last few years.

16 The military group, as I said, did most of
17 our work on the GAG genes. And then in the entire
18 database of the world of complete sequences of the
19 GAG gene, we've contributed 60 GAG genes compared to
20 the rest of the world analysis of 24, all of which -
21 - almost all of which from the rest of the world
22 have been on viruses from North America and from
23 Europe. We've been looking at viruses from around
24 the world.

25 Similarly, in the envelope gene we've made

1 a significant contribution. So all in all, in terms
2 of analysis of viruses spreading around the world,
3 the U.S. military has a very important more than
4 half of the total analysis.

5 One of our major purposes was to study
6 these viruses for vaccine development, but another
7 one is to understand where the viruses are going so
8 that we can match the vaccines to the viruses found
9 in different parts of the world.

10 An important part of this overall program
11 has been an excellent Army-Navy collaboration where
12 the Navy oversees laboratory collecting specimens,
13 doing the serologic studies and doing preliminary
14 strain characterization on site.

15 The Navy laboratories have a common
16 protocol that works through our system and have been
17 collecting viruses from a number of different
18 countries, not only the places where the Navy
19 laboratories are located.

20 If you combine the complete sequences that
21 I mentioned earlier, plus even partial sequences,
22 and what we did here was to go through all the
23 viruses anywhere in the literature or in the
24 databases, even partial sequencing, and ask of the
25 total number of strains that have been typed so far

1 in the world, continent by continent, how many are
2 of each type.

3 And so of the 669 viruses from which
4 there's at least even fragmentary information about
5 what type of virus they are, this shows by the
6 continental distributions.

7 In the Americas, of the 164 that have been
8 typed, 157 have been the B genotype and 5, all of
9 which are in Brazil, have been the F genotype. In
10 Europe similarly it's almost exclusively the B
11 genotype.

12 There are different viruses found in
13 Africa; the A's, the D's, the C's, the E's and
14 others, and relatively few B viruses in Africa.
15 Four of these were in a nosocomial epidemic in
16 Egypt, probably American blood products.

17 In Asia, again there are B viruses but
18 predominant viruses now are becoming C and E
19 viruses. So that in different parts of the world,
20 there are different genotypes of viruses.

21 If we go into this in more detail -- and
22 what I'm after here is to give you the gestalt.
23 Again, the Americas, Europe, Africa and Asia,
24 country by country, with the different clades of
25 viruses or different genotypes across the top here,

1 starting with B, and then A, D, C, E, F, G, and H.
2 And I put these in an order so that it was easy to
3 group them. All of the viruses here almost
4 exclusively B, with the F viruses in Brazil and an
5 epidemic of F, again nosocomial, in Romania.

6 In Africa, almost all the viruses are A and
7 D through out Sub Saharan African, except for --
8 I'll come to these down here. And then in
9 equatorial Africa, in the Congo basin, particularly
10 in the rainforest regions and particularly in the
11 countries of Gabon, Zaire, CAR, that there is a wide
12 variety of viruses. All of the genotypes are
13 present in this region.

14 In South Africa, Zimbabwe, Malawi, South
15 Africa and on the Horn of Africa, there's a
16 different type, the C genotype, which extends over
17 to Western Indian in Bombay and Pune.

18 And in Asia, although they have the
19 cosmopolitan B virus, they also have a new epidemic
20 of the E genotype in Thailand.

21 So that given today, if you give me a virus
22 today, I can give you with a pretty good certainty
23 where that virus came from in the world just simply
24 by genotyping the virus.

25 This is a map of the world that was

1 published in 1988 in a Scientific American article
2 that said that there are three types of transmission
3 pattern of HIV: the homosexual and drug use pattern,
4 pattern one; the heterosexual, African, pattern 2;
5 and then the rest of the world was pattern 3,
6 meaning there was little or nothing to report.
7 Interestingly I should point out that in 1988 there
8 was nothing to report from Asia. That was only
9 seven years ago.

10 The B genotype corresponds very closely to
11 these countries that have the pattern 1 distribution
12 patterns. And everything else, the A's, D's, and
13 C's particularly, correspond to these. And it
14 suggests that maybe there are either some very tight
15 social networks around the world for these
16 transmission patterns or the possibility that
17 certain viruses have a proclivity for transmission
18 by different routes of transmission.

19 Based on these data of the distribution of
20 viruses worldwide, you can make a case that the
21 viruses are all found in equatorial Africa and that
22 there have been a series of cloning events that have
23 occurred over the last 20 years in a chaotic and
24 unpredictable fashion. The one that we're most
25 familiar with is the B genotype epidemic with a

1 patient zero that occurred in the late 1970's in the
2 United States and in Europe.

3 However, you can make a pretty good case
4 that there was a patient zero for the E genotype in
5 Southeast Asia and a patient zero for the C genotype
6 in India as well, based on the fact that these
7 genotypes are phylogenetically very, very similar to
8 each other.

9 The E viruses, early in the epidemic from
10 different individuals were as similar to each other
11 genetically as you would find within one individual
12 in the United States or more similar, implying it
13 was a clonal event. And that's why I call these
14 clonal expansions at each point.

15 So the chaotic model that we're working on
16 now on disposals is these viruses found in
17 equatorial Africa with a number of different seeding
18 events that have occurred around the world as
19 independent epidemics, not single epidemics but
20 independent epidemics.

21 But if you take the World Health
22 Organization estimates from a few years ago on
23 incident infections worldwide in terms of millions
24 of infections per year in different regions of the
25 world, the African curve went up. And this is

1 arguable whether or not it's actually declined or
2 plateaued. But what is indisputable is that the
3 Asian epidemic now, there are more incident
4 infections in Asia than any other part of the world
5 and that the other parts of the world are relatively
6 small and flat in comparison.

7 If you then take those data of the
8 incidents and geographic regions and multiply them
9 simply by what we know the proportion of strains of
10 each clade in those regions and ask worldwide which
11 are most important genotypes of HIV, this is a rough
12 curve here. The B genotype, the North American-
13 European type is actually a minority variant
14 worldwide, and that the E genotype and the C
15 genotype that are now clonal -- recent clonal
16 epidemics in Asia, now are accounting for most of
17 the infections worldwide.

18 One of the properties that we've become
19 aware of in the last year or two is this notion --
20 it's been known for a long time that retroviruses
21 can recombine with each other. That each viral
22 particle has two complete strands of RNA and that
23 there can be crossing over. And Howard Temin, one
24 of the discoverers of retroviruses and a Nobel
25 laureate in the last few years of his life spent a

1 fair amount of time analyzing recombination of
2 retroviruses in the laboratory.

3 And the general mechanism is that two
4 viruses infect -- here's a virus from the same virus
5 D and virus A genotype -- infect one cell. They
6 have their RNA. It's put in, injected into the cell.
7 It integrates as pro-viruses. These then dimerize
8 to form the pre-encapsulation of dimerization
9 complex. A new virus is made which is a
10 heterozygous virus. And when this infects a new
11 cell then the reverse transcriptase jumps back and
12 forth across the strands to make a recombinant
13 virus.

14 An inherent reason for a recombination
15 potential for these viruses is the reverse
16 transcriptase as a relatively low fidelity as it
17 moves along the strand and can jump back and forth
18 across the strands and copy from both individual
19 strands.

20 But if you think of a phylogenetic tree of
21 the HIV's as being up here, these are the HIV-1's
22 with the A, B, C, D, E, F, G, and each of these
23 circles represents the different clades branched off
24 from the central point, the starburst phylogeny.
25 There are other viruses like the SIV's of

1 chimpanzees that are somewhat related, found in
2 equatorial Africa.

3 The HIV outlier groups are also found in
4 equatorial Africa and then there are a number of
5 Simian viruses from Mandrill Sikes monkeys, African
6 Greens, Sooty Mangabeys. And the HIV-2 viruses are
7 very, very closely related to the Sooty Mangabey
8 viruses, suggesting a relatively recent production
9 into the human population as the source for this
10 particular type of virus.

11 But not long ago, Beatrice Hahn and
12 colleagues recognized that there was a recombinant
13 virus between the African Green monkeys and the
14 Sooty Mangabey viruses and the SIV-AGM Sabeus, and
15 that re-wetting our interest and our observation
16 that we had a virus. And the E viruses had an
17 envelope of one type but a GAG gene which was
18 similar to yet another type, suggesting that maybe
19 there was a true E parent out there that we had not
20 yet discovered and leading to the possibility that
21 this could be recombinant.

22 So we went back into our databases of
23 different viruses and asked of the viruses from each
24 of the clades, how many might be recombinant
25 viruses. And when you do this, shown here are the

1 GAG genes and the envelope genes from a number of
2 different viruses. That if you tried to --if you
3 take apart the different genes that have been
4 sequenced so far, for instance, this K124 virus in
5 Kenya, the left-hand side of the GAG gene is clearly
6 an A virus but if you do the taxonomy on the three
7 prime end of that gene, it's a D virus. And
8 similarly you can go through the envelope and look
9 at different parts of the virus taxonomically fit
10 with different groups of HIV.

11 And so you can go through. There are quite
12 a variety. Here's the Thai viruses which have an A
13 GAG and an E envelope and there are other viruses
14 that have a G GAG, A envelope, et cetera.

15 And this was published in Nature just a few
16 months ago. What it suggested is a surprising
17 number of the viruses, particularly in the countries
18 in equatorial Africa are recombinant viruses. And
19 I've redrawn the phylogenetic tree here to show now
20 that we have the first wave of the evolution of HIV
21 into this starburst phylogeny and now we're seeing
22 what I think is a second wave of the evolution of
23 HIV in the fact that we're seeing recombination
24 between the different strains. And that some of
25 these, actually this one, are important in the

1 evolution of HIV worldwide.\

2 Out of the 114 viruses where we have enough
3 information to complete GAG or envelope sequences so
4 far, 12 are clearly mosaic viruses, almost all of
5 which can be traced back to equatorial Africa. So
6 our model right now is that there is -- anyplace
7 where there are two viruses in a country where the
8 viruses may co-infect an individual, that it's
9 possible to give rise to recombinant viruses and
10 that these may have different epidemiologic fitness
11 for transmissibility.

12 I do want to spend a little time on a case
13 study of Southeast Asia and the E genotype viruses.

14 In 1990, I was asked by the Assistant Surgeon
15 General of the Thai military to look into a very
16 high rate of HIV positive among their recruits in
17 Northern Thailand who were donating blood. They
18 weren't doing routine testing at that time. They
19 just were blood donors. And were finding a number
20 that were positive and yet didn't have any illness
21 in that population. They were puzzled by this.

22 And this is what we knew about the sera
23 prevalences in Thailand at that time. In Bangkok,
24 show here are the different years. On this axis,
25 what was known about the intravenous blood use, sera

1 prevalences, the female sex workers and blood
2 donors, compiled by Bruce Linager from the CDC.

3 We had actually done this study expecting
4 that if anyplace in the world was going to have HIV
5 fairly early on, it might be a place where there was
6 an active sex trade, but didn't find any. And in
7 fact, we didn't find any for a long time. And the
8 first viruses that we or anybody else typed were in
9 1989 where we got four viruses from Bangkok and we
10 typed them and they were all the B genotype. And we
11 said, ho-hum, this is just like the epidemic that's
12 in North America in Europe; nothing particularly
13 unusual or interesting.

14 When this epidemic began in Northern
15 Thailand, some prevalence studies had been done
16 prior to this that had found no HIV. And then in
17 1988 or 1989 is when the epidemic started to appear
18 in drug users and exploded in 1989 in commercial sex
19 workers. And in the blood donors over here, we
20 obtained 13 isolates and found 12 of them to be
21 genotype E.

22 So we were surprised to find that in two
23 different populations in Thailand there are two
24 different variants causing two separate epidemics,
25 and we never would have expected that at all, based

1 on the -- it was in country. It didn't make a lot
2 of sense. But in fact, that is what has been borne
3 out.

4 If you look at the map of Thailand with the
5 sera prevalences -- can we focus that please? Thank
6 you.

7 At among the recruits entering into the
8 military, the Thai military began testing recruits
9 in 1991, and this was prevalence among 21-year old
10 males entering the military, that the recruit
11 prevalences were on the order of 15 to 20 percent
12 that quickly, almost all of which were E genotype
13 infections. So one out of every six of these guys
14 is HIV infected.

15 Chin Y Ou of the group with CDC did studies
16 by serologies and serologic typing of viruses by
17 transmission route, and found that of those who had
18 sexual transmission, most of them had the E
19 genotype, whereas those who had intravenous drug
20 transmission, most of them had the B genotype. And
21 this has held now for several years in Thailand that
22 there has been an association of how you got
23 infected and which virus you got infected with.

24 Now this doesn't prove causality about
25 transmission and it may just be social networks.

1 But it raises the suspicion that there may be
2 different transmissibility patterns. So it's the
3 same observations we had been seeing world wide. B,
4 the genotype, is associated with different
5 transmission patterns.

6 We can reconstruct the epidemic in
7 Southeast Asia this way now that somewhere in
8 equatorial Africa a virus with an A GAG gene and E
9 envelope were recombined; that that got transmitted
10 as a clonal event to Southeast Asia; that it has now
11 in Southeast Asia cause somewhere on the order of
12 one to three million infections over the last seven
13 years, and that despite the fact of introduction of
14 the B genotype into Southeast Asia, that has
15 actually not turned into a major epidemic in that
16 region, despite probably multiple introductions into
17 that region.

18 We do know that this virus, the E genotype
19 now, by working with other military and peacekeeping
20 forces from Uruguay, Indonesia and other countries,
21 now the E genotype is spreading actively in the
22 region as well right now and it's the predominant
23 virus in Cambodia, Malaysia, South Vietnam and is
24 moving rapidly in this region.

25 The peacekeepers that were deployed from

1 Uruguay to Canada, were known to be deployed to
2 Cambodia -- we have typed them and five out of the
3 six that we've gotten specimens of, of the 10 we
4 know were infected by or E genotype of all those who
5 were affected in Uruguayan military. To this date,
6 all of them of the B genotype typical of the region.

7 So again, confirmation that this was a
8 deployment associated infection.

9 The Navy has done, I think, a beautiful
10 study of matching incident infection to known port
11 of calls for personnel assigned to ships and asked -
12 - and we have done the typing with them. And that
13 most of the sera conversions among persons who had
14 overseas deployments have been -- where they sera
15 converted during the shipboard time have been B
16 genotypes. But three individuals have gotten E
17 virus during deployments to Pataya, port of call,
18 and one A virus to Mombassa, Kenya. This is a
19 Marine assigned to Uganda. So that there are
20 infections going on with the different genes that we
21 can prove are not U.S. acquired because of the
22 genotype of the virus.

23 One of the questions from a vaccine point
24 of view is what does this matter. Although this is
25 maybe a useful tool to track the epidemic, does it

1 matter in terms of vaccine development. So we've
2 compared our viruses that are from the B genotype
3 versus viruses from the E genotype and taken virus
4 and plasma from those individuals. And our
5 assumption has been that if you have a virus from
6 one group and have plasma against that, then you
7 should get good neutralization. Conversely, from
8 the B and B, you should get good neutralization.
9 But heterologous neutralization should be somewhat
10 lower. So we have tested that.

11 And most of these neutralizing antibodies
12 are directed against the surface envelope protein.
13 This is the GP160 molecule here. It's in the form
14 of a multimer, either a tetramer, trimer. And this
15 is the GP160 portion of it.

16 We know that the viruses are very different
17 in this region. That if you compared the gene
18 sequence of the viruses in the region of the GP160,
19 these green areas are known to be hypervariable
20 regions of HIV. And the red dots are where there's
21 a difference between the Thai virus and the North
22 American virus. And in many of these regions,
23 they're almost entirely different between the two
24 viruses. So, we expected differences in the
25 neutralization profiles.

1 So that when we do compare the
2 neutralization of the U.S. antibodies against the
3 U.S. virus we are very good. U.S. antibodies against
4 the -- or Thai antibodies against the Thai virus,
5 not very good, and conversely. So there is a sera
6 typing of viruses that can be done, not unlike
7 adeno-4 and 7 and the like, HIV's A, B, C, D, E, F,
8 and G.

9 So one of the problems that we have then is
10 that if there's an epidemic in Southeast Asia of the
11 E genotype, can we get industry to help us make a
12 vaccine that would be appropriate for testing in
13 that region? This is an article that was in the
14 Washington Post about a year ago by Don Francis and
15 Don Kennedy who identified with us this problem of
16 not being able to get industry interested in
17 anything other than a B genotype vaccine. And even
18 that, marginally interested. A private sector AIDS
19 vaccine, don't hold your breath.

20 But one of the problems that we have here
21 is that there are a number of different ways to make
22 AIDS vaccines, either through synthetic or
23 recombinant DNA sub-units or vectored like smallpox
24 vector or whole inactivated virus or live attenuated
25 virus. Remember that almost all the other viral

1 vaccines are made these ways with whole inactivated
2 or live attenuated. And then you ask -- and you can
3 either makes vaccines against the B genotype or
4 other international types. And where the activity
5 is today is all clustered up here in those products
6 that are perceived to be very safe and perceived, I
7 think it's fair to say, to be profitable. And we are
8 having a hard time getting industry partners
9 involved for the international epidemic.

10 The Kyron Biocene Company is one that has
11 entered into a partnership with us. This is meeting
12 with Thai officials and the Epi-Kyron Biocene
13 headquarters, to go into a product development for a
14 GP120 vaccine against the E genotype that we will be
15 responsible for some of the testing of Kyron for the
16 vaccine development and the Thai Ministry, the
17 approval and participation in the trial.

18 The WHO has taken the position that we
19 don't know what the correlates of immunity are with
20 HIV but in the absence of the known immune
21 correlates, based on the information that we could
22 proceed with Phase 3 efficacy trials as tests of
23 concept to obtain definitive information about the
24 ability of candidate vaccines to induce protective
25 immunity.

1 So that our approach has been a multiple
2 group working together on international vaccine
3 trials with the Thai nationals here. The vaccine
4 study population, we have at least five different
5 cohorts that we've been looking at as possible Phase
6 3 trial groups in Thailand, working with Hopkins and
7 others. Johns Hopkins has a study site in Northern
8 Thailand, the World Health Organization and the
9 vaccine manufacturers. And trying to keep this
10 group working together is no small task.

11 One of my colleagues at the NIH has pointed
12 out to me that subconsciously I drew this in the
13 shape of a pentagon. It may be true or may be not
14 be.

15 (Laughter.)

16 But nonetheless, we are working together in
17 an effort to evaluate the significance of these
18 viruses worldwide and possibly do field trial
19 testing.

20 We have begun a Phase 1 trial of the B
21 genotype in Thailand and we expect the Kyron Company
22 to be making the E genotype for a Phase I trial of
23 the E genotype, the first of its kind in Asia,
24 probably the first quarter of FY '96.

25 Thank you.

1 DR. KULLER: We have a few minutes for
2 questions.

3 DR. ASCHER: Mike Ascher. We know your
4 program in the last few years has experience some --
5 I won't say attacks but some ups and downs and
6 potential risks. Is there anything the Board could
7 do in terms of formulating a response to any
8 questions that might help you focus this program
9 against some of these issues?

10 COL. BURKE: Colonel O'Donnell made me
11 promise that I wouldn't grovel for money, and so --

12 (Laughter.)

13 -- so I won't do that.

14 COL. O'DONNELL: Go ahead and grovel.

15 (Laughter.)

16 COL. BURKE: The problem comes down to one
17 which -- it's not a question of money. The question
18 is is the international HIV epidemic a legitimate
19 concern, national security concern for the
20 Department of Defense or not. And it depends on
21 your position.

22 If you view this as simply a war fighter
23 issue, then HIV is not a war fighter issue. It is
24 not an immediate or direct threat, except through
25 blood, to the individual who's in combat. And I

1 agree with that entirely.

2 However, there are some implications of the
3 epidemic worldwide. For instance, the impact on
4 foreign militaries, where we know that in many
5 militaries of the world the prevalences are 20, 30,
6 40, 50 percent of active duty troops in Africa and
7 now in Asia. We also know the impact that that will
8 have on a number of countries around the world when
9 50 percent of the individuals who are responsible
10 for the maintenance of order in those countries, or
11 at least police activities, are HIV infected. And
12 that we also know that the UN peacekeeping forces
13 are more and more affected by the HIV epidemic.

14 So, is it a national security concern? I
15 think so.

16 Second count. Is it a national security
17 concern about the evolution of this virus? My view
18 is the epidemic is still in an unpredictable and
19 chaotic stage. New variants are coming out of
20 Africa on regular basis. The viruses are
21 recombining in Africa. That at least one of the
22 viruses is causing a major epidemic in Southeast
23 Asia, which was totally unpredicted seven years ago
24 is a recombinant virus that emerged from Africa just
25 seven years ago under our nose as we watched.

1 Now, to me, that is a concern whether or
2 not the epidemic is going to continue to have this
3 kind of unpredictability. It may not happen and
4 that would be great. But if it does happen, we'd
5 better be prepared for it.

6 DR. STEVENS: Don, you were indicating the
7 concept that some of these variants may be more
8 readily spread by one route or the other. Have you
9 done any work to look at the secondary transmission
10 from the individuals who are infected with say the E
11 clade?

12 COL. BURKE: We have not. Our primary
13 purpose in Asia has been to do vaccine development.
14 We got into this epidemiology as a byproduct of our
15 vaccine development efforts. The CDC has done some
16 very nice studies looking at the relative risk per
17 encounter of the E genotype compared to the B
18 genotype, what's known in the United States. The
19 problem is those are cross-cultural. One's in the
20 United States, the hemophiliac populations, as
21 compared to contacts where there may be other STD's
22 or there may be other local factors that are highly
23 uncontrollable.

24 But when you do that, the E genotype, the
25 risk per sexual encounter is 10 to 100 times greater

1 for the E genotype than the B genotype.

2 Max Essex has a couple of public meetings
3 now, and it's going to be reviewed in Science next
4 week, as a post-doc who's been looking at the
5 ability of E viruses versus B viruses to grow in
6 skin Langerhom cells; presumably the type of cells
7 that would be first encountered in the genital
8 tract, either female or male genital tract.

9 The E and the C genotype viruses grow much
10 more readily in the Langerhom cells than the B
11 genotype do. And conversely, in blood lymphocytes
12 that are PHA and ILT stimulated, the B genotype grow
13 more readily in those. And it was a perfect
14 correlation with P values that were infinitesimal.

15 So no one has reproduced those data to say
16 that there's a different cell trophism of the E and
17 C versus the B genotype. I think a reasonable
18 construct is that all the viruses were
19 heterosexually transmissible originally, but what
20 may have happened is the B genotype that we have in
21 the United States and Europe today and that is
22 essentially a pattern 1 virus, somehow lost that
23 trophism or at least partially lost that trophism
24 for the Langerhom cells. Whereas, all the other
25 genotypes now are still highly -- relatively highly

1 heterosexually transmissible. The B gene may be
2 better adapted to non-Langerhom cell, non-skin route
3 of transmission. That's a reasonable and testable
4 hypothesis and that's the state of the art.

5 DR. STEVENS: I was asking the question I
6 guess because of the issue of bringing that
7 particular variant of virus back to the United
8 States.

9 COL. BURKE: That's what I meant by the
10 second type of legitimate national security concern
11 is that the epidemic still is in an unpredictable
12 stage and the E epidemic has essentially outstripped
13 the B genotype in Southeast Asia by a factor of 10
14 to 20 to 1 over the course of seven years.

15 Now, that may just be chance. It may be
16 the E genotype grows better in Asians. It may be --
17 there's a million reasons why that may be true. But
18 it may also be that the E genotype is simply more
19 heterosexually transmissible than the other viruses
20 are. And there's data to suggest that that may be
21 the case and there's data to say that it may have
22 different trophisms than the B genotype.

23 Put that together and that suggests -- and
24 I have to be careful here because I don't want to
25 overstate the case. I don't want to -- you know,

1 there's so much of this mongering that has gone on
2 before in the past. But I think that it's
3 reasonable to say that we ought to be looking at
4 these issue pretty carefully and be concerned about
5 it.

6 DR. KULLER: Other questions?

7 DR. CHIN: Just to add something. I think
8 with regard to the incidence of new infections now,
9 especially in Thailand,
10 there's good data in the several years to indicate
11 that the incidence of new infections is going down.
12 So I think there is that concern about the E
13 genotype spreading throughout Southeast Asia, but
14 other than most of the countries within -- sort of
15 contiguous to Thailand, there hasn't been too many
16 outbreaks of -- large outbreaks, at least, in Asia
17 yet.

18 COL. BURKE: Yes.

19 DR. STEVENS: When military personnel are
20 deployed to some of these areas overseas, are they
21 routinely screened when they come back?

22 COL. BURKE: U.S. military or other foreign
23 militaries? The issue is a very touchy one for the
24 UN peacekeeping operations because the UN
25 peacekeepers are supposed to be healthy before

1 they're assigned overseas and some countries do
2 routinely test and then test afterwards to see what
3 the impact is on their troops. And that's how the
4 Uruguayans found this and some other countries have
5 found that the incidences have been appreciable
6 among UN peacekeepers in high prevalence areas.

7 The Rwandan -- the Belgian Army in their
8 Rwandan operation, only sent 400 people. Five of
9 them were HIV infected while they were in a six
10 month deployment in Rwanda. And there's good data
11 on that. But that was done anonymously, by the way.
12 It wasn't linked to individuals.

13 So the data is sketchy so far on that. The
14 UN will not demand that that be done on every
15 deployment because certain countries, particularly
16 Scandinavian countries, said that they'll pull out
17 of UN peacekeeping operations if that's one of the
18 requirements for deployment.

19 DR. STEVENS: How about our troops that
20 went to Haiti?

21 COL. BURKE: Not on a routine basis. The
22 assumption is that all of those people are tested
23 through periodic testing anyway and that all of them
24 are HIV negative at the time that they go.

25 Thank you.

1 DR. KULLER: Thank you very much.

2 Major Rubertone?

3 He'll talk about Army medical surveillance,
4 I believe.

5 MAJ. RUBERTONE: Good morning. My name is
6 Mark Rubertone. I'm assigned to the Army Medical
7 Surveillance Activity which is part of the Center
8 for Health Promotion and Preventive Medicine.

9 I welcome the opportunity this morning to
10 describe some of our efforts on medical surveillance
11 that we've been doing at the Medical Surveillance
12 Activity, and I promise that I'll go a lot shorter
13 than the scheduled time so that you get back on
14 schedule.

15 What I'd like to do is first describe the
16 background in terms of some of the progress and
17 timelines that we've undergone at the Surveillance
18 Activity; look at some of the system components that
19 make up the surveillance system; give a functional
20 overview of what we try to accomplish and what our
21 vision is; and finally, look at some of the current
22 on-line capabilities and data that we have in the
23 system; and lastly, just look at some future data
24 acquisitions and other things that we may be
25 involved in in the future.

1 This slide is a little busy, but
2 essentially, there's a couple of points I want to
3 make.

4 First of all, at the bottom of the slide it
5 says U.S. Army HIV Data System. The Army Medical
6 Surveillance Activity and the system in it grew out
7 of the HIV data system. That system was developed
8 back on 1985 to help track epidemiologically the HIV
9 epidemic. However, a lot of the data sources that
10 were collected for that mission, it was known that
11 they could be used for other purposes. And in fact,
12 they were used over time to do some other studies.

13 So with the new contract awarded in January
14 of '93, the wording of that contract allowed for --
15 to do epidemiology analysis for other diseases of
16 military importance. At that time, we knew that we
17 had to change the system to allow to have a really
18 integrated capability, so we underwent a pretty
19 thorough system assessment and review process back
20 at that time.

21 This, I might add, was a full year and a
22 half before the CHPPM ever stood up, although there
23 was writing on the wall in terms of what our mission
24 may be in the future.

25 After a long assessment review and design

1 phase we finally got some hardware which allowed us
2 to move off of the mainframe platform which we were
3 on into a client server environment. And finally, we
4 developed the system and that was fielded in March
5 of this year.

6 Concurrent with that process, there was
7 planning in the Army to help automate the reportable
8 disease system that was current at that time. At
9 that time, there was a hard copy reportable disease
10 form called the Med-16 form and it was hard to get
11 any kind of data, consistent data, from that system
12 to make any kind of summaries or analysis.

13 So that process went on, planning for
14 addressing the reportable disease, and then some
15 phase one and two pilot testing of the software.
16 Finally, delivery to all the PM activities in 1994.
17 Those two systems have merged along with a couple
18 of others that I'll get into to form really the
19 heart of the surveillance activity.

20 In terms of I guess a functional overview
21 of what the activity tries to accomplish, we store
22 personnel and medical event data from multiple Army
23 and DoD sources. We do so so that we have an
24 integrated, rapidly accessible system; essentially,
25 a longitudinal database of all the personnel who are

1 on active duty or reserve component.

2 We can link the personnel data to presumed
3 high risk exposure, such as deployments, or other
4 medical events, outcome events. One of our
5 deliverables are routine and special reports and
6 summaries to both the research and operational
7 community of this data and one of our services is to
8 produce tailored datasets to support either the
9 operational or research needs.

10 In terms of the functional components of
11 the surveillance system, this slide actually says
12 Army Medical Surveillance System. For that reason,
13 all of the information systems that are funded by PA
14 funding are managed at a higher level by Health
15 Affairs. We are currently the only surveillance
16 system, epidemiology based system, which is
17 considered a migration system at the Health Affairs
18 level.

19 The components of the surveillance system
20 are these four, and even though I'll talk about them
21 a little bit independently, they have been merged
22 into one comprehensive system.

23 First is the Reportable Disease
24 Surveillance System that I mentioned a couple of
25 slides ago. Second is the continuation of the US

1 Army HIV Data System to continue that mission. The
2 last two are the Deployment Medical Surveillance,
3 which really at this time is a post-deployment
4 medical surveillance capability, and the Acute
5 Respiratory Disease Surveillance system, which we're
6 also charged with.

7 The Reportable Disease System is an
8 automated notifiable disease collection system. One
9 of the main thrusts of that system was to add some
10 consistency in terms of the data coding, data entry
11 that goes on at each post on notifiable disease and
12 to have some reliable transmission, electronic
13 transmission of this data to one central location.

14 We've added other features, such as
15 updating of the reports, epi-info compatible and
16 various reports, so that the local users of the
17 system would get something out of doing all this
18 surveillance effort.

19 I think it's hard to require surveillance
20 efforts on the part of people if you don't provide
21 something back to them. And what comes out of
22 Reportable Disease System are, first off, a daily
23 report of all the reportable diseases in the Army
24 that occurred the day before. And that goes to
25 OTSG, MEDCOM, to the CHPPM and to TRADOC and

1 FORSCOM surgeons so they can actually track whatever
2 reportable disease they may be interested in.

3 Otherwise, there are weekly and monthly
4 reports that are generated by the Army Medical
5 Surveillance Activity on reportable diseases.

6 The USAHDS function or the HIV data system,
7 continues to acquire and maintain on-line all
8 relevant data for the Army HIV testing program. We
9 receive information about all the tests that are
10 done in the active duty and reserve component for
11 the Army. We establish the health care beneficiary
12 status for all of all records provided. And that
13 really is the heart of the quality assurance/quality
14 control that goes on at the activity.

15 Our data sources are often not as reliable
16 as we'd like them to be and we make sure that we try
17 to assign things correctly.

18 USAHDS functions. We report the dates and
19 results of HIV testing in the military to the
20 Reportable Disease Database, DMDC in California.
21 Also, to the personnel systems in the active duty
22 and reserve component and provide a method for the
23 medical treatment facilities to access information
24 on patients they may be seeing.

25 We also maintain the HIV registry of all

1 confirmed cases seen at Army medical treatment
2 facilities.

3 The Deployment Surveillance System, as I
4 said, it's really at this point a post-deployment
5 surveillance system capability. What we have is we
6 maintain rosters of all deployed forces, of deployed
7 forces for all major deployments, and we have the
8 last four major deployments on line. We are able to
9 match those to either individuals that did not
10 deploy or to the rest of the total Army and then
11 look at various medical outcomes that may occur.

12 I put the Army/Navy Serum Repository, which
13 I know members of the Board have heard about on
14 previous sessions here, because I think this is
15 where it has great potential, is to provide the kind
16 of epidemiologic, serum epidemiologic analyses that
17 could be important to look at linked to deployments.

18 The surveillance activity houses the link
19 to the Army-Navy Serum Repository. We have all of
20 the information that gets the serum at the
21 repository to an identity of a person. The serum
22 repository which had been managed by the Division of
23 Retrovirology at RARE has moved now to the CHPPM and
24 is managed by the surveillance activity.

25 The last is the Acute Respiratory Disease

1 Surveillance System. That collects ARD information
2 from Army basic training centers. As I believe
3 Colonel Takafuji mentioned, the ARD surveillance is
4 ongoing and we plan on continuing to do so. That
5 reports weekly on the status of ARD admissions and
6 the strep ARD surveillance index.

7 I'd now like to turn attention to the data
8 that we have on line. As you can see with the
9 active duty, reserve and national guard components,
10 there's over three million individuals that are in
11 the system currently. That dates back to 1985,
12 anyone who's been in any of those services over
13 time. The next line, the demographic data, we have
14 over 33 million -- 34 million snapshots, if you
15 will, of demographic data on these individuals.

16 So at each tape that we receive from DMDC,
17 we store it on line. We maintain a history of any
18 changes that occur to changeable variables; marital
19 status, duty location, primary duty MOS, et cetera.

20 So it's quite a tremendous resource in terms of
21 doing longitudinal studies.

22 There are over eight million serum samples
23 which are linked to these individuals over time. A
24 number of people are tested more than once and their
25 serum are in the bank. The current testing policies

1 in the active duty Army is every two years. In the
2 reserve component it's changed to every five years
3 concurrent with the physical examination.

4 We also keep track of the Medical Entrance
5 Processing Stations individuals. This number, 4.3
6 million, is not mutually exclusive of this number,
7 since a lot of these people end up going there, but
8 we do have records on 4.3 million individuals who
9 have gone through MEPS in the last 10 years. And we
10 also have a link to their serum sample.

11 The serum repository is an Army-Navy serum
12 repository. However, we're fortunate enough to have
13 any Air Force person that went through the MEPS
14 station as part of the MEPS. We have their serum as
15 well, which would give us a baseline serum on most
16 of the military population.

17 In terms of the HIV registry, we have over
18 16,000 clinical evaluations which we have on the
19 5,680 individuals who are HIV infected and have been
20 seen at Army medical treatment facilities.

21 In terms of medical events, our two major
22 databases are the in-patient database for active
23 duty Army and the reportable disease database. We
24 have from 1989 to 1995 on line and linked to
25 individuals in our database. That's 741,000

1 admissions. And we've been able to report out both
2 hospitalization rates and non-effective rates for
3 various diseases in various reports.

4 The reportable disease database has been on
5 line since 1994 and we have 10,960 reports through
6 that system. Over 60 percent of those reports are
7 sexually transmitted diseases. We have at least 13
8 or 14 sites which are sort of functioning as
9 sentinel sites throughout the Army who are very
10 consistent in their STD reporting. I think that
11 will be a wealth of information over time.

12 In the Army-Navy Serum Repository there is
13 currently over 17 million bank serum; about eight
14 million from the active duty and reserve component,
15 another 4.3 million as you saw from MEPS. And the
16 remainder would be Navy serum.

17 Just quickly looking at future data
18 sources, these are data sources which we made more
19 than just a first contact with. We've had some
20 experience. We've seen where the problems may be in
21 terms of trying to get access to the data.

22 Disability data from USAPDA. that should
23 be a fairly simply one to tap into and we've made
24 the contacts and should be getting the data quite
25 soon.

1 The Health Risk Appraisals is being
2 analyzed by a number of individuals at the CHPPM and
3 that would certainly add risk determinant
4 information data into our database and we should get
5 that on line.

6 Mortality data from the casualty office
7 would be a little bit more complicated since they
8 don't have a truly automated system of collecting
9 mortality information right now. A lot of it is
10 just card coded and that would take some time to
11 actually get that on line.

12 The ODS exposure data, as Jack Heller spoke
13 to the Board yesterday about, we're not actually
14 involved but there is always talk about whether the
15 data that he has on the geographic information
16 systems and the exposure data would be linked to the
17 personnel data and especially to the medical outcome
18 data that we keep on line.

19 Finally, in summary of the products and
20 services of the surveillance activity, where we
21 really see the heart of what we do is to provide
22 analysis and summaries of the data to the
23 operational and research community. We have a
24 capability of providing information for policymakers
25 and company commanders, whatever, on an

1 unprecedented level, being able to produce tailored
2 datasets either to individuals that want to analyze
3 the data themselves or to provide summaries.

4 We provide the link to the Army-Navy Serum
5 Repository currently and we produce routine and
6 special reports on various diseases or conditions of
7 military importance. What's become a bit of our
8 calling card -- and I've handed out at least to the
9 Board members a couple of issues of the Medical
10 Surveillance Monthly Report. That, we're trying to
11 essentially mimic the morbidity/mortality weekly
12 report that the CDC puts out, a way to capture
13 surveillance information, get it back out to the
14 people who need to know or are contributing to
15 providing that information to us.

16 And the two issues that I handed out, the
17 April issue is our first issue and contains a
18 summary of reportable diseases and hospitalization
19 data from 1994, and August has -- we operate from
20 Ft. Jackson -- Coxsackie-21 virus, which I thought
21 might be of interest.

22 That's all I have. I can answer any
23 questions.

24 DR. KULLER: Can I ask you a question?

25 MAJ. RUBERTONE: Yes.

1 DR. KULLER: This really relates to your
2 follow-up. Can you link your -- are you going to be
3 able to link your system with let's say the DA in
4 the future in terms of -- I mean, I can see the
5 serum repository especially being a substantial
6 value, but all this other data that's been
7 collected. What's the average length of time in the
8 military currently for active duty personnel? I
9 mean, you might say the median because I'm sure the
10 average would be kind of screwed up; right?

11 MAJ. RUBERTONE: Yes.

12 DR. KULLER: The distribution.

13 MAJ. RUBERTONE: At this time, the only
14 efforts we've made at looking at linking to other
15 services has been through the Defense Women Health
16 Research Program, as Colonel Jones alluded to
17 before. And we are working to get the other
18 services, namely, Air Force and the Navy up to speed
19 to that there's compliant and compatible systems
20 that we can network together and truly have a tri-
21 service relational database.

22 The VA, we've not made any attempt to link
23 into their system, but I think the way our system is
24 constructed, as long as they're compliant in terms
25 of certain software features, it wouldn't be

1 difficult to link into that.

2 We have had some experience with VA data
3 through the medical follow-up agency but
4 specifically looking at HIV follow-up.

5 Does that answer your question?

6 DR. KULLER: What's the -- I mean, you have
7 this huge serum bank which I'm sure is not
8 inexpensive to maintain and fairly complex, I'm
9 certain. Is there -- can you essentially link this
10 to both the military's -- both your own, with people
11 still in the military? But my concern primarily I
12 guess is that when they leave the military and when
13 you can hook this up with something like the VA
14 system or some other sera program or something like
15 that.

16 MAJ. RUBERTONE: Sure. We certainly have
17 the capability since we have a link to each of the
18 serum specimens through identifier information,
19 Social Security number, name, date of birth. We
20 could provide anyone who needed to tap into that
21 resource and have the right information, serum
22 specimens. And in fact, there's been a great deal
23 of talk about opening up the serum repository to
24 other outside agencies, if you will.

25 So the capability is there. We're not

1 actually involved with trying to make a
2 collaborative link to the VA. They haven't really
3 approached us. But the capability is there.

4 DR. ASCHER: Mike Ascher. One of the
5 concerns that we had in terms of our ongoing
6 discussions of the Gulf War illness issue is the VA
7 has become a major player and they don't connect
8 very well on the data side. And I think it would be
9 very important for the elements you have of data,
10 such as the deployment status and particularly the
11 environmental stuff we saw yesterday, to be in their
12 system.

13 I don't know what the motivating factors
14 would be to make that happen.

15 DR. STEVENS: Money.

16 VOICE: Politics.

17 DR. ASCHER: Yes. But it also becomes an
18 issue of what is the purpose of the linking. And as
19 I said yesterday, it's to determine the true
20 deployment status of the veterans that have come
21 forward. That has the downside of saying are you
22 going to request or require that the Gulf War
23 illness require deployment overseas. And we've all
24 heard in the past that that may not be the whole
25 story.

1 So it's going to be come an important
2 variable in the outcome measures of that study. And
3 if they don't get it, it's going to be suspect very
4 heavily.

5 So I don't know how to make the link other
6 than we could contribute some money, I guess. Is
7 that what you're saying? Maybe we could emphasize
8 that when we have discussions with the commission
9 that that link is going to be key to understanding
10 the nature of the problem.

11 DR. KULLER: Any other?

12 (No response.)

13 Thank you very much. That's very nice.

14 Dr. Smith?

15 DR. SMITH: We were asked to come and
16 summarize our observations that we made recently in
17 Colombia. We were down there to help them manage
18 their outbreak of Venezuelan equine
19 encephalomyelitis.

20 Beginning in the first week of September,
21 an explosive outbreak of Venezuelan equine
22 encephalomyelitis, or VEE, occurred on the
23 Venezuelan side of La Guajira Peninsula and over the
24 next two weeks resulted in over 10,000 human cases.

25 Despite a rather prompt and vigorous

1 response by the Venezuelan health authorities in
2 both vector control and equine vaccination, this
3 epizootic spread to the Colombian side of La Guajira
4 Peninsula and infected an additional 13,000
5 individuals.

6 Dr. Ludwig and myself had been asked
7 previously by the Pan American Health Organization
8 to go to Colombia to train the people in the
9 laboratory there on ITG and IGM assays and also to
10 facilitate the vaccination of their laboratory and
11 field workers.

12 This was under the auspices of the PAHO,
13 and they expedited our trip in response to the
14 outbreak.

15 We've just returned on Tuesday and were
16 asked to give you this update. We've not really had
17 time to analyze our data or prepare many slides, but
18 we can certainly give you an overview and a summary
19 which we believe to be accurate in most respects.

20 My plan is to follow an outline which I'll
21 just describe, I think, as opposed to using the
22 overhead. I will try to give a little background
23 into Venezuelan equine encephalitis, what it was
24 that USARMED was prepared to respond, a summary of
25 the outbreak in Venezuela and Colombia, a summary of

1 what we were able to do in their laboratories, and
2 then finally a value for USAMRED's own programs.
3 And then Dr. Ludwig, who was in the endemic zone,
4 will give a description of what he saw and did
5 there.

6 The alpha viruses are a genus within the
7 togavirus family. There's about 28 different alpha
8 viruses that are known. Ten of these are pathogenic
9 for humans. They're all mosquito borne, different
10 vectors. They're maintained in nature by mosquito
11 vertebrate cycles with relatively simple viruses,
12 cytolytic replication.

13 In terms of the diseases caused by these
14 viruses, the 10 different viruses that are
15 pathogenic for humans essentially cause three
16 different types of syndromes. Most of them cause
17 predominantly polyarthrititis. Venezuelan equine
18 encephalitis is largely a systemic febrile illness
19 very similar in adults to dengue, except in
20 children, where there's a relatively high incidents
21 of encephalitis. And then the final two viruses are
22 Eastern and Western, which are predominantly
23 encephalitic syndromes.

24 The Venezuelan is actually a complex of
25 viruses consisting of a number of basically six

1 major subtypes and several serologic variance within
2 some of these subtypes. The first, the 1A, B and C,
3 are so-called epizootics, epizootic viruses. These
4 are capable of establishing far ranging epizootics
5 mostly because of their virulence in equines and
6 their ability to cause high baremia in equines.

7 The remaining viruses are so-called
8 enzootic, which, as I'll show you, are maintained
9 mostly in rodent vector cycles.

10 This is a picture of an enzootic cycle in
11 which the virus is maintained between rodents and
12 mosquitos, generally of the Melanoconian species.
13 And in order for man to be infected, he pretty much
14 has to intrude into these enzootic foci. That's not
15 true from the epizootic subtypes in which there are
16 many mosquitos that are capable of maintaining these
17 epizootics and man becomes infected by the same
18 mosquitos that are vectoring the virus between the
19 horses.

20 So this is a map showing the overall range
21 of Venezuelan. There's enzootic virus in Florida.
22 There are enzootic viruses in Brazil and Peru and
23 Colombia and up on the Pacific and the Atlantic side
24 of Central America. And the viruses that we're
25 going to be talking about today are classic viruses.

1 Actually, I think this slide was made in the '70s.

2

3 This is a 1C subtype showing the
4 distribution along the northern coast of Venezuela
5 and also Colombia. It's now known that this subtype
6 actually extends well down into Colombia. And in
7 fact, is the cause of the current problem there now.

8 There have been Venezuelan equine
9 encephalitis epizootics, the first one described in
10 Colombia in 1935. There have been many through the
11 '30s, '40s, '50s and '60s. In 1969 and 1970 to '71,
12 there was a major epizootic that probably was
13 introduced into Central America from Peru or Ecuador
14 and then extended north through Central America
15 despite vaccination barriers and then through
16 Mexico, despite vaccination barriers, and in 1971
17 arrived in Texas.

18 This was the last major epizootic that had
19 been reported prior to the one which I'll describe
20 in a moment.

21 If we look classically now at the
22 epidemiological features of Venezuelan epizootics,
23 the morbidity in horses is about 40 to 50 percent.
24 Inapparent to apparent infection, about two to one.
25 Mortality is about 20 to 40 percent. That's

1 essentially what was observed here. The case
2 fatality is 50 to 80 percent.

3 In humans, the morbidity is about 10 to 40
4 percent, although there were some villages in the
5 area that we'll describe today that had over 60
6 percent incidence. The inapparent to apparent
7 infection is one to one. Neurologic illnesses is
8 mostly seen in children. Case fatality is very rare
9 except in the neurologic cases where it's about 20
10 percent.

11 In terms of clinical features, incubation
12 period is one to four days. Acute onset with high
13 fever, severe headache, nausea and vomiting in some
14 of the cases.

15 This is actually wrong. It should say four
16 percent of infected children developed CNS
17 infections. Acute phase last one to three days.
18 Some people would say up to six days. There's a
19 prolonged period of convalescence, two to three
20 weeks. Mortality rate less than one percent.

21 This is a description really of the 1971
22 epizootic, which I indicated went up through Mexico
23 and into Texas. That epizootic reached Texas in
24 June of 1971, resulted in a national emergency being
25 declared. Ninety-five percent of all the horses in

1 the 20 most southern states were vaccinated, over
2 three million horses. The Air Force was involved in
3 terms of ultra low volume vector control. Total
4 eradication cost in 1970 dollars of \$20 million.

5 Just one point about why USAMRED was
6 requested by PAHO to participate and why we were
7 prepared to respond.

8 VEE is considered to be both a biological
9 defense as well as an ID threat. Has a high
10 priority within our rapid diagnostics program. And
11 we also have an extensive vaccine development
12 program for Venezuelan Eastern as well as Western.
13 We hope to have a new vaccine -- actually in CGMP
14 production at the beginning of next year, but it
15 will of course not be ready to help with the current
16 epizootic.

17 Okay. So as to the epizootic that's
18 occurring now, the initial observations by the
19 Venezuelans in the state of Falcon and Zulia east of
20 Lake Maricaibo, was that there were small brush fire
21 epizootics or cases of horses and humans, and then
22 in the last days of August there were dead equines
23 reported north and west of Maricaibo.

24 Over the next seven days, there was a major
25 epidemic in the people, resulting in this kind of an

1 observation. These are four hospitals that are
2 reporting acute febrile disease by day. This is the
3 beginning of September, about here. These are the
4 number of patients that are coming to their
5 hospitals per day, so you can see that right at the
6 beginning of September there were, in this case, 250
7 patients a day that were coming into these
8 hospitals.

9 These four hospitals are separated by about
10 50 miles and so this epizootic blew up along that
11 entire side of the La Guijara Peninsula in
12 Venezuela. The disease was similar to dengue in
13 adults but caused encephalitis and convulsions in
14 some children. There were at least 10,000 cases
15 reported. That's almost assuredly underreported and
16 it's continuing to date but at a lesser rate because
17 of vaccination responses.

18 Much of the human population in here are
19 actually indigenous Indians which have permission to
20 move back and forth across the border. They bring
21 their equines with them. And because also heavy
22 rains were in this Peninsula, promoting high vector
23 populations, the epizootic spread over onto the
24 Colombian side of the Peninsula where it has caused
25 at least 13,000 human infections.

1 This is in September of 1995, last month,
2 in two hospitals in Manalre and in Riohacha. These
3 are the number of cases plotted by the date, day of
4 initiation. And I think you can see that this is
5 500 cases that were reporting to this hospital that
6 has a total of 13 beds.

7 The response in Colombia was not quite as
8 rapid as that in Venezuela. The local government
9 blamed the federal government and vice versa. This
10 headline says that the epidemic arrived but the
11 state didn't. But eventually they did release a lot
12 of money, as well as resources, to try to confront
13 this.

14 But still it was confused because they knew
15 they had dengue in the area at the same time. They
16 had no means to discriminate the two, at least in
17 acute cases.

18 This is a magazine article from the
19 equivalent of Newsweek that says, "Is it
20 encephalitis or not." This is a child infected in
21 Manalre that says here, that it's infected with an
22 unknown disease. However, there was little question
23 that this was Venezuelan. The Venezuelan
24 authorities had made a number of isolations and it
25 was clear that it was the same epizootic.

1 We arrived in Colombia on the 28th of
2 September and our first assays were able to show
3 very high levels of specific IGM in both human and
4 horse samples. The vaccination of equines and
5 mosquito control efforts were underway by the third
6 week of September and Dr. Ludwig will describe these
7 efforts.

8 In the 1960s, the Magdalena River Valley,
9 which is just south of this peninsula, supported an
10 epidemic causing between 250,000 and 500,000 human
11 infections. And the assumption is that the same
12 thing would happen now if it escapes out of that
13 peninsula and gets into the Magdalena River Valley.
14 That type, an epidemic of that magnitude, would be
15 expected to result in up to two to three thousand
16 deaths in children.

17 So the objectives of the USAMRED team in
18 Bogota were to set up a laboratory in the
19 agricultural research laboratory, known as ECA, and
20 to transfer the technology for IGG and IGM capture
21 assays for both human and horse; to facilitate use
22 of our IND vaccines to protect the laboratory and
23 field workers; to monitor the spread of the epidemic
24 among the human and equine populations; and to run
25 diagnostics on fire drills for possible breakout

1 events to determine whether there should be circle
2 vaccination monitored around human or horse
3 infections; and also to provide advice on bio
4 containment.

5 The IGM assay developed by USAMRED's
6 Diagnostic Systems Division proved to be especially
7 valuable in rapidly diagnosing acute febrile disease
8 in humans at an early stage of disease and in
9 differentiating current from previous infections or
10 vaccinations in horses. The HI assay,
11 hemagglutination inhibition assay that had been
12 previously run in the agricultural laboratories was
13 unable to provide this discrimination.

14 So if we look, for example, this is a --
15 okay. These are IGM assays. I can't read whether
16 this is human or horse but they're pretty much the
17 same. These are screening assays run at one to 100.

18 This is an IGM capture assay. These are run
19 against a positive antigen, a duplicate and a
20 negative antigen in duplicate, so I think just by
21 putting the plates on the floor and taking the
22 picture, I think you can easily see which are IGM
23 positive and which are IGM negative.

24 And this is again -- I guess this says
25 human, so the previous one was horse. These are

1 some of the samples actually that Dr. Ludwig brought
2 back. These are children in the hospital and it's
3 pretty clear that they're problem is Venezuelan.

4 These assays were critical in assessing
5 sick horses outside of the vaccination barrier.
6 There was, for example, one situation where 100 --
7 there was a ranch with 150 horses. Fifty of the
8 horses died within a few days. They were reasonably
9 certain that it was Venezuelan. This is in an area
10 several hundred miles south of where the epidemic
11 had been occurring. We initially had run IGG assays
12 on those horses. They were all positive. However,
13 the IGM turned out to be absolutely negative. It
14 turned out later that the horses were vaccinated in
15 previous years, explaining the IGG, but the IGM was
16 negative. So there was no indication of the current
17 problem.

18 Actually, the horses were probably dying of
19 parasitic infections but this was important from the
20 standpoint of epidemic control because it meant that
21 the Colombian authorities could use their vaccine to
22 widen their vaccination barrier in the peninsula as
23 opposed to running down and trying to vaccinate
24 around this problem.

25 So, I think we were useful for the Colombia

1 government. I think we also gained some things for
2 our own problems. We had very good results with our
3 tests that we had developed for diagnosis. We've
4 obtained positive sera for control and validation of
5 our assays. We've established personal contacts and
6 we've had discussions with officials for future
7 vaccine trials with our new live attenuated
8 candidate, which will be necessary for licensure.

9 I'd like to ask Dr. Ludwig now to come and
10 just tell you a little bit about what was in the
11 epidemic zone.

12 DR. LUDWIG: As Dr. Smith mentioned, when
13 we arrived we did all our work in Bogota, which is
14 the capital. It became clear very quickly that we
15 did not have enough samples to adequately conduct
16 the training course.

17 In addition, we didn't have a clear
18 understanding as to what was actually happening in
19 the epidemic zone and there was a large desire on
20 local officials that we get up there and actually
21 see what was going on, collect samples, bring them
22 back to the laboratory for further testing. And in
23 fact, it proved to be a very fortuitous event.

24 As Dr. Smith mentioned, the epizootic
25 epidemic zone is the La Guajira Peninsula at the

1 northern part of Colombia. I traveled to Riohacha
2 which is city here in the epidemic zone. In my
3 travels, we moved south and east to a city called
4 Maico. We covered hospitals in both Riohacha and
5 Maico, collecting samples from humans.

6 In the southern area we also looked at
7 samples in horses and also traveled to a city called
8 Santa Marta, which is outside the epidemic zone,
9 following down some possible leads of sick horses in
10 that area.

11 Upon arrival, it became very clear that
12 there were in fact getting very heavy rainfalls.
13 This is outside the ECA laboratory in Riohacha.
14 Standing water. But this was not unusual. Standing
15 water was found everywhere. The rains were frequent
16 and heavy. The rainy season is actually this time
17 of the year. However, the rainy season in the La
18 Guajira Peninsula started much earlier and the
19 rainfall was much heavier.

20 The standing water never left the area, and
21 in fact we saw it all over the peninsula. So vector
22 populations were very high as a result of this.

23 This is the ECA laboratory, a very nice
24 facility. Underutilized because of lack of funds,
25 but we were able to process all our serum samples

1 here.

2 The hospital in Riohacha is a typical
3 developing country urban hospital, relatively small,
4 20 to 30 beds. The waiting room was actually
5 outside and most of the indigenous people coming to
6 this hospital are in fact Indians from the area.

7 Traveling outside of the city, it wasn't
8 more than about five miles before we came across our
9 first dead animal. This is a burro. It has died
10 within the last 24 hours of pretty classical
11 Venezuelan. You can see the foot scrapings and the
12 head movement which is also typical of this disease
13 in encephalitic horses just prior to death. A lot
14 of leg flailing and head flailing which is typical
15 of encephalitis in these animals.

16 And on several farms in the southern
17 regions that I mentioned before, we found sick and
18 dying animals. This animal exhibited extreme
19 uncoordination in walking and difficulty in
20 remaining standing. As you can see here, it's just
21 recently fallen over after being lassoed by its
22 owner.

23 We collected blood samples from this and
24 other animals that were in a similar state. This
25 animal was probably within about 24 hours of dying

1 itself.

2 This is difficult to read. I'm just
3 putting it here for a point. We stopped at several
4 clinics in the area. Signs are on the door saying
5 that there's equine encephalitis around. The local
6 name for it is called peste loco, which means crazy
7 pest, because this is the syndrome that the horses
8 exhibit. The sign basically says what to do if you
9 see sick horses; call local veterinarians, what the
10 symptoms are in humans so that they can come in and
11 get treatment.

12 So this is something the local people are
13 very aware of and are handling very nicely.

14 As Dr. Smith mentioned, the main control
15 measures for Venezuelan equine encephalitis virus is
16 vaccination in equines and vector control. And this
17 shows a vaccination station where people would bring
18 their animals for free vaccinations.

19 The vaccination effort in La Guajira at the
20 time we were there included about 20 to 30 animals.

21 Only about 20 percent of the total number of
22 animals in that area, but much higher concentrations
23 in the areas where they're focusing their
24 vaccination efforts. And I'll show a little bit
25 more detail on that here where that is actually

1 occurring.

2 This again is a map of La Guajira and you
3 can see here that there's a very large mountain
4 called Sierra Nevada right here at the southern base
5 of the La Guajira. This mountain rises from
6 essentially zero elevation to 5,000 meters, greater
7 than 5,000 meters, in a very short period. It's a
8 very impressive mountain. Snow-capped and often
9 cloud covered. Forms a very nice natural barrier.

10 The vectors for Venezuelan equine
11 encephalitis virus don't occur above 1400 meters.

12 In addition, there's a mountain range that
13 runs north-south along the Venezuelan-Colombian
14 border. This also forms a very nice natural barrier
15 to infection. The height is not nearly as high but
16 certainly goes higher than 1400 meters.

17 The vaccination efforts, the major
18 vaccination efforts include the area along the coast
19 north of the Sierra Nevada range. Very heavy
20 vaccination in this area, in the valley between the
21 Sierra Nevada and the mountain range running north-
22 south along the border. In addition, they're
23 working very heavily in the area just north of the
24 Sierra Nevada range.

25 As the vaccination program continues,

1 they're working up into the epidemic zone. When I
2 was there, they were beginning their vaccination in
3 this effort. This again is Riohacha here. Maico
4 was right over here. So they're working very
5 strongly vaccination efforts in these areas.

6 As Dr. Smith mentioned before, dengue is
7 also present. They have very high vector numbers of
8 aedes egypti, as well as the vectors of Venezuelan,
9 aedes tenurincus, aedes sollicitans, several
10 sorophorous species, very common vectors for VEE.

11 The vector control efforts are mainly
12 focused on the urban areas, although they are doing
13 ULV fogging via trucks and backpack mounted units in
14 this area. The cover is very heavy. It's been very
15 wet. The low ground cover is very heavy. Aerial
16 spraying in my opinion would not be very effective,
17 so the ULV spraying is going to be essential for
18 control.

19 The number of roads and their quality is
20 fairly poor, so most of it is going to have to be
21 done by backpack units. And they are in fact
22 working at this.

23 The current epidemic has declined in recent
24 weeks and in direct proportion, direct correlation
25 to the number of vaccinations and the amount of

1 vector control activities that have been going on.

2 And I think that's all that I have.

3 I think both Dr. Smith and myself will be
4 glad to answer any questions that anyone might have.

5 DR. ASCHER: Thank you for that excellent
6 presentation.

7 Are there any questions or comments from
8 the Board or the audience?

9 I'd just like to comment a little bit from
10 the USAMRED perspective. This is an example of
11 capability that survived the reorganization and
12 there was much more that did not. And it is an
13 example of what this institute can do. And I think
14 the Board's aware of the vulnerability of these
15 programs. And you're to be congratulated. Keep up
16 the good work. But I know it is hard.

17 DR. LUDWIG: Thank you.

18 DR. ASCHER: And it's a remarkable tribute
19 to the program to be able to do this sort of thing.
20 I know the government surely appreciates it as
21 well.

22 DR. LUDWIG: One point I would like to
23 make. For this operation, USAMRED took the lead
24 role. However, this week, beginning Wednesday, a
25 CDC team from Fort Collins will be arriving in La

1 Guajira to take on some additional epidemiologic
2 studies. So the point being that these sorts of
3 operations now utilize resources from a variety of
4 areas and we have worked well and often with CDC,
5 particularly the recent eboli outbreak in Zaire we
6 worked together with CDC and other world
7 organizations.

8 So these type of epidemics now are more
9 difficult to handle with any one organization but
10 utilize a variety of resources. So we can't take
11 all the credit.

12 DR. ASCHER: Great.

13 DR. PERROTTA: Do you ever see in the
14 history of the EE that you're familiar with, human
15 epidemics in the absence of the equine epizootics or
16 do they always go hand in hand?

17 DR. LUDWIG: I think I can see where your
18 question is leading. Human transmission. In the
19 history of epidemics there have not been any
20 association of epidemics without equine cases. One
21 of the questions that CDC is going to look at is the
22 possibility of human transmission or mosquito-human-
23 mosquito transmission, both of which are
24 possibilities. The virus can be isolated from
25 throat swabs, from vaccinees of TC83. And in some

1 studies it's been shown that human develop biremias
2 of sufficient titer to infect vectors.

3 So, it's a possibility. I would be willing
4 to guess and go out on a limb that it probably does
5 occur but I'm a little reluctant to say that it's an
6 important mechanism for maintenance of the
7 epizootics.

8 DR. PERROTTA: I was actually looking at
9 the human-mosquito-human, the second issue.

10 DR. LUDWIG: Right.

11 DR. PERROTTA: Especially in an area where
12 you have a huge number of human cases. We don't
13 need the horses there if we've got the people
14 carrying the virus.

15 DR. LUDWIG: Right. Undoubtedly it
16 probably occurs. I just don't know what the
17 relative importance is. And based on the
18 observation that vaccination of horses and vector
19 control -- difficult to separate the two, but
20 probably the horses are playing a major role, at
21 least in this epidemic.

22 DR. ASCHER: We have the opposite problem,
23 as you know, in California. We do intensive
24 surveillance for these viruses and have an ongoing
25 experience of three years of widespread western

1 virus in the environment with a heavily vaccinated
2 horse population. In fact, the only horse that's
3 not vaccinated in an area will get sick and die, but
4 it's about once a year. And no human cases, in
5 spite of intensive surveillance of hundreds of
6 suspects.

7 So, we don't know what's happened there.
8 Whether the horse out of the equation has modified
9 the whole system and whether the mosquito ecology
10 has jumped along as well. So, we need some help
11 with that one. We may be able to get some viruses
12 to you, I hope at some point.

13 DR. LUDWIG: Wonderful.

14 DR. ASCHER: The viruses on first pass, do
15 not appear to be attenuated in any way.

16 Okay. I have a couple of -- thank you very
17 much.

18 DR. LUDWIG: Sure. Thank you.

19 DR. ASCHER: A couple of logistic items and
20 then -- Frank, did you have anything you wanted to
21 say?

22 We had three sort of informational
23 items/questions yesterday and Dr. Kuller wanted me
24 to indicate that he will be preparing a response to
25 the sickle cell issue. There will be something

1 written up and circulated to the Board for comment.

2 At the present, we are not going to write
3 anything formally back on the primaquine issue. I
4 think the comments to the people presented from the
5 group were clear that it is something that has
6 potential for a targeted limited use that could be
7 effective, but its widespread use is doubtful and
8 therefore it will have to sort of compete among
9 priorities. And it's something that will have to be
10 worked out.

11 If groups would like further discussion of
12 that in the way of formulating a real formal
13 question, we might be able to elaborate on that, but
14 I think that was the sense -- at least one persons's
15 sense of the group discussion.

16 On the salmonella issue, the information we
17 considered good information for the purpose of
18 modeling and certainly for other vaccines as well,
19 but did not necessarily feel that we had to review
20 anything about the salmonella policy at this point.

21 Correct me, if I'm wrong.

22 The last thing, I'd like to congratulate
23 the injury control program for their efforts and the
24 product. Dr. Joseph's discussion yesterday is
25 clearly that these kind of things are going to be

1 what will move the Board forward and it's a nice
2 job.

3 And I'd also like to thank the Institution,
4 General Adams and others, for the hospitality. It's
5 gone very smoothly.

6 B.G. ADAMS: You're welcome back any time.

7 DR. ASCHER: We appreciate the visit.

8 Anybody else want to add anything? Any
9 comments?

10 The Officer's Club is open for lunch. Is
11 that right still?

12 DR. BAGBY: Tom Bagby. I don't suppose we
13 can come to any resolution yet on the date for the
14 Spring meeting because of the new members coming on
15 board. Is that the problem? It's needed as soon as
16 possible because I'm holding those dates open for
17 two different meetings.

18 COL. O'DONNELL: Actually, as I mentioned
19 yesterday, we had polled the membership and my plan
20 is basically to get with the membership next week,
21 obviously at a distance, but just sort of propose
22 some dates based upon your input you've already
23 submitted. Propose some dates and see how that
24 works out and do that next week because I know the
25 Board had wanted to get that over as soon as

1 possible and settle that. So I think next week --
2 you'll hear from us next week.

3 DR. ASCHER: For the audience, you may or
4 may not know that six individuals are rotating off
5 or will be replaced in the next cycle and the
6 nominations are coming in.

7 And Dr. Joseph's intention I believe at the
8 next meeting was to have a briefing for them,
9 probably prior to the meeting in the form of a
10 meeting retreat to sort of bring that group, the new
11 Executive Secretary and Dr. Joseph all onto the same
12 page. And I think that's a very good suggestion.

13 The last thing I had was that --I'll pass
14 this on to Jean. This will be on the written record
15 as well, that I think all the Board members would
16 like to see this routinely be added to the mailing
17 list through the office, and that would be very
18 nice. It's an interesting document and
19 congratulation on that as well.

20 And I'll hit this one time and we're all
21 done.

22 (Whereupon, the proceedings were concluded
23 at 11:50 a.m.)

24
25

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