UNITED STATES OF AMERICA

DEPARTMENT OF DEFENSE

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ARMED FORCES EPIDEMIOLOGICAL BOARD

PUBLIC MEETING

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FRIDAY

MARCH 1, 1996

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WASHINGTON, D.C.

The Board met at the Walter Reed Army Institute of Research, 14th & Dahlia Streets, N.W., Building 4D, Room 3092, at 8:00 a.m., Dr. Lewis H. Kuller, Chairman, presiding.

MEMBERS PRESENT:

Dr. Lewis H. Kuller
Dr. Michael S. Ascher
Dr. Claire V. Broome
Dr. Gregory A. Poland
Dr. Dennis Perotta
Dr. John R. Bagby
Dr. Russell V. Luepker
Dr. Gerald F. Fletcher
Dr. James Chin
Dr. James R. Allen
Dr. Martin Wolfe

STAFF PRESENT:

Colonel Vicky Fogelman, Executive Secretary

BOARD CONSULTANTS PRESENT:

Commander Trueman Sharp
Colonel Frank O'Donnell
Lieutenant Colonel Michael Parkinson
Captain David Trump
Commander David Arday
Colonel Robert Leitch

ALSO PRESENT:

Rear Admiral Web Young
Read Admiral Noel K. Dysart
Colonel Bruce Jones
Lieutenant Commander Rick Schaffer
Dr. Ann Nelson
Andrea Lunsford
Captain Bill Berg
Dr. John F. Mazzuchi

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

8:12 a.m.

COLONEL FOGELMAN: I have a few administrative announcements before we get started here. First of all, I know that some of you have made donations for coffee and donuts that were so nicely provided for us the last two days. For those of you that haven't, we would appreciate a donation. Probably a couple of dollars would be acceptable, and this is on the honor system so we won't stand by the box.

Also, for those that have questions from the audience or comments, if you would please stand and either come up to the microphone here or come and speak into one of the table mics so that the recorder can pick up your questions. We've been missing a few of the questions and comments because of soft speak, and we try to transcribe everything so please do that.

I'd also like to welcome Rear Admiral Web Young, Jr., who's the Senior Advisor of the Office of Emergency Preparedness for the U.S. Public Health Service.

REAR ADMIRAL YOUNG: Filling in for Admiral Frank Young who couldn't be here who is

at the Appropriations Committee and is unable to be here.

DOCTOR KULLER: We're going to start out this morning with the report from Colonel Leitch who'll give us the British liaison report.

COLONEL LEITCH: Boreda. That is actually Welsh for good morning. Probably you're not -- there's no reason why you should be aware, but this is actually St. David's Day, the 1st of March. St. David is the patron saint of Wales, and I am Welsh, which is a bit like being a West Virginian. I was, in fact, a very serious West Virginian. I was actually born in a place called Blini Fastillia, which has Lord knows how many Ls and Lord knows how many Fs with no vowels in between. If any of you have seen that appalling film called the First Knight with Richard Gere and Sean Connery, which has something to do with, I think, King Arthur, well, it was actually made in the town in which I was born or at least the hole in the mountain where I was born. I was amazed. It hasn't changed in 40 years.

That's the main reason why I'm wearing this spectacular sweater today. Somebody said, Where on earth did you get it from? Donna

Karan's and the military. The truth is, we're issued with these. I think every now and again we have hankerings back to the days when we all wore red coats, and we have different colored ones depending on which arm of the service you're in. The most spectacular of all, I think, combination because you're probably aware that the British army also wears all kinds of different clothing. The most spectacular combination of all is to be a medical officer wearing this sweater with the Royal Hussars because the Royal Hussars are called the cherry pickers because they hid in a cherry orchard during the battle of Waterloo because they were frightened to fight the French, and Wellington was so irritated at this cavalry regiment that he made them wear red trousers, and they are the most spectacular cherry colored trousers. For ages they had to walk round with these things. It was a sort of badge of disgrace. But after some of the battle, I think in the Crimean War, another foolish war -- you know, they threw themselves at the Russian guns -- they then had a position of honor in the army and so they wore these cherry trousers and they wear them even now

as a matter of honor. Well, you can imagine being the medical officer of the Royal Hussars because you're permanently in pink and it behooves you not to walk down the street with your hand like this.

Anyway, I thought I would open by speaking to you about Wales this morning, and now it's gone.

This is my swan song. This is probably going to be the last time I shall come, although I may bring my successor. The truth to tell, that you've got to me. I said when I first came here, my last job was working in the central staffs in London where I was responsible for our version of the roles emissions 733 study, and I did such a spectacular job on our own medical service so I was exiled to the colonies. And I said at the time it worried me because if I made a mess of this, where would I go next? And I was looking at places like -- well, I think the Falkland Islands. Well, guess what. And I leave the army on August the 14th because I've decided I want to stay here. My wife finds this appalling. She views it with the day I stopped smoking about 31 years ago. She never thought

I'd do it.

But I have decided to stay here, mainly because I'm fascinated by: A) this country, B) the people, and C) health care and, coming from a country which does things in the most pedantic and slow fashion, convinced it's right. Faced with the same problems that you have in health care, unwilling to recognize it. I want to see how you solve the problem. I know that the crisis in health care in this country is so big and so spectacular. I know you'll solve it. And the moment you come up with that solution, I'm going to go home with the answer and make my fortune in England with all the work that you've done. That's the theory anyway.

In the interim, I'm going to work locally. I'm going to do a number of jobs, hopefully one of them at G.W. University teaching the poor benighted folks who come in and out of there. So that's by of introduction.

I promised Doctor Kuller that I would say something other than stand in front of you and show off. The two things I want to talk about are TBE vaccine. We have decided that we're not going to vaccinate as an actual policy.

I had the most garbled e-mail yesterday because I insisted one more time before I stood up in front of you that I have the precise facts because I know what happens here. There's a man with a tape recorder and there's somebody else that writes from it. And the last time I stood up -- the first time I stood up in front of you and said something as a matter of fact, I read off a sheet of paper, and it served me well to do so because it concerned Persian Gulf Illness and within three weeks the good Senator Boyer castigated not me, lucky enough, it was the good Doctor Gwaltney who sadly isn't here because I wanted to thank him enormously because I remember those words. They ring home. I went the color of this sweater when Boyer -- he's quite a frightening character really, especially on his home ground in the House hearings or whatever -- laid into first me for I was anonymous, but then the good doctor caught me. I remember it vividly when off the record, off the mark and off the walls was the comments that he made.

It brings me on to the second point and that is the Persian Gulf Illness. Some or all of you will be aware that it continues to dog

the Brits and we have become now it seems the central gravity for a short while. For those of you who are not aware of it, we have a fundamental difference between our version of Persian Gulf Illness and yours, and ours is that we do not have a Ferres Amendment and some years ago, I think because the Queen was frightened by her position, we repealed the Crown Immunities Act. So in other words, if you are a serving soldier, a citizen of Her Majesty's armed forces, you can actually take Her Majesty's armed forces to court. You can sue in a court of law.

We have approximately 500 members and ex-members of our armed forces who served approximately

-- and it is approximate -- who served in the Gulf who have given notice that there is something wrong with them as a consequence of their service. Of those, 350 to date have actually had a medical examination. The balance refuse, but they are registered with lawyers who have served notice that they intend to sue Her Majesty's government. If they fail in a court of law in the U.K., then they will take their case to the European court, and they've said that.

The impact for us is enormous, but I believe the impact on you is even greater because, as I remember two years ago when we discussed this with the AFEB, if the Brits managed to win their cases in a court of law in the U.K. in small numbers, what impact will that have on this side of the Atlantic? And this is certainly a phenomenon of the Internet. I read the pages at least once a week to see what Persian Gulf Illness veterans are doing on this side of the Atlantic and those on the other side. So that's the fundamental difference, and it worries me that we've got this impact.

We have next week a team coming out from the U.K., about 10 of them. It shows we're taking it seriously. And the good Nicholas Somes -- this is not going to be on tape, is it? It probably is anyway. The good Nicholas Somes, who is our minister for the armed forces has stopped being rude and bombastic now and decided to take a more measured approach. He made a fundamental mistake a few weeks ago on television because we have now moved past the stage where we've got young men saying I don't feel very well or my hair is dropping out and I've got piles. We had

a whole series of young women who said my baby is deformed. And he used the same approach. Oh dear, how sad. The difference in this country is that you've had a very much more measured approach to the whole issue and despite our criticisms -- and they're quite real -- of the politicking we've done, we have at least approached in this country the whole issue in a measured manner, giving people due course of their feelings. And I don't think that's true in the U.K.

So this team is coming out next week. It's going to look principally at joint endeavors. This is a cloud with a silver lining because I gather that the broad agency agreement, one of the major contracts is going to a Brit firm. But I do know that next week we're looking very much at some form of major joint endeavor, as major as we can be with a few hundred to your thousands.

I want to finish by saying that I think more than anything else the effect of the Armed Forces Epidemiological Board on this particular issue has been fundamental for us because it has given us the confidence to know

that we've been going down the right track. Doctor Ascher, Kuller, and Gwaltney, in particular, on my first day out here when I stood up and spoke gave me sufficient confidence to write back to the U.K. and keep that dialogue going saying that we should do this together. There is an organization here that sees common sense. And I have recognized throughout that the threat to defeat science by soap opera is being held check by an organization like this.

The sum of this is that I know that in the U.K. we don't have a structure like this. We don't have the ability to bring in world class experts and sit down and look at the major issues and draw scientific and rational conclusions from it and to have this outside agency that has at least a chance to look at the way we do things.

It's been a pleasure for the last couple of years. Great fun. And you never know. I might come back and say something in the future.

I thought I might leave you with a story, Doctor Ascher, because you'd hate me if I didn't. It's a monastery with a contemplative order, i.e., monks that don't speak. Not allowed

to. Anyway, it appears in this contemplative order there are special rules and that is that once every five years you're allowed to say two words. So fifth year goes past and Father Stephen comes down and sees the abbot and the abbot said, "Okay, Stephen, say your two words." And he said, "Food bad" and walked away. And the abbot went, "Okay."

Another five years went past. We've now 10 years. And down comes Father Stephen. "Okay, Stephen, say your two words." "Bed hard" and off he went. Fifteen years are now passed and Father Stephen is still there and he comes down to say his two words. "Okay, Father Stephen, what have you to say?" "I quit." And the abbot said, "I'm not surprised. You've done nothing but whine and moan since you came here."

Ladies and gentleman, it's been a pleasure standing before you and reading what you've had to say over these last couple of years, and I thank you for being who you are and great fun, and I hope you continue to do what you're doing.

(Applause)

DOCTOR KULLER: Thank you very much

again, and it's been delightful having you over these years and joining us in the dialogue.

Are there any questions? Usually we have active discussion.

DOCTOR ASCHER: Let me ask a question about TBE for a second. Your assignment is Slovenia. Is that right?

COLONEL LEITCH: It could be.

DOCTOR ASCHER: One of the sectors.

COLONEL LEITCH: You're not too far away. I might actually have to go to Slovenia.

DOCTOR ASCHER: But in terms of where we assess the risk for tick-borne encephalitis, that is really the only area of Yugoslavia where there's well-documented activity. Are you doing a surveillance program with the proper diagnostics in place if you're not immunizing?

COLONEL LEITCH: No. This is not a subject that I think the British army recognizes being a serious problem at this stage, and I think they'll do what they've always done which is react.

DOCTOR KULLER: I presume they'll be out of there by April.

We're going to move on now to a

continuation really of a very important area, I think an area the Board has taken a great deal of interest in over the last three to four years and has helped, I think, in some ways to move forward, and that is the area related to the injury problem in the military, and Colonel Bruce Jones who's Chief of Epidemiology at CHPPM now is going to I think lead off with the discussion.

COLONEL JONES: Thank you, Doctor Kuller.

COLONEL FOGELMAN: You can pull that mic out of the handle if you want to, if you need to.

COLONEL JONES: Can everybody hear? Great.

Well, what I'd like to do today is give you an update, a brief update on injuries and introduce, I think, one of the most interesting speakers we've had on injuries later in this talk. I'll actually have Colonel Fogelman introduce him. I'd like to divide my part of this into two portions. One is an update and the other one I guess you could call a status report. Those of you sitting at the head table here, most of you have a copy of the report that

has been reformatted. The content has not changed drastically. I think it's been edited so that it's more readable and all the graphics have been rekeyed so that they're in the same program, and I'll talk more about that later.

If I could have the next slide. Briefly, what I'll do is I'll talk to you, as I said, about an update on injuries. First, Operation Joint Endeavor and then some injury prevention successes. And then I'd like to look at the Work Group Report, discuss a little bit of the Board's review and recommendations. I haven't seen those yet, but something that I think we could do with those, re-look at some of the key recommendations of the work group and then talk about what I think is a very important issue, publication of the report and some conclusions.

Next slide. One of the key focuses of this report was on deployment and combat surveillance, medical surveillance, and the work group recommended not just injury surveillance but medical surveillance. And I'm happy to say that we're moving into the next generation of surveillance systems.

Next slide. Yesterday you saw some

data, but for some weeks now we have been tracking the frequency of hospitalizations for disease and non-battle injuries for primarily U.S. military forces deployed to Bosnia and, as you saw yesterday, we can now track the incidence of injuries, not just the frequency. That's a key factor. What you see here is that the incidents of disease and battle hospitalizations had been rising and then plateauing and now probably going down, which is what you're expect with the deploying force that's getting in place and very busy early on, but it's increasing in size. But the actual incidents of injuries and disease have been going down over this period of time. What I'd like to emphasize those in the next slide is that if we track the percent of hospitalizations attributable to battle injury and disease that battle injury hospitalizations have fluctuated between 20 and 30 some percent of the total hospitalizations fairly constant, you know, and this is what we saw in Operation Desert Shield/Desert Storm data.

Next slide. But just comparing disease with injury is misleading. In the past

we've assumed that the bulk of that disease is infectious disease, but it really isn't, and if we look at the principal diagnostic groups from the ICD-9 code book, what we see is that injury and poisoning make up 25 -- this is Bosnia data now, and actually I haven't properly attributed this to the source, but it's the Army patient administration systems and biostatistical activity in Fort Sam Houston. This is their PARRTS database which stands for patient accounting, reporting and real time tracking system. This is a very valuable system.

In any case, what we see when we look at the percent of total hospitalizations due to injuries and other causes that injuries make up 25 percent of the total, infectious diseases about 13 percent. What's of interest over here though, as we've seen before, is that musculoskeletal system and connective tissue diseases, which in this setting are largely injuries, are another big percent of this and, in fact, this is a very interesting category because many of these injuries are really delayed, chronic or recurrent effects of a past injury, something that we might be able to screen for.

Anyway, injuries are very important in that theater of operations as they were in Desert Shield/Desert Storm and other operations.

Next slide please. Now, several Board Members, including Doctor Broome from the CDC who's not here, have either written to me or talked to me. Oh, here she is. Doctor Broome felt, with others, that I had not and we had not adequately emphasized the potential for prevention of injuries and I had been searching for good examples, of which we have a few, and I'd like to show you some of the big ones.

Next slide. Now, this is labeled Naval Aviation Successes. This was some propaganda put out by the Navy Safety Center, and what I forgot to get on this was Navy Aviation Successes Fatality Prevention. And what this is, this plots the rates of Navy aviation fatalities per 100,000 flight hours from 1949 to the present, and what we see is a very dramatic success story with the rates coming down from over 50 per 100,000 to somewhere on the order of two. I think this is important because all of the service safety centers started out as aviation safety centers. It was a place where we

had a big problem. It was costly and it was fatal. We had data systems to track that. This is a key point in our report. Where you have systems and you have a problem you recognize, you can solve it. The Navy has done it here, and I want to show you the ongoing success because if we look at this graph from here on, it looks fairly flat. But if you show me the next chart, we have ongoing success, even though the rates are very low. This is what's happened since 1978. The rates have come down from six per 100,000 to a little over two. So this is an ongoing success story.

Next. Now, this slide is of interest because what we're doing right now is revisiting an effort of the Armed Forces Epidemiologic Board that began in the 1950s. There was a report that was made in 1957 and I believe published in the early '60s that we cite in this report, and one of the key recommendations they made -- in fact, the major focus of that report -- was on motor vehicle accidents. And what we see here is Army Safety Center data, but I might say that this is mirrored in the data from the other service safety centers, as is the aviation data from the

Navy. So what we see here is from 1980 to 1994, 15 years of data, we've decreased the incidents of private motor vehicle accident fatalities in the Army by over 50 percent -- by about 50 percent, from 40 per 100,000 to about 20. But it's interesting that even military vehicular accident fatalities have been decreasing. With the exception of this blip in Desert Shield/Desert Storm, tremendous success story.

Next slide. Now, the trickle down theory of economics did not work so well in the 1980s, as we're now hearing in this election, but I'm here to tell you that the trickle down effect of fatality prevention has worked. If we could see the next slide. You saw in the previous slide that fatalities from motor vehicle accidents have decreased. What we see here is that hospitalization rates for motor vehicle crashes in the Army have decreased as well. And I'm pretty sure -- I haven't plotted it like this -- that the data shows the same thing for the other services.

Next slide. Now, what I'd like to do at this point is say that some of the key data that the Board has seen has dealt with risk

factors for training-related injuries in the Army and the Marine Corps, and we have been looking for a large intervention trial to demonstrate that the principles we've been highlighting work. And it's unbelievable how uncanny it is the way things are falling together. It turns out that just late last year the Navy completed such a trial, and Colonel Fogelman and I invited the Navy Health Research Center to present the results of that trial, which I think still has room to be highlighted in our report, our final report, in some way. If you could introduce Commander Schaffer for us.

COLONEL FOGELMAN: We have with us Commander Rick Schaffer, who's the Chief of the Musculoskeletal Injury Project in Naval Health Research Center in San Diego. He's going to talk about the injury intervention trial at the Marine Corps.

COLONEL JONES: Rick, I'd like to congratulate you before your talk and I'll congratulate you again afterwards. This is a great achievement.

COMMANDER SCHAFFER: Thank you. I have handouts.

COLONEL FOGELMAN: Just start them around. Just hand them to the guys.

COMMANDER SCHAFFER: Good Morning. My name is Rick Schaffer. I'm from the Naval Health Research Center. At the Naval Health Research Center we have a Division of Clinical Epidemiology which his headed up by Captain Stephanie Brodine who sends her regrets for not being able to be here. She had to head the other direction from San Diego for a study that we've had planned with the 3rd Marines for a number of months.

What I'd like to do this morning is just give you a quick overview of what we've done in the last couple of years, which will take me about two minutes to show you about two years worth of work, and then I'll move on to the intervention that Colonel Jones was mentioning.

The idea was that we spent about -- this program started out with some very basic background from Colonel Jones and some ideas. We started the Clinical Epidemiology Division with a program that was funded by the Navy Medical Research and Development Command to look at injuries in the Navy/Marine Corps training

population. We started doing that in 1993 and used that information to follow a number of goals that we have set for ourselves to work within the musculoskeletal Injury Project. Each of our studies have kind of followed the same basic pattern. We like to first determine the rates of injuries at a given site, then develop predictive profiles for the injury susceptibility which, as Colonel Jones mentioned, is to establish the risk factors for the injuries and the types of injuries that we're seeing, and then thirdly, the plan is to develop and evaluate intervention to reduce these injuries, and this third step is what I'm going to present to you this morning. But I'm going to skip over quite a number of issues and work that was done in the first two years of this project.

We're now starting a very similar project in Navy Recruit Depot -- that's Navy Recruits Training Center in Great Lakes to do the same type of project. There we ought to be able to do that in about a year from lessons learned in the two to three years it took us to do this at the Marine Corps Recruit Depot in San Diego.

Just as a quick background of what

we're currently doing in the area of musculoskeletal injury research at the Navy Health Research Center, we've got five main sites that we're working on currently. The Marine Corps San Diego, which I'll talk about this morning, and the Fitness Training Modification. We've got a similar study going on the Marine Corps Recruit Depot Paris Island in women, the OCS Quantico, we've got a research project going on there looking at injuries in women which have, by the way, the largest injury rate of any female training population, Navy/Marine Corps. We're looking at similar information at the Naval Special Warfare BUDS training, which is where the Seals go to train, and we're now, as I mentioned, finally looking at a study at the Naval Training Center Great Lakes. Kind of following the pattern of all four of these other sites.

The project basically started out and the main impetus for most of this work is the fact that in the first year of the project, using an outpatient surveillance system that we developed in NHRC, we developed a fiscal and operational readiness impact of the outpatient not hospitalized, which goes without saying,

lower extremity injuries that occurred during training. In Marine Corps boot camp, which is an 11 week program -- back in 1993 was a 12 week program -- the fiscal cost of outpatient injuries was about $16.5 million, and this was attributed to re-recruitment of recruits that have to separate due to injuries, the cost of putting people in temporary medical hold, the cost of re-outfitting and medical treatment of the injury, and then the rehab. We also calculated readiness that in Marine Corps recruits in 1993 males had a per capita lost training days of three days per recruit due to injuries. So out of a population of just under 25,000 recruits, they lost 53,000 training days due to musculoskeletal injuries. So this was kind of the foundation for what we started doing based on this impact to the program. And as I said, this is just per year per site. So basically you can double this per year in the Marine Corps, and it occurs every year.

Just as a background, the type of injuries that we typically see in these populations -- and this is data from 1993 from our tracking system -- is the majority of them

are over-use training type injuries from a drastic change in the physical activity of the recruit as they walk in the door. And I'll tell you a little bit about what we found to be the risk factors of that and what types of training aspects we could look at to try to reduce these. Basically, as you can see, with the exception of ankle sprains, the rest of these are over-use type injuries, repetitive injury trauma injuries.

The incidents of the injuries began to spread out over the period of training but, as I said, in 1993 the training at Marine Corps boot camp was 12 weeks long. We started to plot out when the injuries were occurring. We started to look specifically at stress fractures as a separate group. We also looked at the overall group of over-use injuries and at ankle sprains as an indicator of acute injuries. It just needs to be said that the acute injuries at Marine Corps boot camp are very low. About 80 percent of all the injuries occurring at Marine Corps boot camp are in the over-use injury type. So it's a very safe, from a safety point of view, program. The injuries by far are from the type of training and the drastic change in physical

activity. We start plotting these injuries over a period by week. We started to look to see if there was something going on in the training program that maybe we could pinpoint to try to reduce the types of injuries we're seeing. We did the same thing in 1994. A little bit different type of distribution, but the main reason for this is the 1994 data that I'm showing here is only from the June/July entry to boot camp. This is an indication that injuries in groups coming in at different times of the year -- which I think is pretty well known -- are very different. And so we had to take into account the time of year the recruits show up at boot camp and also look at the time that the injuries are occurring during training.

So we started to get an idea in 1993 and '94 of what types of injuries and when they were occurring and we began to look at our risk factors for injuries, and this is based on work that's been done for a number of years in the military, mainly through Colonel Jones's efforts, and we put our injury risk factors into two main groups, the extrinsic and the intrinsic factors. We're currently looking at some extrinsic

factors for interventions, but the effort that we directed our efforts at back in 1994 was at the intrinsic factors, seeing if we could determine what individual risk factors could be used to predict stress fractures and over-use injuries and then see what we could do to modify those.

What we did in '93 and '94 is developed a profile to predict stress fractures. The reason we used stress fracture as an outcome measure is because it basically mimicked the over-use injury incidents across training. It was also a very hard end point that we needed that we currently are doing some work with looking at the distribution between injuries and motivational problems. What we're seeing is pretty much like a balloon that if you squeeze one end of injuries, the motivational, the mental health unit separations go up. If you bring down the mental health separations, you end up with injuries going up. So we needed something that could not be necessarily associated with malingering. It was also, as I said, a correlative of over-use injuries, and then it also had a very hard outcome in high impact costs. Stress fractures in the Marine Corps

Recruit Depot in one year occurred about 700 stress fractures out of the 22,000 recruits that show up and that cost is just about $10 million per year.

What we did is we actually put together a model for predicting stress fractures, and we validated this model, and this is basically the model here. We actually as the recruit walks in the door can, based on five simple fitness questions and their run time on the mile and a half run, place them in either a high risk or a low risk category for stress fractures. This is a model that we presented here before and has been kind of our mainstay at a number of the intervention projects we're doing. But as you can see, there's over a threefold difference in the stress fracture rate among those recruits -- and it's a small portion, about 20 percent of the recruits -- that are put into a high risk category. As I said, this high risk category is not just not good fitness. It's very poor fitness. So approximately 20 percent of the recruits walking in the door by our measure are in very poor fitness. About 30 percent of them are in poor fitness compared to

the Ken Cooper type aerobic fitness standards.

So we developed this model in 1993 and '94, and our plan was to then intervene to try to reduce the stress fractures in this high risk category, understanding that the stress fractures occurring in the low risk category may be a cost of training. About 60 percent of all the stress fractures occur in the 20 percent of the people in the high risk category. You'll see the data from this graph again in the results of the intervention.

So the summary of the previous couple of years was that over-use injuries were a significant cause of injury and fiscal costs in recruit populations. The primary intrinsic factor was poor fitness level on arrival. The primary extrinsic factors were rigorous training and inadequate footwear, which we're addressing both of those, and the key point was that these factors were modifiable, and that's what we set out to do. The point was that we needed to figure out a way to deal with the fact that the population showing up on the door needed a little help getting up the road, and so the idea was that we gave the Marines three options. We told

them that you can potentially address the fitness of the recruit as they walk in the door and so give some kind of pre-recruit training regimen. That has some medical/legal problems and it has some other problems with structuring, and so that wasn't one of the options they opted for right off. Another option we gave them was footwear and equipment. They did opt for that. We're in the middle right now of designing a new Marine Corps boot and some different equipment changes to help with this.

But the main effort that everybody decided on in major conjunction with the training staff, the Marine training staff, was to address the training schedule to alter it such that 30 percent of the recruits coming in the door have very poor fitness. That's what I want to show you the results of today. We put together a training panel. This included Marine Corps drill instructors, medical experts, experts in the field of strength and conditioning training, and we put together a panel in December of '94 that came up with recommendations for changes to the training, and the training was based on the standard, not rocket science type of physiology

training, with the idea that you need to build a good aerobic base before a recruit starts into this strength and power training, which is what the Marine Corps tended to do first. They tried to do the top part of the pyramid without getting a good foundation in the aerobic training, and we felt like that was a large portion of why the injuries were occurring.

We also based it on a premise -- and this is data courtesy of Colonel Jones and Doctor Pollack from prisoners in 1977. We also worked on the premise that there is a point of diminishing returns on activity, physical activity and fitness, and there is a point at which the fitness gains stop increasing and the injuries gains continue to increase and even dramatically. Our point was to try to find that level between the 30 minute per day in this data and the 45 minute per day where the fitness gains are no longer making and the injuries are continuing to rise. So this is what we were looking for is that particular point in the Marine Corps recruit training.

So in 1995 we enrolled about 2,200 recruits that walked in the door. We put them

into one of two programs. We spent a lot of time waiting on the Marine Corps to find a time when nothing else would change during this training program. So the only change that occurred to these recruits during this time was the fitness training change that we had made a recommendation.

We did three comparisons, just as a matter of pointing out. The historical comparisons are what we used as what used to happen. We didn't run a concurrent program of the old way versus the new way, partly because we had two full years worth of data on that. It was very consistent for the two years, and we felt like a historical control was a very appropriate thing to use. The other reason we did that is the Marines wanted to try to come up with their own new program to compare to the Navy medical program because they thought it would be kind of a weenie program and they wanted a real program. I won't tell you which program the Marine Corps program was and which program the Navy medical program was, but we did do head to head trials on these two programs, so that's why you see program one and program two.

The basic breakout of these programs was as follows. We added 1,117 recruits in program one. Separation rate was about 17 percent. The overall injury rate, injured at least once during training, was about 28 percent. Program two, the study enrollees were about 1,097 recruits. Separation rate was slightly higher. The breakdown of the separation rate is there. There is no difference in the injured separations between the groups, but what you saw is that the injured at least once rate in the program two was lower. The training efficiency is a Marine Corps determined separation rate and that's a little different than we calculate it. They don't calculate a recruit to separate unless they've actually started past a certain point in training. We calculate our separation based on the number of recruits that show up on the door at boot camp.

So this is the overall profile of these study populations we looked at. Just as an idea, since we were saying that a good potential cause of some of these injuries was incoming fitness, we wanted to ensure that the incoming fitness between the recruit coming in the door in

our trial and the recruits coming in the door in 1993-94 was the same. This is based on the IST, the initial strength test the Marines do, which is a mile and a half run, pull-ups in two minutes, situps in two minutes. There was no difference between any of these parameters in the recruits coming in in the '95 trial versus '94 and '93 historically, so we wanted to make sure there was no fitness difference as they walked in the door. We also graphed out the initial strength test per mile. The yellow line is the historical controls. The light blue line is the 1995 intervention group. So there was no difference in run times or any measure of the initial strength tests on the group that walked in the door.

As this group showed up, they showed up with about the same type of injuries that we saw in the 1993-94 group but the rates were somewhat lower. But the key to it is -- and I'll move on to it -- is the stress fracture rate here in 1995 was just about half of the rate that was in 1994, and that's kind of the punch line, but let me move on to the actual showing of that data. I just wanted to kind of show the

distribution of the other types of injuries we show from 1993 and '94. The distribution of that training rate was very different than what we saw in 93-94. As you remember from the 93-94 graph, most of the rates, the high peaks of these rates were up to about 80 recruits per 1,000. It never broke 40 recruits per 1,000 in any given week during boot camp. During the intervention -- and this is for both groups combined -- you can see the stress fracture rate is quite a bit lower. The over-use injury rate is quite a bit lower. The only thing that actually remained the same was the ankle sprains which is not what we addressed, and we had hoped that there wasn't something different that would change the acute injury. So this was the overall injury distribution during the intervention compared to '94 controls. I got those backwards. Those are your '93 controls and, as you saw, there was a dramatic change in the rates from '93 to '95.

So the bottom line. The comparison between stress fractures that we looked at is presented here. In 1994 the stress fracture rate among recruits for a two full year period which didn't alter very much -- it hovered between 3.7

to 3.9 percent per hundred recruits showing up. In 1994 the rate was 3.7. The overall rate in the intervention trial was 2.2 which you can see is a significant reduction from the previous two years, and then we actually broke out the program one and program two rates and you can see that there's actually a difference between those two, and that the program two rate, which is the bottom line program which the Marines have now adopted, actually reduced the stress fracture rate by more than 50 percent. This is a two percent reduction, and I'll show you some of the dollar and cost figures, but that is actually an important enough reduction that the Marine Corps and for anybody that can take a look at it to see that you can make an impact based on these fitness changes and nothing else occurring.

To further support this information -- and this is one of my favorite slides as an epidemiologist's dream for this kind of thing to come out -- what we did then is we actually -- as you remember, the model we had put together in 1994 which are the two yellow bars, we actually compared that based on the incoming fitness profile or risk reduction profile. You can see

that in 1994 the high and the low risk groups there in the yellow bars. Well, in 1995 the overall group, which is the teal bar there, the reduction there was from about 2.4 percent to two percent in the low risk group, which are recruits that showed up in good fitness to start with, but the reduction in the overall group in that high risk category, which is where we wanted to address, we reduced the stress fracture rate from 8.5 percent to 3.4 percent in the group that came in the door in very poor fitness. The idea was, as we hoped, that we could show them that fitness was really the key, and we addressed the poor fitness group that walked in the door and reduced that to the point of almost being the same as the low risk group when they walked in the door. And, as you can see in the red bar which is the program two, we actually eliminated the difference between the high and low risk incidents rates for stress fractures based on this program.

So the idea was that you could take this group, make absolutely no difference between the stress fracture rate and whether a recruit comes in in poor fitness or good fitness with a

program -- and this is the part the Marines like -- with a program that actually kept the outgoing fitness of the recruits exactly the same. This is program one and program two. Historical data from program one and program two, the 93-94 data which the Marines have. We used this slide kind of show there is no difference between program one and program two to reemphasize to the Marines that there wasn't any difference between the Navy medical weenie program and the Marine Corps very difficult program.

The fitness scores. To fail the Marine Corps PFT you need a score of 130. It goes up to 300, so you can see that their scores were very high and very acceptable to the Marines. We gave the three mile run times. There was no difference between program one, program two and the 1994 results. Pull-ups were very much the same. Situps were very much the same. The bottom line is the outgoing fitness, the outgoing military part of the training also was absolutely not different at all from before the intervention. The only thing that was changed was the injury rate, the stress fracture rate and as summary from what we saw, the cost

savings, that Based on a 50 percent reduction -- and actually with program two they showed a 60 percent reduction -- a 50 percent reduction in stress fractures will cause approximately 370 less stress fractures in a year per site reducing about 15,000 lost training days, cost savings of about $4 million per year -- that's a conservative estimate -- per site. And the idea was that this is now something that they can implement and we're happy to say that today, March 1st is the first day they implemented this program, the new program at MCRD San Diego. We're currently working MCRD Paris Island which is where the males and females train to do the same type of information.

So in summary, the idea was, as Colonel Jones pointed out, we wanted to take a risk factor profile study and move it on to an actual intervention trial and show that risk factors can be used to actually do interventions and reduce these injuries. Now, there's a number of things. There's a very finite training population. It's a very standardized training. We're now currently doing similar work in the operational forces in the aviation command in San

Diego and in the operational Marines up at Camp Pendleton to see if this similar type of effort can be done in a group that does not have a standardized exercise program, does not have a standardized training day, and it's also very difficult to track for injuries.

And that's currently where we are but our main take home message is that we can make a difference in these types of risk factor profiles and risk factors that occur during training. We expect to be able to reduce some of these injuries even further with our equipment training changes, and we're in the process of currently making some updated recommendations to recruiting commands as to what they can do for their recruits to try to get them better prepared for boot camp, both Navy and Marine Corps.

As an aside, the Navy recruits coming in the door are only slightly less physically fit than the Marine Corps recruits coming in the door, and so the aspect should be about the same in looking at the Navy recruit populations that we're currently doing in Great Lakes.

(Applause)

COLONEL FOGELMAN: Questions?

DOCTOR FLETCHER: Reflecting back again on the Marines in the late '60s, there was an enormous problem with the stress fractures and it was felt at that point that marching on the grinder -- I guess they still do -- was the major factor. Is that still done in the boot camp early days as vigorous as it was?

COMMANDER SCHAFFER: Yes, sir. It's done as vigorous. There are a number of things they've done. They've outlawed some types of different heel snap type marching which has been officially outlawed. Still if you go and watch them, you might see some of it. You also see some boot wear that indicates they may still be doing that. But what we actually are doing now is segment out just the drill, the drill grinder marching from the overall fitness program because, as you can see, even after addressing the fitness program, there still are some stress fractures occurring. And the clinical people on site at MCRD feel that this has a lot to do with the grinder drill type work. The grinder drill type work is done in the beginning, the first three weeks of training. Then they go out to the field work for about four to five weeks and they

come back and do grinder work near the end. Indications from our peaks in our two slides of incidents rates kind of support that these injuries are occurring during those times or at least reported during those times.

DOCTOR FLETCHER: Because a conditioning factor should not affect that. That's a separate entity.

COMMANDER SCHAFFER: And that's part of what we feel were some of the remaining stress fractures and over-use injuries. We are addressing that. As I've said, we've developed now a new boot for training which we are currently testing in Hawaii at this point in the 3rd Marines which is where the other part of our group is this week, and the idea is to try to look at impact-reducing boots for training. We've actually put two sole types on the combat boot which at the lab significantly reduces stress impact, and we want to see if it does that in populations.

DOCTOR POLAND: Do I understand also that the recruits are allowed or will buy out of their own funds running shoes?

COMMANDER SCHAFFER: Yes, they have

that option. Actually, right now both boot camps, Marine Corps boot camps, and the Navy boot camp are trying to establish which ones the exchanges will carry so that these recruits can buy them. They can either buy them, they can bring them with them, and actually what the Marines do is if they show up with really worn looking running shoes, the DIs will make them then buy new ones. They aren't issued any at this point, but they can go to the exchange and buy them. They also can buy a sock liner and insole, shock absorbing insole, if they choose, to put in boots and in sneakers, but they're right now trying to determine which type of sneakers or running shoes they'd like the exchange to carry and then which ones the DIs are going to have them buy if they buy any.

DOCTOR ASCHER: I believe one time you presented or someone from your group that smoking was a high risk factor for injury, and I noticed yesterday there was a considerable still level of smoking in the Marine Corps, and the use of smokeless tobacco. Are these people learning that if they don't smoke and they switch to smokeless tobacco, they have better fitness?

COMMANDER SCHAFFER: I don't have any data on that part as far as the switching. What we have seen in our male and female studies now is that a simple measure of smoking, which we asked them by questionnaire, in our data at least, is not associated with the particular types of injuries we're looking at for controlling fitness, but we don't have a real good measure of smoking as they come in the door. These are 18 year old kids for the most part and it's hard to really pinpoint that. I think Colonel Jones has some different data in the Army, but our Marine Corps data doesn't at this point have an association with smoking.

Yes, ma'am.

DOCTOR NELSON: Yesterday Commander Sharp talked about a high attrition rate in the Marines. Is there any correlation between the low fitness group and the attrition rate?

COMMANDER SHARP: You weren't here yesterday, were you?

COMMANDER SCHAFFER: No, sir.

COMMANDER SHARP: What I said yesterday was that somewhere around 30 percent of Marines don't make it through their first tour of

duty, and so that's all the way through the first four years. But my understanding is much of that does occur in the training cycle.

COMMANDER SCHAFFER: The recruits in 1993 are the longest ones that we could follow, and our numbers pretty much mimic the recruit attrition headquarters and Marine Corps numbers which is about 32 percent don't make it through the first four years. About half of that attrition though occurs in the first year and that first year is 12 weeks of boot camp and another number of weeks, anywhere from four to 12 weeks, of school of infantry training, Marine combat training, infantry training, and about 17 percent of the attrition occurs between boot camp and the follow-on training before they hit the fleet, at least based on our numbers, and I think that's pretty much what Major Estridge at the recruit attrition office at headquarters also shows.

The idea was that in the early days about 50 percent of all stress fractured recruits separated and at that time 50 percent of all separations were due to medical reasons. As I mentioned earlier, there was kind of a balloon

between mental health separations and injury separations. We know that we've reduced the injury separations. It's not clear to us though that we've resolved the overall attribution problem because many of those recruits then get out by going to the mental health unit at MCRD and get out. But our numbers at least show that more than half of the separations do occur before they actually hit the fleet and then a total of 30 percent of them do eventually separate.

COLONEL PARKINSON: A comment and a request. It's interesting just for the group, the Air Force actually also through our Office of Prevention Health Services Assessment, has revised in conjunction with the trainees at Lackland, their recruit fitness program. We had just the opposite problem in the sense that our injuries are relatively low but our fitness was actually being de-conditioned during basic training because what they had done for years was basically have the recruits train in their basic unit and they would basically run to the level of the lowest or slowest member of that unit so that we had conditioned people coming in and actually getting de-conditioned over the -- we have a

shorter period of time, about six weeks or eight weeks, I'm not sure what it is at this. So our job was to increase their fitness without increasing injuries and essentially we went in, we have incorporated athletic shoes -- and that may be something that you want to look at is the brand and how they did that through the military system -- and showed that there was no increase in injury rate while we basically significantly improved everybody's run times and fitness.

Interestingly, the way they did that was by cohorting the high performance with the low. Now, I don't know if culturally that would fly in the Marines, you know, that type of thing. But our goals were basically to make sure that everybody incorporates daily exercise into their regimen and see it as the norm rather than the exception and #2, that it improves their fitness. But the bigger issue here is also how you get into the mind set of the trainees. We talked about that yesterday, and the training commands. There's going to be our annual recruit medicine conference. The Air Force is sponsoring it this year in San Antonio, and the request is is that you present this alongside the Air Force program

and whatever is going on as we continue to move this forward. I think it's just great.

COMMANDER SCHAFFER: We've been notified. I think April 4 - 5 in San Antonio for that. And also, we actually contacted -- and I apologize for not remembering his name -- the colonel that was the commanding officer at the Recruit Training Command there at Lackland back in April. We talked to him because they started the ability grouping to put the recruits in basically we call them divisions or platoons based on their fitness as they walked in the door. We presented that to the Marine Corps. That wasn't exactly what they wanted to try to do with the Marine Corps, but it's exactly the problem we're running up with the Navy right now. They're the exact same situation the Air Force was, is that the recruit in good shape was de-conditioning during nine weeks of basic training. The injury rates were very low. We don't want to currently alter that because we're afraid we're going to push the injury rates up. And one of the options they're considering right now -- and I was just in Great Lakes Monday and Tuesday -- is the option of trying to ability

group separate the recruits as they walk in the door. So the information from the Air Force that we actually heard back in April was very helpful in trying to determine what kind of things we could do to the interventions, and we've worked pretty closely with them.

We're now moving into the Navy because it's a very similar situation. The Marine Corps was quite a bit different, and they do a lot more individual training and testing than both the Air Force and the Air Force used to and the Navy currently does. The Navy does all of the physical testing as a group. As you say, the group passes. If you fall out of the group, you fail. You can't do better than the group. And so you're kind of all in the same little bunch. The Marine Corps does very little of that for their testing. They do all individual testing, so it wasn't as much of an issue with the Marines.

DOCTOR KULLER: Can you predict before they come in the service what are the characteristics of the individuals who are in this 20 percent high risk group? In other words, before they get into the military, what's the

unique characteristics of the 20 percent that are in your high risk group which contributes substantially to the stress fractures?

COMMANDER SCHAFFER: We think we can predict, and we've validated that once in a second follow-up study. The bottom line. It's very simple issues. It's the physical activity in the two months before arriving at boot camp. We've actually been able to break it out between if you do any kind of exercise or activity, not even structured exercise, but if you do any kind of physical activity at least two times a week in the two months before coming to boot camp, you have a significantly reduced stress fracture risk. You also have a reduced stress factor risk if you had an injury and have recovered fully from that injury. In some of the runner studies, it shows that the previous injury is predictive of subsequent injuries but in the recruits, that's not necessarily the case, and we think it's an indicator of activity and fitness. A recruit that has had an opportunity to get injured and then has also recovered before they come at 18 years old is much less likely to get a stress fracture than a recruit that's never been

injured before they show up at boot camp, and we feel that's a marker for just simply being an active teenager.

We also are able to show that based on run times, the run times could be done before they come, the runs times could be done when they get there. Currently the run times are done that we use when they get there, and run time by itself is very useful in predicting stress fractures and even most over-use injuries. Actually, run time is used for predicting attrition also. In female recruits, just simply the measure on their three quarter mile run time can predict their separation or attrition. Now, we know that's not the only -- obviously that's not the only thing, but that's a marker of it.

So yes, sir, we feel like there are a number of things that we could be looking at. We've also been using that information to try to provide recruiters information of things they can just simply do, and most of them are very simple, as I said. In the two months before coming, at least three times a week doing some kind of activity to the point that they sweat and then just kind of getting a screening of injury type

information and having them ready for their mile and a half run, which doesn't occur a lot.

DOCTOR KULLER: But it's not related to the size of the individual or is there social class phenomenon or smoking-related, as somebody mentioned? These factors. It's primarily this activity level in the two months prior to the service is the primary moving factor.

COMMANDER SCHAFFER: Yes, sir. According to our data -- and the disservice I did was not to present the huge array of things that we've looked at over the last three years, and we've looked into probably three to four hundred variables in the last three years and tried to predict this injury profile, used this profile based on other information, and we've looked at a wide array of socio and geographic factors, demographic factors. We've looked at all kinds of dietary habits, all kinds of, in women, menstrual history. We've looked at a wide variety of medical history. In the Navy currently right now they've actually got an automated medical history scantron type of work that's being done where they gather over 300 questions on previous medical history and

behaviors. We don't have any association with most of those, and injuries.

So at least in the data we've collected, really the only thing that continues to fall out is this fitness and activity before coming to training, and I'm sure Colonel Jones has more information on that. But in our data we don't really see anything else. The only other thing that really has a strong association with injury is the platoon they get into once they get into boot camp, and that's something we're currently working on now. But that pretty much is all of it.

COLONEL FOGELMAN: If we could hold questions to Colonel Jones.

COLONEL JONES: I'd like to make one quick comment here in addressing Doctor Kuller's question. There are a variety of risk factors that we have identified in various populations, not just recruits. But the most consistent risk factors, as Commander Schaffer has pointed out, have been level of physical fitness and training. One has to presume that the training is the primary risk factor. If you don't do vigorous weight bearing physical training, you don't get

these kind of injuries. So that's the primary one. And so I think that the emphasis was really appropriate in this talk, and that was on the intervention they succeeded. All the evidence has been pointing in this direction, and the Navy took the ball and ran with it and showed that those assumptions were really right.

Well, with that, Rick, I guess I'd like to congratulate you and your compatriots at the Naval Health Research Center. I think this is an excellent job you did that needed to be done. This is the first trial of this type that's been done, and the primary intervention was really a more gradual introduction of weight bearing training, a reduction in the total miles. I took part in the expert panel, and this was really one of the most exciting efforts of my life and watching this study evolve has really given me a great deal of satisfaction. And I wish I could have done it myself, but it took them, and I think that they deserve a great deal of credit for having the vision to see that this needed to be done in a large population and putting in place the mechanism to really study it properly.

DOCTOR KULLER: Colonel Leitch, you had a question.

COLONEL LEITCH: First, have you lengthened the time of your recruit training?

COMMANDER SCHAFFER: No, sir. It actually has been shortened. It used to be 12 weeks and it's gone down to 11.

COLONEL LEITCH: The second part really concerned recruit selection itself. How much do you believe that this is a function of the problem of actually recruiting? In other words, trying to make a silk purse out of a sow's ear.

COMMANDER SCHAFFER: I think that's a large part of it. Actually, there doesn't seem to be any efforts put towards recruiting in any of these areas that we've seen and are predicting, and I think it's -- you know, not being a recruiter -- almost every recruiter you talk to, it's more along the lines of a quota issue.

COLONEL LEITCH: Bruce and I had a conversation about it yesterday because we're certainly seeing the problem. It seems to center on recruiting itself. We found a peculiar

phenomenon. Lord knows why we haven't seen blinding glimpse of the obvious really, and that is the medical officers who are responsible for the recruit medicals in the first place, the majority of ours are doing it on payment basis. They are not people who are involved in the long-term effects of whoever they recruit. They go, thank you very much, here's the money, good-bye. Whereas if it was some guy who was actually part of the system and knew that what he did he would be responsible for, in the long term things might be different. It's concerning us all that you are having to put right the problems that perhaps shouldn't exist in the first place.

REAR ADMIRAL DYSART: One of the real problems we have is, as you know, the birth rate going where it is. We're in the trough and it's very, very difficult to get recruits at this point in time. The interesting thing about the Marines though, and I think one of the things the Marines have done and that gives you an advantage, is that the Marine recruiter doesn't get credit until the guy finishes boot camp, which I think makes a lot of sense. Now if you can educate him and you find there are factors

and you say, hey, you know, you're more likely to get a guy to go all the way through if you look for this, then when he has some flexibility it may get there, but that's a real problem.

The other specific problem -- and our physical exams are exactly the same as yours. I mean we have MEPS medical and we have a few -- we kind of have the people who couldn't hack it anywhere else. That's who we put in charge of our medical processing stations, and then they have a bunch of civilians who work for them, so I mean we don't have any advantage over that either, but the other piece is that I think -- and I've been talking to the recruit command which relates not to this physical side but the mental side -- if down the road we're able to look at the mental health by doing a simple test and now putting the kid in a computer at the recruit station and finding out the people who are going to wash out, maybe we can reduce the effort we spend on the other group because there's a lot of money we lose in taking recruits through every year and then having to recruit so many. If you can get good quality, then you may be able to reduce the number.

So I think those are both factors and, like I say, probably the biggest factor though is the shortage of potential recruits right now. That's a real problem for us, all three services.

DOCTOR KULLER: Bruce, I have one more question for you. This is just semi-scientific. You diagnose a stress fracture by an x-ray, I presume. Is that right?

COLONEL JONES: We've used a variety of definitions. X-rays, bone scans. And actually, clinical presumption is very highly predictive. If you've got all the signs and symptoms, point tenderness over bone, increasing pain with increasing activity, that sort of stuff, that's very predictive. So the different studies have used different methods. I believe that they had a very good, very rigorous definition. It involved bone scans, as I recall, and x-rays.

COMMANDER SCHAFFER: Bone scans, x-rays, point tenderness, and to be clinically presented ahead of time. It was not an active surveillance. We didn't go out and look for them with bone scans.

DOCTOR KULLER: I was just wondering

if you took recruits at the end of training and you sort of sometime during training you x-rayed them, some way of identifying stress fractures. Are there stress fractures which are essentially relatively asymptomatic? In other words, one of the questions is do you modify the strength of the bone or do you modify the kind of response to the stress fracture? Do you modify the muscle, you might say in the tendon primarily, or do you modify the strength of the bone when you do this training approach that you're using?

COLONEL JONES: I think you modify all of them, and perhaps the reason why recruits who do some exercise in the couple of months prior to coming in benefit in terms of stress fractures is because there is good evidence that you strengthen bone. You exercise the bone. You do more weight bearing, load the bone more, and you strengthen it.

Your question about stress fractures and what would happen if you x-rayed everybody, we haven't x-rayed everybody but we did a study a few years ago at Fort Bliss where we x-rayed a random sample. I mean we got so many volunteers that we had to do a random subsample, but

basically everybody at the end of recruit training in the seventh week volunteered for this study to have bone scans, and so we did a random sample of 25 percent of them. In 250 normal individuals -- these were individuals who hadn't had a stress fracture or any indication of a stress fracture -- 97 percent of their bone scans were positive. But that doesn't mean that they had stress fractures.

DOCTOR KULLER: What do you mean by positive?

COLONEL JONES: By positive I mean using criteria in the literature by Swass et al. They had bone scan evidence of what would have been called a stress fracture, but these were asymptomatic individuals. What that told us was that bone scans were overly sensitive as a diagnostic tool because clearly 97 percent of them did not have stress fractures, which is a pathological condition. What they had was evidence of remodeling of bone, and that's what the bone scan shows you is that the bone is actively remodeling.

DOCTOR ASCHER: But it's a continuum. It's a continuing through remodeling to painful

remodeling to fracture.

COLONEL JONES: Yes, to pathological, and the fracture is really a misnomer because most of these stress fractures have no cracks or anything. It's just overly exuberant remodeling of bone and weakening. It's a very interesting area, and there's a lot more to tell about this.

We should probably move on to get on with the rest of our business here. What I'd like to do now is talk about the AFEB report, and what we have just seen is very close to my heart and was really one of the most exciting projects I have seen in my scientific life. Having been involved in this area so much, it gives me a great deal of satisfaction to see the success of their study out there. I would like to say, however, that this report which most of you at the front table have and those of you at the front who don't have it, I think I have enough copies for you over here. I don't have enough copies for everybody, but if you'd see Ms. McFerrin, who's at the viewgraph machine here, afterwards and give her your name and address, we can send you reports when we have final approval to send those out.

In any case, this is one of the proudest achievements that I've contributed to in my professional life. I owe a great deal of thanks to the members of the work group that I chaired, co-chaired with Doctor Hansen, who could not be here, and Commander Schaffer was a part of that work group. I owe a special thanks to Doctor Kuller and to Doctor Hansen. They were the ones who really energized me to move ahead with this smartly, and for those of you who have been present through all of this, you will remember that this all started with a memorandum from the Army Surgeon General in January of 1994, so here we are two years later. I don't think that this could have happened any more rapidly than it has, but it would not have happened this rapidly if it was not for the interest of Doctor Kuller and Doctor Hansen.

Next slide. What I'd like to do at this point is just reemphasize what I think are some of the key points of this report. The first one is perhaps the most critical. If you have a problem but you don't recognize it, it is very unlikely that you are going to solve it. I think for that reason the primary thing that we need to

take out of this report is that injuries are an important, if not the most important, cause of morbidity, mortality and disability in the three services. The Air Force has a little bit less of a problem, but certainly for the Army and the Navy, and it's right up there for the Air Force.

Now, the next thing is is if you do not have systems to measure your problems to identify them, you also aren't going to solve them. We needed the systems that you've seen. Now, one of the things, you might look at this report and say, well, the systems are in place, but they aren't. The problem is is that these databases are administrative databases. It took a tremendous amount of energy to pry this data out of them, but we're on the verge of having those systems in place, so I think we need to recommend that we have those comprehensive integrated medical surveillance systems.

I think the other thing is, and what Commander Schaffer's data shows, that if we invest money in research, it's going to come back and pay off, but we need to make that investment.

The other thing is once we have

surveillance and research, we need to communicate with the people in the safety community and the other prevention communities who can go out there and actually get the job of prevention done. I think it's important to emphasize and to implement prevention strategies where that's warranted. I think that we have evidence today that we could make recommendations on prevention of training-related injuries. However, I think that it would be shortsighted to make that the primary focus of any of our recommendations because you may get immediate successes but then you don't have the infrastructure that you need to do this on an ongoing basis.

And the recommendation is not just for injury surveillance. Although the injury work group was made up primarily of injury epidemiologists, their primary recommendation was for medical surveillance, and I think that that's where the money is. But in the area of injuries, we need to convene a tri-service workshop or something like that to bring together all the players from the safety community, from the research community, and from the surveillance community and elsewhere to carry this the next

step.

Next slide. Now, you have in your hands the report of the work group, but the final chapter has not really been written on this, and what I would like to do, with the Board's permission, is include their recommendations and perhaps some of the data you saw in injury prevention successes in a final chapter that would be the Board's chapter in a final report.

I'd also like to solicit a forward from a current or former Board Member to have a forward and then what I'd like to do -- next slide -- is I really think that the effort and the quality of the data that went into this report is too good to let it sit on someone's desk and gather dust or in a limited space. I'd really like to seek to have this published. I know we can publish it as a military technical report or a technical note that will get in the defense technical information centers, library, where it's reference and it can be accessed by military people and others, but I also think that we could get it out in the open literature.

I have approached *Military Medicine* where I think it is most appropriately sent. The

editor I talked to has not seen this report. With your permission, I'd like to send it to him. But they are interested. They think that if the report is what I say it is that they would publish it as a supplement and send it out with their monthly journal that they normally send out. The publication costs would be somewhere between $5,000 and $10,000. I think we or someone else would have to absorb that, but that's what I would recommend that we do with this. We need to polish it a little bit more. I'd like your guidance on that.

And in conclusion I'd like to say that I think that -- well actually, before I go on with that, you have an extra handout here which is another table of contents, and I've reserved a space there that's highlighted, Chapter 7, for the Board's conclusions and comments.

And with that I'd like to say that I think that this report provides a blueprint for how we can establish the medical surveillance systems to do a more effective job of preventing injuries, but I think also preventing other diseases as well, and I think you've seen evidence here today that where we have the

information systems and we have the coordination, we can be highly successful at preventing injuries.

Thanks.

(Applause)

COLONEL FOGELMAN: Other comments?

DOCTOR KULLER: Bruce, I would hope that it might be possible to publish this also in a nonmilitary journal. I think there are several journals that publish supplements to the journal without a cost that I think would be extremely interested in publishing in this because for the civilian population that's very much involved in injury-related research and prevention and especially I think at programs which are involved in training now in high schools, colleges, etcetera, this becomes extraordinarily important and the data in here is extraordinarily important, so I hope that it may be possible to get this published also in a nonmilitary journal so that it again doesn't get buried, you might say, but really will be useful to people working in the accident and injury field because it's a very important document.

COLONEL JONES: Well, I appreciate

that vote of confidence. I'm really looking for suggestions and I'm open to publishing this wherever we can legitimately do that. I think that there are clearly a number of avenues, and I think that the work group put in a tremendous amount of effort. I would like to say that this work is based on data that was collected by a companion work group who is putting together an atlas of injuries in the military that goes beyond the data here. It doesn't have as much text and it doesn't have as much in the way of insight into databases, but it does collect the data and I'd like to show that to the Board at some time, too. I think that you'll be very interested in a summary of that. But this report, I agree, I'd like to get it. If you will get your information to me, I will do whatever is necessary to coordinate the effort to get this out to the audiences that would benefit from seeing it.

I've greatly appreciated the support that I've gotten from the Board over the years. There have been times when my energy levels have run a little low, but I must say that this group charges me up every time I come here and it

rejuvenates my own strength to go on with this. It's been very exciting, and you all have been a key part of this.

DOCTOR FLETCHER: Bruce, I'd second that having this out to a general medical journal even before you submit it to *Military Medicine* because it would not be good to duplicate probably. Try to go for some very general medical --

COLONEL JONES: Sure. I'm open to suggestions and I don't think we have to hurry with this, but I would like to move ahead.

COLONEL LEITCH: I spoke with Bruce about this yesterday and I genuinely believe it. It's a much bigger issue than a medical issue because at the end of the day, this is a personnel -- this is what makes DP, Chief of Naval Personnel, Chief of whatever you call it. Unless they understand what this means and the impact that they have on training and all that goes with it, all we're ending up doing is repairing other people's mistakes. Recently, having taken some of the first cases that Bruce gave me, I had a look at the British army and as it refers to April of 1994, we had, out of

120,000 active men and women in the army, over 5,000 who were medically downgraded. That's a brigade's worth of soldiers in a very small army.

I asked them two questions. Firstly, where are they now and who are they? The second question was how did they get there in the first place? That really has become a major focus for us now is to try and understand how we took fit 18 year old men and women and before their fortieth birthday we made 5,000 of them at any one time physically unfit. What are we doing that's wrong? Lifestyle, training and everything else. No matter what we do within the medical services -- and that's the people who are actually doing it -- change their minds, we're going to be permanently treating as opposed to preventing. And I think this really begins to focus the whole business of what we were saying, the wider meaning of health. You know, this is not a medical issue per se. It's a much, much bigger one. It's a focus for what we're moving into, I think, in military medicine which is away from treating and away from sick care into health care. However, I think a much wider circulation than purely the medical is needed.

COLONEL JONES: Mike.

COLONEL PARKINSON: Yes, Bruce, three points. First of all, the impact of this document is already good, is already being hopefully leveraged in the Air Force. Sandy Zelnick, who's our chief of occupational medicine, was on the verge of flying down to San Antonio to talk to them about the problem of E coding and standardization of injuries, and basically I said this is your hammer. Essentially and AFEB-produced DOD-wide document that says this is a major concern as to how we collect information. So we're already putting this document to use, even though it's not published per se, and I think that's the very intent of it.

Secondly is I think what we have not talked about is for a tri-service DOD-brokered. It has to be at the DOD level. We in the Air Force are trying very hard to get our injury people together with our medical people, our safety people, etcetera, and we're making some headway working through the Secretary of the Air Force's office, but there must be a broker who brings us all to the table at a level even above

the Air Force, and I think that's where the DOD level, either health affairs or in ES, environmental.

COLONEL JONES: Well, this is really a joint effort because Colonel Seibert represents DOD environmental security, and this was a joint effort from the very beginning and it was through their sharing data that we were able to do this report here. But I think we have that partnership already in place, and I think that that makes a lot of sense, and Doctor Joseph could bring some pressure to bear to do this. I know the safety community is also interested.

COLONEL PARKINSON: The third point though, and I wonder if there shouldn't be more specificity -- and I haven't read this and I apologize for not going through this because I flipped through it very quickly -- is that perhaps the group could have one other chapter that calls for short term and long term specific research initiative. I mean globally we talk about research into prevention, this type of stuff, but when we're down talking to Mike Pollack, for example, on our fitness study, what are we really doing about research and state of

the art programs for prevention of low back pain in terms of the types of focus studies done by the Navy in terms of in our civilian work force using our research priorities and research dollars in the work site aligned with what you find here. So if I had to take this product and go right now to Armstrong Laboratory and say, does your research articulate this, this, this, this and this, which are promising areas that could be advanced in much the way that you've done in training injuries, I think you're very close to having that and this document could be much more hard hitting by delineating five or 10 key areas in each of those things. I don't know if you could do that, but I know it would be very useful rather than just generically saying we need more research on surveillance and prevention. Something to think about.

COLONEL JONES: I agree. I think with only three meetings under our belt it was very hard, but we felt that we needed to push ahead smartly with this, and I know others on the Board have made similar comments, and I agree with you wholeheartedly. I think it would take at least another meeting or a couple of day workshop to do

that, maybe as a splinter group of this tri-service workshop that we're talking about.

COLONEL FOGELMAN: We can talk more about that after the meeting. I think in the interest of time we ought to go ahead and press on and if you have additional comments or questions, you can bring them up at the break.

DOCTOR KULLER: Our next speaker and the next topic is a question for the Board, PCB assessing adverse health effects of environmental contaminants. Andrea Lunsford, who is the head of Public Health Support Department at the Naval Environmental Health Center in Norfolk, Virginia.

MS. LUNSFORD: You should all have a gray folder which has information on this topic in it.

Good morning. Thank you for providing me the opportunity to provide you a very short overview of some of the issues about PCB toxicity and epidemiology. The topic that I've chosen is addressing evidence of adverse health effects from PCBs. I'm going to present a paper by three researchers at the Cancer Center at Michigan State University and talk about the critical need to assess the epidemiological evidence of PCB

toxicity.

Just a very short background information on PCBs for those of you who haven't thought about them or know their long history. I actually put a PCB molecule up on the drawing behind the flags. But there's two biphenyl rings with a variable number of chlorine attachments. So PCBs are really a chemical family. They differ in structure just by the number of chlorines attached, and they have excellent dielectric and insulating properties which is why they were used all over the world in hydraulic equipment and electrical transformers. They're also lipophilic. They're thick, oily liquids or solids. Their lipophilicity makes them adhere strongly to soil particles, sediment particles. That is how they accumulate in the environment and also in the context of bioaccumulation and partitioning within the body. They partition to fatty tissue.

They extremely stable, resistant to lots of sorts of degradation. In fact, from a chemical point of view, these were sort of wonder chemicals at the time they were invented back in the 1920s and 1930s because of their stability

and apparent lack of toxicity, it was thought at the time.

These are some of the uses. They were used as heat exchange dielectric fluids, hydraulic equipment. They were also used as plasticizers, and this is going to be of more interest to the topic that I'm going to talk a little bit about, some of the current regulations. They were used as extenders for pesticides. They're often mixed with chlorobenzenes as a solvent to make them less viscous. They're also ingredients, we've now found, in caulking materials, in paints. They help retard photodegradation. They add a plasticizing ability. They're found in adhesives and they're used quite widely as fire retardants in small quantities.

There were also some historical uses like carbonless paper and the ballast and florescent lighting fixtures.

I like to look at things from a historical perspective, and I think this is particularly important in the case of PCBs. So I'm just showing a very short history here. Between 1929 and 1970, I said thousands of tons

but it was more like hundreds of thousands of tons were produced annually in almost all of the developed countries. In 1966 there was a researcher who was looking for DDT in the environment. You remember back in the 1960s the persistence of DDT in the environment was a big issue. And his chromatographic equipment -- he had a GC mass spec -- was more refined than former instruments. He was looking for DDT residues in fish, in ocean water, in Baltic seals, and every single sample that he took of ocean water or biological samples, he found two peaks were coming out almost at the same place on the chromatograms and it was very close to the DDT peak but he found this other peak and decided to find out what it was and it turned out it was PCBs, what we now know were PCBs. And this was really the first time that people were aware that it was everywhere in the environment. After that, there was lots of testing. You can find PCBs in polar bear livers in the Arctic ice, in breast milk from U.S. women and Argentina, a number of places in the world. So it's a ubiquitous persistent chemical.

But the importance of the 1966

discovery is in conjunction to the DDT scares. In 1977, after PCBs were discovered, there was a lot of research as to how far reaching was the contamination. EPA banned the manufacture and distribution in commerce of PCBs. Since then, PCB levels in the environment have decreased. They've been monitored in ocean waters, in air, in soil, in biological tissue.

I just want to go also over the epidemiological/toxicological information we have about PCBs because currently there's a raging debate about risk assessment in general and PCBs are sort of at center stage of some of that debate. Persistent chemicals, I should say. Back in the 1930s was when people recognized that people working in some of the factories in Germany that were making the halogenated hydrocarbons, they were working in solvents. It was kind of a new industry. They had halogenated napthalenes, chloranapthalenes, that sort of thing. Two young men died of jaundice and they had been exposed to chloranapthalenes of this big mixture of things. Also, one of them had been exposed to what they called chlorodiphenal at the time. But toxicities from an occupational sense

were also being discovered for a number of regular hydrocarbons that were halogenated hydrocarbons. For example, carbon tetrachloride, methylene chloride, trichlorethylene. So in the 1930s if you look at some of the old handbooks on occupational disease, they sort of throw in chlorodiphenyls in with these halogenated hydrocarbon toxicities.

I've already mentioned the 1960s. Really the big event in the 1960s was the discovery that DDT, a very persistent chemical in the environment, was causing detrimental effects to wildlife and that had such far-reaching consequences. There is a PCB incident that is shown next here. In 1968, there was a poisoning over in Japan from rice bran cooking oil and rice bran cooking oil has to have a clarification step where they're put in big vats, the rice bran is. The oil needs to be clarified, and that's done with sort of heat transfer pipes. There was a state in Japan -- they call them prefectures -- where a number of people -- it was almost 1,000 people -- became ill and there were a variety of symptoms but the commonality between them was this rice bran cooking oil from one distributor.

And it turns out that the heat transfer fluid that had been used by the company making the rice bran oil was old equipment and it was leaking and it had leaked a lot of PCBs into the rice bran oil and people had ingested that. As I'm going to show a little bit later, there were also other things in it.

Coming right after this discovery by Jensen of the persistence and ubiquitous contamination of PCBs to discover there was this real poisoning incident, and I've also put down here Yucheng incidents. There was another poisoning incident in China. Same cause. Rice bran oil.

So between the 1970s, there were a lot of laboratory animal studies to determine the toxicity of PCBs. This escalated dramatically. The first case they started because of DDT had reduced the bald eagle population. What would PCBs do to wildlife, but then as soon as these poisoning incidents happened in 1968 and 1969, then there was a big increase in the amount of research done on PCB toxicities.

There were several other incidents along the way. There was in the 1970s a factory

in Italy that was making herbicides, etcetera, and it blew up so there were other populations. Occupational studies also included once PCBs were going to be banned, there was a large manufacturing capacity in the United States for capacitors where PCBs are used and also the people that work in the electric industry working on PCB transformers, electrical transformers containing PCBs.

In the 1990s there were non-occupational studies and also a re-look at some of those populations which were at first implicated in some of the incidents of the Yusho Yucheng as well as the capacitor manufacturing populations. And then really coming down to the late 1980s and 1990s there's been some molecular biological studies done to try and elucidate the mechanism of PCB toxicity.

So very quickly, what were the symptoms of the Yusho incident? Well, they had acute effects, very obvious lesions on the face, back, external genitalia. These are eruptions that look like an acne. They don't go away very easily. There was hyperpigmentation of the face, nails, gingiva, chronic bronchitis in some of the

patients, sputum, persistent cough. There was some neurological symptoms noted like vision loss, not permanent, but headaches, dizziness, numbness of the extremities and also the general malaise category -- at the time they reported it under general malaise -- was stomach pain, joint pain, diarrhea, irregular menstrual cycle, general fatigue.

They looked down the line. There were several infants born of women who were pregnant during this incident, and 10 out of 13 of the infants born of impacted mothers exhibited this hyperpigmentation. Nine out of 13, increased eye discharges, sort of a cheesy-like discharge. And adults were found to have elevated serum levels of PCBs at the time. They also did some liver enzyme tests like aspartic transferase. They were found to be elevated.

However, down here at the bottom in the 16 year follow-up study, there was a statistical excess of the risk of cancer, liver cancer, found in one prefecture meaning one of the states, one of the counties. Relative to the incidents in that county, there was an increase of the population that had been poisoned.

One of the things that somehow didn't make it onto the slide. They also looked back at the Yusho infants and found that there were no long-term effects. In other words, no morphological changes or neurological changes.

All right, need to get going along with this. So there's this long history of PCBs. Why is it that it's still a big issue? Well, because right now more restrictive regulations have been proposed by the EPA in December of 1994. There's a broader application of methodology called risk assessment methodology that came out of the Superfund program and it's being more widely applied to other health studies. State health agencies have adopted it, etcetera. There's been a re-look at EPA toxicity values. EPA themselves are issuing some toxicity reassessments like the dioxin reassessment and this year -- I believe September is now the projected date to have a PCB reassessment published.

The current debate about cost benefit analysis in general. I want to talk just a minute about the proposed PCB rule. In the *Federal Register* December, 1994 under the Toxic

Substances Control Act, EPA has proposed some amendments to that act. And the differences between the current existing rule, TOSCA was issued back in 1976, was banning the production and manufacture of PCBs and that rule covers liquid PCBs. It says transformers have to be -- the concentrations can't exceed 50 parts per million and so you have to clean out old transformers, that sort of thing. Liquids that did not have greater than 50 parts per million were not regulated under the old TOSCA Act.

The new proposed amendment is going to also regulate solid materials and there would be requirements for determining the PCB concentration in a number of things like multiphasic combinations of liquids and solids. And what that means, I'm going to show you in a minute what some of the components for Navy. Some of our ships have big electrical cables on them and that's sort of like maybe three wire bundles and that'll be enclosed in a matrix of polymer. That polymer then has a number of -- the whole cable has sheathing around it. But within that polymer matrix, it's been found that there's PCBs. Well, if that polymer, regardless

of if that polymer matrix is one percent, 10 percent, 25 percent of the whole item, if that matrix has greater than 50 parts per million PCBs, then the whole item is considered a PCB contaminated item and will have to be regulated. Things like paints on the hulls of ships. So I want to get at some of the other requirements, marking, storing, disposal.

As written, the proposed rule would require anything found to contain more than 50 parts per million PCBs in any component to be labeled and so one envisions if you want to be facetious, PCB hazard warnings every 10 feet down the hull of the ship. Same thing with the electrical cable inside and, in fact, in some of our shipyards where they are decommissioning ships, some of the areas that are known to contain PCBs, you walk in there and there are these little labels about every 2 feet.

Reporting and record keeping requirements. The proposed rule requires that if -- it is purported to be in order to enable and allow use of PCBs in solid materials but what it says is that if you find the material has more than 50 parts per million PCBs you have to

monitor the area in which that item is located and for the first year you'd have to do quarterly air monitoring and subsequently you'd have to do annual air monitoring every year. In the same way, you'd have to take white samples, surface white samples, quarterly in the first year and annually thereafter. Well, if you look at a ship, you have various compartments. You have engine compartments and you have galleys where you eat and you have forward compartments and you have bridge compartments. So in other words, if something like an electrical cable went through all of those compartments and you have to pick like a representative portion, you have many different classes of ships. Well, you can see the number of samples that would have to be taken just to assure that there's not being occupational exposure beyond significant levels.

One other thing -- and again, I didn't put it on this slide -- but the proposed rule would lower the standards to 10 micrograms per meter square of surface area contamination. Right now, it's 100 micrograms per meter square and I believe the Coast Guard risk assessment

that was just recently completed -- I'm using some of your data because we don't have ours yet -- measured, I think one of the maximum concentrations for table surface in the galley where you eat was like 320 micrograms per meter square. Background levels in buildings are 50 to 100 micrograms per meter square.

Also for air, currently OSHA has permissible exposure limits for air. For lower chlorinated PCBs, that's one milligram per meter cubed for air chlora 1040 which is 40 percent chlorinated. It's .5 milligrams per meter cubed. This would lower it to one part per billion in air.

DOD responded to EPA's comments. I think the letter is dated May 5, 1995. Part of that response, Army gave comments, Navy gave comments. Navy estimated that because both active and retired ships contain these components, PCBs, it would cost $500 million annually above our PCB programs now to comply with this regulation. Perpetual air monitoring was one of the aspects. However, Navy ships right now are resold or scrapped after -- well, many of them are sold or scrapped. And some of

the provisions of the rule prohibiting resale, distribution and commerce would preclude a ship that still contains electrical cable to be sold for scrap.

Now, one of the things I just need to mention here is we already remove all the major sources of PCBs. For example, any remaining PCB transformers on ships. Those are removed. Belts on submarines that were impregnated with PCBs, the sound damping and insulating. Those are removed. So we're not talking about that. We're talking about integral components and the cost to remove them before being sold. So there's really three scenarios. We're looking at resale to foreign countries that may not have the same occupational controls as we have. The need to blast down to bare metal before you can resell high grade steel on the world market. Platforms could not be used for SINKEX. I've put down there Navy target practice. Seven or eight ships a year that are used for certain exercises. Actually, the way the law is written, a skipper of a ship might be liable for taking a ship out of American territorial waters and tying up in a foreign country. So you can see why Navy feels

the need to respond to the rule.

There is a mechanism for requesting an exemption from the proposed rule and that mechanism is to perform a health risk assessment and submit that information to EPA. Lest I not get to the end of my talk, Navy has initiated -- we're in the planning stages now. We've taken some sampling and we're developing a comprehensive health risk assessment to address occupational exposures, exposures when ships are being decommissioned, and some of the foreign sales issues.

So in the process of a health risk assessment, what you have to do is you have to use certain methods that EPA has developed basically for Superfund that are now being used in other arenas. That brings the whole issue about EPA risk assessments. There have been a number of bills. I'm going to show you in a minute just some of the current literature on risk assessments and toxicity reassessments. But essentially one of the issues is that there are some really ultra -- what some people consider ultra conservative toxicity values have been incorporated and so one of the criticisms of the

current methodology is that the models that are used to derive toxicity values are based on linear non-threshold dose models that basically originated from radiation physics and cancer.

The other issue is low dose extrapolations. I don't have time to go into any of these, but essentially data is being used that were developed -- toxicity data that were developed using high doses in animals extrapolating back down to very, very low doses in order to estimate exposures over, say, a 30 to 70 year period. I've just thrown up a representative sampling of some of the literature that's been published in the last few years. Science and judgment and risk assessment had a major impact on requesting EPA to re-look at some of the toxicity assessments. More science and judgment in risk assessment. The dioxin reassessment document that EPA has been developing for a number of years. It was published. Chapter 8, the dose response relationships was reviewed by the Science Advisory Board and the responses to it, it was fairly critical in some areas including the areas we mentioned about still using non-threshold dose

response models.

I brought along a risk policy report. It's an interesting publication that tells you a number of the debates going on in EPA, etcetera. The House Risk Reform Bill that you've all heard about. I'll go on from there. That was just to show you that there really is a national debate right now about risk assessments.

And in this latest risk policy report Doctor Cogliano, who's with EPA's National Center for Environmental Assessment, has stated -- this was BNA in February of '96 -- that the PCB reassessment that's going to be published, they have some of those volumes published, and they are going to revise the toxicity values for PCBs. They're reevaluating the old study. They're reevaluating the classification system for carcinogenicity of PCBs.

Why is it really critical for us to look at epidemiological evidence again? Well, the reason is because Yusho Yucheng poisonings were a long time ago. We've never seen those effects in the human population since. The second thing is after the fact they found out that the symptoms exhibited by the Yusho patients

were most likely caused by furans and dioxins. That's been fairly well established. They found very high levels in samples that had been taken. So all of the studies of PCBs in humans so far, the cohort studies, etcetera, have not found anywhere near those severity of symptoms. However, over here on the left is just a very quick listing of the various effects that have been found in laboratory animals, and they're pretty severe. I mean they range from tumorigenesis in rats to thymal atrophy in the progeny of monkeys. But the point is the type of epidemiology that is occurring for environmental contaminants is this. You're not seeing your ebola virus which has an immediate effect, but can you really bump off that health benefit effect against something that might be low level and perhaps be causing, say, infertility in our population or more subtle immune effects that might be lowering immunological response in general? And that's sort of where we're at with PCBs.

ATSDR, the Agency for Toxic Substances and Disease Registry, is an agency of the U.S. Public Health Service. We like to call it a

sister agency to CDC. They're mandated under the circle of laws for Superfund to perform public health assessments at sites and they recently issued a draft toxicological profile, an updated draft toxicological profile for PCBs. It contains over 800 references to PCB studies. One of the things that they've tried to show with their lowest observed adverse effects levels, that sort of thing, is to differentiate between serious effects and less serious effects.

The paper that I've provided with this briefing looked at a number of epidemiological studies and they set up a study criteria and evaluation matrix. This is such an excellent paper. After you read some 100 or 200 PCB epidemiological study reviews, laboratory animal studies, etcetera, this was a rare find in my point of view and admittedly, I'm not an epidemiologist. But the matrix that was set up, I'll just go quickly to that. They actually evaluated things like the response rates, whether they were 75 percent or higher, 74 percent or lower, that sort of thing. And then the statistical significances of the reported data. I had planned to go into that a little bit more,

but I'll leave it for you to read after the fact.

One of the things I really wanted to point out. They cited -- they show four -- sorry the fourth one didn't make it on here. The authors, Swanson, Ratcliffe and Fischer, cited these four sources as providing the evaluation factors that they developed and they asserted that this is standard epidemiological methodology. Not coming from that field -- I'm a biochemist -- I don't have the wherewithal to evaluate are those in fact the norm, the standard for epidemiology, and that is one of the things I would appreciate if the Board were willing to consider looking at.

The conclusions are very important. Out of 39 occupational studies that were reviewed, only three of them -- and we're talking about large cohort studies in many cases of the capacitor manufacturing workers, that sort of thing. Only three of the 39 studies showed actual evidence, conclusive evidence of adverse health outcomes. And of those three, the symptom in two of them was chloracne. There was one study that showed a statistically significant increase in melanoma. I think there were three

melanoma persons in that cohort. And that statistical significance was relative to the state's incidence of melanoma. Actually, even in that case, if you looked at the local areas incidents, it would not have been statistically significant. Of those 39 studies, in addition to the three that gave conclusive evidence, there were only two that provided suggested evidence and both of those were chloracne. And this is very important for those of us working in the environmental arena. None of the 33 environmental studies provided conclusive or suggestive evidence of any specific effect.

Other conclusions. Majority of the studies, 70 percent could be classified as inconclusive because of deficiencies in methodologies or deficiencies in reporting information. There was obvious speculation and extrapolation presented as discussion. This is something that I can't over-emphasize. Many, many, many of the reviews about PCB toxicity and epidemiology are along the venue of well, we saw no absolute effects but we saw this effect and, therefore, we think it likely that -- And one of the small statements in the conclusions of this

report is that is there really a place for that in scientific literature? I mean how much speculation do you want? So it's important where we are in PCB epidemiology and toxicity to differentiate between those data which really show an effect and those which have suggestive evidence, nonconclusive evidence but then speculate. So the questions that we had developed for the AFEB Board is based on available epidemiological evidence, is it likely or unlikely that PCBs cause adverse human health outcomes? And we're talking in the regime of low dose chronic exposure. I think environmental persistent chemicals can fall under that study. Epidemiology of very, very low doses over very, very long time frames. And you may feel that because there's not immediate incidence that are dramatic and you can monitor that it may not be a problem, but as an example of the potential of adverse health outcomes, if lowered fertility or lowered immune response were in effect. We have women on ships now, for example, and one of the things we'll have to consider in our health assessment looking at the toxicity is well, what about pregnant females? You know, we'll have to

at least address the potential epidemiology of pregnant females onboard ships that have PCB components in our risk assessment that will be handed to the EPA.

We'd like to be able to use this study. One of the things about an EPA health risk assessment is that there's this section of it, a defined section called Toxicity Assessment, and one is allowed to provide new evidence, to discuss evidence. You don't just have to use EPA default parameters. You want to consider their parameters, too. We'll be using things like the ATSDR tox. profile, but also evidence like this. GE is a big industrial company who's also commented on the proposed rule and has, in fact, done some research showing elimination rates in humans and that that's primarily the reason why we differ from animals, a lot of the laboratory animals. Dogs and humans have great elimination rates, and other animals do not. But that literature hasn't been peer reviewed yet. So even though EPA is considering it, it's not made it into some of the tox. profiles and other literature of PCB toxicity.

So what I was trying to say is if you

could look over this evidence, that would be an assurance on our part that we could reasonably include it in our toxicity assessment of the health risk assessment that will be being developed.

And secondly, a very important part of this is is the evidence insufficient to draw a conclusion and, if it is, what are the major deficiencies? And I'm speaking specifically about this critical assessment that we've provided.

I apologize for the last bullet. We were discussing possibly putting down here simply the June meeting because if the Board would be amenable to it, we are going to be developing this health risk assessment. We're putting our sampling plans together now and if there would be interest in our presenting it at a later meeting, we would be glad to present that and send copies of our assessment for review ahead of that meeting. I simply told our administrative assistant to -- I said put a heads up for the July meeting, so that's why we have heads up July meeting.

Well, thank you very much.

COLONEL FOGELMAN: Questions?

DOCTOR KULLER: I think you have a very unpleasant problem. I mean the unpleasant problem is is that this is part of a society that believes that everything is risk free and that is that you reach a point in society where you make the presumption that there is no risk from anything and that, of course, is untrue, and then you get to risks which are nonmeasurable but could still exist and so that the conclusion always is of all of these committees, if you only have to read the first paragraph and the last because there's always more research in the first paragraph is always that the evidence is inconclusive. What's in between in generally nothing but rehash of what was stated many, many other times. And I'm afraid exactly the same thing will go on here. Your best hope is that we'll keep having reports and so you go on forever with reports without any action, and that may be the way that people will spend their money.

I think the Board could probably be helpful or part of the Board in essentially trying to help out, but this is like the dioxin

issue, of course, in the population. And about the problem of whether there are hormone modifiers that are modifying the hormonal patterns causing male infertility or causing breast cancer in women or causing changes in fertility, etcetera, overall. There's a lot of opinion, not much data, and it's very hard to collect the data and I doubt very much whether the Board could come to the definitive answer except for the fact that the attributable risk is probably so low as to be unimportant and the relative risk to any single individual is even going to be lower so that for any single person the relative risk is practically zero and the attributable risk compared with everything else in our society is going to be so unbelievably low as again to be unimportant.

You might suggest to the Congress or to the government that they sink all the ships and clean them in some kind of oil bath and then they bring them up again. Maybe that solves the problem. Make some ridiculous recommendations.

MS. LUNSFORD: Well, sinking ships, one of the beneficial purposes that the Navy likes to do. For example, state of South

Carolina likes to reef build and the substrate under that part of the ocean is just sand. There's no organic content of any significance to accumulate PCBs, that sort of thing. And essentially we'd be precluded from using ships for reef building if it were shown that that sunken ship could lead to a food chain pathway where the fish that you catch had PCBs, that sort of thing. So we need to address that.

DOCTOR ASCHER: There's also the societal perspective. In one of the asbestos reviews it was stated that if you have the high school football teams of all the high schools in America remove the asbestos from their high schools with no protection, they would incur in a life time less risk than one year playing football. That has to do with where does it fit into the big picture. How is the public to judge? I mean what is the proposed conclusion from the EMF stuff, from the breast implant stuff? As Lou says, it becomes an industry. *USA Today* says the studies are definitively inconclusive. More research.

MS. LUNSFORD: As opposed to more research, you know, I wasn't always a PCB

researcher. You get on a particular project and then you see how much literature there is on it and that sort of thing. What really is lacking is somebody having that standard. In other words, OSHA in some of their occupational parameters, they define de minimis risk. Right now epidemiologists are working on PCB toxicity. Right now there are studies going on. The last study looking at women who eat more fish in the Great Lakes area versus women who don't eat and looking at head circumference and lowered birth rate. There was a *Scandinavian Journal of Occupational Health* just published last week a study of women who ate more -- fish eating women on the east coast and the west coast, the east coast being near a more contaminated marine source, etcetera, and they found some differences. They did correlate this time with smoking which that hasn't been always the case in the past with many of these studies. And Greenpeace is using that study right now to stir up people's sentiments again about these dreadful effects. That doesn't mean that there isn't an effect.

And I think what I'm trying to say is

there are epidemiologists working in the field but there are many, many other epidemiologists who never viewed environmental pollutants as within their scope of what they'd even like to address because if you look at incidents of cancer and that sort of thing -- I brought along one show and tell article with me. This is an announcement for a risk assessment conference which followed the molecular biology conference down in Orlando last month. I wasn't able to go but I wanted to. They had a point/counterpoint session the first day. Doctor Bruce Ames -- I don't know how many of you have read about him -- from University of California, and he's come up with some of the values of natural pesticides. In other words, plant species evolved because they want to live, too, and they have these insecticides and other sorts of things against bugs eating them. And Doctor Ames's research shows, I think, that there's like 10,000 to one natural pesticides in natural foods versus manmade pesticides in our food sources.

The counterpoint of this session was Doctor Ames was going to say, well, you know, his perspective is that environmental pollution

accounts for less than one percent of overall cancer rates. The counterpoint was presented by Doctor Richard Wilson who's a physicist at Harvard, and his perspective is that you'd have to have at least a 10 percent lifetime increase in cancer incidents to be able to detect it. But that doesn't mean -- and the words in this point/counterpoint description was, you know, but we should use our -- that doesn't mean that we shouldn't be looking at it because there's situations where there's definite evidence of hazard at low levels could still impact the population. And there's this big issue about fertility decreasing in developed countries and persistent chemicals, therefore, are always looked at.

COLONEL FOGELMAN: Doctor Perotta.

DOCTOR PEROTTA: You're spending an awful lot of time on toxicity assessment, which is appropriate, but it's a big quagmire. What I haven't heard us talk much about -- and we don't have the time today -- is an exposure assessment. If this stuff is a solid matrix inside a cable and it's no longer the soup inside of big capacitors and transformers that it used to be,

I'm wondering why we're -- I mean I know we have to because of regulations and proposed rules, but the issue is you're talking about exposures to low levels of PCBs. Well, I'm not even sure we have exposure. We don't have much evidence of exposure in our ships. Now maybe we do in certain occupational settings where they're tearing things down or they're fixing things or they're scrapping things, etcetera, and perhaps we need to do something about that. But you're talking an awful lot about toxicity. I don't believe this Board is equipped to deal with that, although our Environmental Health Committee would be happy to work with you on this, but I need to know whether or not people are really being exposed to it before I'm going to sink an awful lot of time and energy of this Board or of my group to do much with.

MS. LUNSFORD: Yes, and that's what we're collecting.

CAPTAIN BERG: Bill Berg, Navy Environmental Health Center. What this is all about is the new rules have the potential to make it almost impossible for us to do anything with our old ships. It may prevent us from selling

them to other countries. It may prevent us from sinking them, either in sink exercises where we use them as targets or for refielding. We may be faced with the prospect as a worst case scenario of literally having these ships tied up from now on until forever. Our reading of the epidemiological literature suggests that for these situations the risk is very low, and we would appreciate it if the Board would consider taking on the task of doing a review of the evidence and either saying we are wrong or that we tend to concur with you and perhaps pointing out some of the gaps in it.

What we have intended to propose at the next meeting is a discussion of some of the ways that we think it might be appropriate to get a handle on the actual exposure risk and we would like to present that to the Board or a subcommittee of the Board and say, here's what we propose. What do you think about this? Are we on the right track? These were situations that were basically set up for a different situation. They're being applied to Navy ships, and it's gotten us terribly confused, and we need some help on how to go with this. And we are more

than willing to approach it and present it in any way that you would feel appropriate. We do not see this as we're here today and tomorrow we're going to have the answer and everything is fine. We recognize this is an ongoing problem that's probably going to require several meetings.

DOCTOR ASCHER: But Bill, if you're required to monitor and you did that in a very nice way by the method you suggested, showed in all of these situations with these seal situations there is no exposure in the environment, then you could come and say, is it rational then to have a continuous monitoring program which costs money? And then, as Dennis said, the only issue is then the scrapping. Is that what they're saying is you have to have monitors in every room in every ship that has a cable running through it?

MS. LUNSFORD: No. We're working with EPA compliance -- well, at least I met two of the people that are going to be involved in assessing our sampling design and working us through an exemption of a health risk by virtue of a health risk assessment. But on the matter of exposure, we're glad to do that in order to be able to

develop a health risk assessment but right now if we use the values that are in the proposed rule, everyone's going to be exposed. I mean background levels in office buildings of PCBs are 50 to 100 micrograms per meter squared. So yes, we have some data on ships that there are those levels. They're lower than the former regulatory levels but higher than the proposed regulatory levels.

CAPTAIN BERG: Bill Berg, NEHC. We're really talking about two different situations. Ships in our day in/day out operating environment which is probably little or no risk although with women on board that adds a little filler to it. The other situation is what happens when we decommission these ships and we break them up, and you envision things like workmen with a cutting torch cutting through these cables or cutting them apart. If we have to take the cables out before we can sell the ship, what is the exposure there? So these are two very different scenarios and we are working on developing ways to address them.

CAPTAIN TRUMP: I think one of the issues in presenting this to the Board was it is

not an easy question. I think what we're asking for is not the solution to the whole problem, but at least a help with the epidemiologic issue. I think one of the issues is, my read is that things are changing. Before we used to have to march to what EPA and OSHA said. I think they're under pressure that what they say may not come out as easily. I think this is one issue where an epidemiologic assessment has been fit. I think there are many others that we will see over time where the same sort of thought will need to go into other exposures. Just again in the area of Persian Gulf illnesses, questions about whether low level exposures to biological/chemical agents in the environment potentially below detectable levels are a risk may need to be addressed at some time. I think this is one area that I think the environmental side of the Board has not been used to the greatest extent in the past and we certainly don's expect an immediate response to this question, but at least a consideration of whether this is an issue that the Board wants to and can address. And I think that's also an issue that can be discussed in the strategy session about

future directions for the Board.

COLONEL PARKINSON: I just want to echo Captain Trump's comments and make them a little more blue. We recently went through in our physical exam section a look at how many types of periodic medical examinations bearing on the opportunity costs that I was talking about yesterday for a health care system that's probably going to take a 10 to 30 percent cut over the next one, three, five years. We do 23 different types of occupational medicine environmental assessment type of examinations at a typical Air Force Base, many of which are related to or linked with OSHA and EPA type of stuff and we also have a mind set which we are trying to get out of if that the 100 parts per million is good, then the Air Force is going to go for 100 parts per billion because we're better, which is another mind set as we build this industry around environmental and health risk assessment. Sometimes the old saying, you've got to dance with the one who brung you, this issue may be the issue where the Board starts to, in a more proactive vision that was articulated by Doctor Joseph, look for ways and

mechanisms to utilize the already existing things in the services to kind of articulate a vision and become more integrally involved with some of these. There are real, real health care impacts of whether or not this standard comes out in terms of how we man staff and otherwise not deliver services to our active duty, and we are just beginning now to ferret those out in terms of the absolute cost of these programs. It's overwhelming in terms of the infrastructure required to support these. And while it's true of all industry, and we're not saying that DOD should be more exempt by quantifying it, I think we can make a very effective case that is the juice worth the squeeze.

DOCTOR KULLER: Let me say again that I think if you ask the Board, I would strongly suspect, or if you ask any rational group of epidemiologists, they'd probably say this whole thing is absurd in what we're dealing with in terms of risk.

MS. LUNSFORD: Will you put it in writing for us?

DOCTOR KULLER: I was just going to say that unfortunately we're giving a course

unfortunately at the Society of Toxicology meeting next week. I think its' called Epidemiologists for Toxicologists. I sort of pointed out to the toxicologists that epidemiology is a very poor science for studying non-epidemics. By definition, it's the study of epidemics and if there are no events that occur, it's very hard for epidemiologists to define them. They don't exist. If there are no epidemics, there's no epidemiology. It's very hard. And that's one of the problems you have. People don't understand that, you know. If the event rate is zero, it's very hard to get good confidence limits around it, and it becomes a problem.

But there are potentials here, I think, that you could ask some interesting questions in using modern science that would probably be worthwhile to ask the Board. It seems to me because you have phenomenal resources. There are much better ways now of measuring individual exposure than existed in the past and there's a potential for the military to link up with some of the -- either within the military or within the government with techniques

which can better measure individual exposure. There are, as was talked yesterday, great variations in how these chemicals are metabolized which is a genetic variation which now can look in the past the genotypic specificity as opposed to the phenotype. So you could look at the genotypic expression. And then there are diseases which most likely, if one was going to bet, are going to be related to these, mainly the areas of lymphomas, leukemia because most of the data on the dioxins at least and other things suggest that, if anything, they work on the immunological system and that they're immunosuppressants of some sort because there's very little -- or liver -- there's very little evidence for solid tumor effects with any of these and with the model even of immunosuppression there's very little solid tumor evidence. And so you have potential with follow-up and with the AFIP, with pathology groups, to be able to perhaps look at some of the potential interrelationships as a research question to make you feel more secure about whether very low levels of toxicity and exposure could have an effect.

The tools we have now can only conclude that there is no risk, and you have to base that on science. You can't generate -- you could presume that 20 years from now we're going to find the risk, but that's what I said. That makes us feel we have to live in a risk-free environment, a risk-free society because we can't define all risks. People do get cancer and they do get it because they've either been exposed to something or they have a genetic susceptibility. That's a truism. It's got to be true. Otherwise, there'd be no cancer. And likewise you get heart disease and other diseases and also die because something happened to you, and that's also obvious.

So you're dealing with an issue of attributable risk, so I think it would be worthwhile for the Board to do this, but I think in reality even now I would suspect -- and I could almost guarantee in the future -- that the conclusions would be that based on the current evidence most of the concern is speculation only and not supported by any solid data. But one would also have to go forward and say that it's possible in the future that you'll find people

who have a certain genotype exposed to very low levels of a certain chemical for a certain place in their life time have an increased risk of a specific disease. But right now, you can't find those people, you can't define the exposure, and you don't even know what disease to look for, so epidemiology is lost.

MS. LUNSFORD: Well, if I could respond to that. You started out by saying well, epidemiology may be a poor science for evaluating. On the other hand, it could be one of the best ones. As devil's advocate, let me do the converse. You have supposition or anticipation of effects in a society and so you go ahead and regulate on your best evidence. But at some point -- and it's been 30 years -- at some point, there needs to come back -- and we have this whole matter of issue of comparative risk, you know, your risk of dying in a car accident is one in 60. We're incorporating that in some of our risk communication techniques, but there has to be a check, I think -- my personal opinion, not Navy's -- at some point on were those initial concerns -- was there evidence that supported those initial concerns or relative to

other things like incidents, injuries and things like that that you're looking at here, relative to those there's insignificant risk. And this paper comes close to at least addressing the epidemiology and that goes back to the issue of epidemiology is happening by non-epidemiologists in a way. Epidemiologists are looking at things like head circumference or shorter gestation time or decreased birth weight in grams of populations eating fish or not eating fish contaminated with PCBs, and that is epidemiology that's driving regulations and costly regulations. So to have some check balance by a board of epidemiologists I think is really important, just in the context of where it fits on the scale.

DOCTOR ASCHER: I saw an example of where in the Persian Gulf syndrome evidence was presented that there was a very low likelihood there was anything present, and the question was, have you proved it's not there? And so we're proving the null hypothesis, and we all know the problems with that.

COLONEL FOGELMAN: I think if Doctor Perotta is willing that we can take the questions that you've posed under advisement and report

back to you, not today but within a timely manner.

DOCTOR ASCHER: Then you can do EMF after this.

COLONEL FOGELMAN: Okay. Thank you very much.

This concludes the agenda items. We're going to go into executive session after this. I think if we could take about a 15 or 20 minute break, meet back here not later than about five until 11.

(The meeting was concluded at 10:35 a.m.)