STATUS OF EFFORTS TO IDENTIFY GULF WAR VETERANS' ILLNESSES: TUMOR DATA

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

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STATUS OF EFFORTS TO IDENTIFY GULF WAR VETERANS' ILLNESSES: TUMOR DATA

THURSDAY, MAY 14, 1998

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:50 a.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Towns, Kucinich, and Sanders.

Staff present: Lawrence J. Halloran, staff director and counsel; Robert Newman, professional staff member; Jesse S. Bushman, clerk; and Cherri Branson, minority counsel.

Mr. SHAYS. I would like to call this hearing to order and to thank particularly the patience of our witnesses and also our guests.

This much we know: Gulf war veterans were exposed to a variety of toxins long associated with the formation of neoplasms, tumors, and certain cancers.

What we don't know and what troubles many veterans is whether current health surveillance and research programs by the Department of Veterans Affairs and the Department of Defense are sensitive enough to detect exposure-related tumors in Gulf war veterans before they appear as mortality statistics.

This question arose 2 years ago when we were told VA health care data would not permit "any scientifically valid inference about the risk of developing a neoplasm" among Gulf war veterans. In part, that is due to the long latency of most cancers which often do not occur for 10 or 20 years after exposure to associated carcinogens. At the same time the VA conceded serious limitations in the quality, quantity, and consistency of the information needed to assess tumor risks.

So we asked the General Accounting Office, GAO, to examine the adequacy and reliability of current data systems in monitoring tumor incidence, the rate at which neoplasms are found to occur over time in those at risk.

The GAO report and additional analysis to be discussed today, concluded that current medical record systems are incompatible and understate the number of tumors. Lacking accurate data to drive research, VA and DOD epidemiological studies have not been designed to detect any increased tumor risk among Gulf war veterans.

That must change. Accurate, uniform medical data and properly focused research act as sentinels—our only warning of an ap-

proaching threat to veterans' health. As a matter of national defense, we would not be satisfied with a low-voltage, limited-range radar system to detect incoming missiles. As a matter of national honor, we cannot be satisfied with the health care surveillance and research system blind to the long-range health effects and delayed casualties of the Gulf war.

We asked today's witnesses to address the GAO's findings and to discuss the specific steps needed to strengthen health care monitoring and research into the risks of exposure-related tumors in Gulf war veterans. We look forward to their testimony.

At this time, I recognize Representative Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me begin by saying that I really appreciate working with you, and I appreciate the fact that you have stuck with this issue. This is the 13th hearing that this subcommittee has heard on illnesses suffered by the Gulf war veterans.

In previous hearings the subcommittee has examined evidence concerning types of chemical and biological exposures veterans suffered during their service in the Gulf. There is no doubt in my mind that these exposures occurred. However, in the vast majority of cases we do not know where, when or what. Without this vital information about exposure incidence, we will never, never know the whole story.

Mr. Chairman, I share your concerns for uncovering the answers to the questions and applaud the persistency and consistency that you have shown. However, I feel we may have to think about the next set of options. We must look down the road and ask where we should go, given this lack of information and the likelihood that all of the answers will never be known.

The GAO observed that cancer usually has a latency period of 15 to 30 years. This long latency period may mean that a search for increased incidence of disease among this population is premature. It may also mean that we should think about veterans who may receive a cancer diagnosis in the future.

Because reliable data on exposure episodes has been hampered by lack of information from the Department of Defense, efforts to develop a theory about possible types of health indications which may serve as a precursor to certain cancers are not likely to be meaningful.

Let me also add that I am concerned that in 15 to 30 years there will be congressional hearings in which Government officials will say there is no evidence of a link between Persian Gulf service and occurrence of certain cancers. Therefore, Mr. Chairman, I think we need to ask what kind of research must begin today to provide enough evidence to set forth a presumption of proof that Persian Gulf service may result in certain types of cancers.

This kind of presumption is not unusual. It has been used in cases of Agent Orange exposure during the Vietnam war and radiation exposure during World War II. Those presumptions are tied to compensation plans and were based on the precise knowledge of the type of exposure.

We need to continue to press for this exposure data, but we also need to ensure that sick veterans will be cared for now and in the future. DOD and VA have recently initiated research efforts to

study information of the incidence of tumors. However, GAO found that these studies are not the product of a systematic effort and that limitations in the studies will hamper their efficacy in providing reliable data on tumor incidence.

GAO recommended that the Secretaries of Defense and Veterans Affairs continue to strengthen existing monitoring facilities with particular attention toward improving the existing data system in a cost-effective manner, but both DOD and VA acknowledge the overall findings of GAO regarding the inadequacy in the existing data system. They concurred with the GAO recommendation on improvement.

Mr. Chairman, I think we have an opportunity for an agreement and future action. I hope that we will use it to move forward.

Thank you again for having this hearing, and I really feel that you are moving in the right direction and you are doing the right things; and I don't say that too often, but with you, I think you are doing the right thing.

Mr. SHAYS. I thank the gentleman, and this is a partnership. We work together in this committee and particularly on this issue, but really on every issue.

I would welcome to our table first Dr. Alexander Cianflone, Captain, U.S. Navy, retired, who comes to us from Denver; and Larry Hawkins, Gunnery Sergeant, U.S. Marine Corps, retired, from Maryland, accompanied by his wife, Margo Hawkins. It is nice to have you as well. And also Jack Kem, Lieutenant Colonel, U.S. Army, Active Duty.

I welcome all three witnesses, but before that I am going to take care of some procedural things.

I ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and that the record remain open for 3 days for that purpose, and without objection so ordered. And I ask that all witnesses be permitted to include their written statements in the record, and without objection so ordered.

Congressman Jack Metcalf had a one-page statement that he was going to read into the record, but will submit into the record. He has been very concerned about Gulf war illnesses and wanted to come make that statement.

[The prepared statement of Hon. Jack Metcalf follows:]

JACK METCALF
2D DISTRICT, WASHINGTON
COMMITTEE ON
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AND INFRASTRUCTURE

Congress of the United States
House of Representatives
Washington, DC 20515–4702

COMMITTEE ON BANKING
AND FINANCIAL SERVICES
CHAIR, REPUBLICAN HOUSING
OPPORTUNITY CAUCUS

Statement made by Congressman Jack Metcalf to the Subcommittee on Human Resources 5-14-98

Mr. Chairman

Thank you for the opportunity to speak to the Subcommittee on this critical issue. I would ask unanimous consent to have my entire statement entered into the record.

I want to take this occasion to thank you, Chairman Shays, and the Subcommittee for your continued diligent efforts on behalf of those who are suffering from Gulf War Illnesses. You have been willing to "stand in the gap," accepting the moral obligation to press for truthful answers. You have insisted that we provide for those affected, the medical and research attention they deserve. Your November 1997 report is essential to understanding the complexities of exposures and delays, and clearly defines why we must have comprehensive legislation to address this issue.

In my district I have many veterans who are sick and struggling with the glaring inadequacies of a system that has been woefully slow in responding to this crisis. Last year, the Defense Authorization Act included a Sense of Congress that I introduced which declared, "all promising technology and treatments relating to Gulf War Illnesses should be fully explored and tested to facilitate treatment for members of the Armed Forces and veterans who served the United States in the Persian Gulf conflict and are stricken with unexplainable illness." That directive to the DOD and VA needs to be heeded and acted upon.

Today, as we hear the testimonies of sick veterans, I hope each of us will be focused with a renewed sense of urgency. What is clear from the GAO report being discussed, is that the federal government does not have a reliable way to determine the incidences of tumors in Gulf War veterans. God forbid that we should rely on mortality reporting before we take decisive action. The DOD and VA must find immediate solutions for monitoring these veterans' health conditions. If they cannot, then Congress needs to identify those who can.

I look forward to the product of this subcommittee's work, and again, thank you for your heartfelt leadership on this issue. Thank you, Mr. Chairman.

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Mr. SHAYS. At this time, I would like our three witnesses and Mrs. Hawkins, if you will be responding, if you would rise and we will swear you in.

[Witnesses sworn.]

Mr. SHAYS. Thank you. For the record, all three of our witnesses and the accompanying guest have responded in the affirmative.

Let me say that one of the central questions that I believe we will try to get at in this hearing is, what will it take to be able to accurately measure the incidence rate of tumors in Gulf war veterans; and are there too few tumors to measure, or is the VA measuring too few tumors?

We will start with you, Captain.

STATEMENTS OF ALEXANDER CIANFLONE, M.D., CAPTAIN, USNR (RETIRED), DENVER, CO; LARRY HAWKINS, GUNNERY SERGEANT, USMC (RETIRED), KENSINGTON, MD, ACCOMPANIED BY MRS. MARGO HAWKINS; AND JACK KEM, LIEUTENANT COLONEL, U.S. ARMY

Dr. CIANFLONE. My name is Alexander G. Cianflone. I am board certified in family practice, emergency medicine, and I hold a certificate of additional qualifications in sports medicine. I am presently retired from the Navy Reserve. I served in the Persian Gulf.

Mr. SHAYS. I'm going to ask you to lower the mic and move it closer to you.

Thank you.

Dr. CIANFLONE. I was recalled to active duty from a Reserve center in Denver, CO. We reported in on January 2, 1991, and our unit was mobilized and united at Fort Dix, NJ. We left for the Gulf around—approximately mid-January 1991. In the Gulf, I served as a triage receiving medical officer at Fleet Hospital 6. I was stationed in various locations, Shakiza Airbase, Baharain, International. I was there to provide multiple casualty triage in the event that there were multiple casualties that were anticipated in Operation Desert Storm. My exposure was limited to some of the casualties in the forward areas and referred to our health care facility for medical treatment.

We did have Scud attacks and a Patriot battery close by us at Shakiza, and we had one Scud which was intercepted within a mile of our encampment. At that time, we were in full NBC gear. We were given the all clear 1 or 2 hours later. We were never notified whether or not there was any chemical or biological agents.

I was released from—we returned from the Gulf, but during the Gulf, I had injured my wrist and required surgery at Fitzsimmons Army Medical Center; and that was treated, and I was released from active duty in June 1991.

Shortly thereafter, I started developing some problems with headaches, nausea and intermittent diarrhea and crampy abdominal pain.

By 1993, I had developed bloody stools and was eventually diagnosed by a colonoscopy with having a condition called ischemic colitis, and that is a condition where your bowel does not get blood flow. Usually that is a condition seen in the very elderly or those seen with coagulation problems where they just form blood clots.

My coagulation workups were negative. I don't know why I developed ischemic colitis. Eventually that was resolved by diet and medication.

By May 1994, I started developing severe suboccipital neck pain. I sought the care of a neurosurgeon and underwent an MRI which demonstrated a disk which required surgery. I was operated and reoperated on later in November 1994. However, that did not resolve my problems; and by May 1995, I was finally, eventually diagnosed as having a very rare, aggressive osteoblastoma, which is a bony tumor involving the upper cervical vertebrae. It is an extremely rare tumor, probably an incidence of less than 1 in 10 million in the United States.

The tumor itself had now encompassed my upper spinal cord, and I started having long track findings. I was hospitalized for 6 or 7 weeks. It required a transoral—that is, through the mouth—resection, fusion and biopsy; and I was left with some postoperative complications at that time. I had a paralyzed vocal cord, and I was on a nasal gastric feeding tube for several months.

I never correlated any of these symptoms with being related to the Gulf. However, shortly after my release from the hospital, I was required to report for a physical examination with my unit, and I was found to be nonphysically qualified for future deployment and was in the process of being medically released from the Active Reserves.

At the time of my physical, there was another young lady from my unit and she had had, starting in September 1994, 7 months of chemo and radiation therapy for a thoracic fibrosarcoma, another extremely rare tumor. We were at the same discharge facility at the Reserve center.

At that time, the question was, maybe this wasn't just accidental, the tumor, bloody diarrhea. I filed with the Department of Veterans Affairs for the Persian Gulf Registry Examination program. Much to my surprise, I got a quick response. I was scheduled within a month of my inquiry for a physical examination, which was performed September 20, 1995.

At that time they did do a thorough exam. They did blood work and x rays. The problems that were addressed were that of my wrist, which was service acquired, I had a knee injury from an accident on an aircraft carrier in 1979, my neck and my ischemic colitis.

By April 2, 1996, I received a letter of opinion claiming that the osteoblastoma and the ischemic colitis were not service connected and no link to my military service. I presented to them the fact that there were other members of my unit that had rare malignancies. Another physical was eventually ordered, and that occurred January 28, 1998.

When I presented myself for the physical, they said you are only here to be checked for your wrist and your knees. The other issues, your neck and your colon are not at issue here; those are not service connected.

Since that time, I inquired with my unit and I have found out there have been 2 other members of my unit of 40 who have come down with other carcinomas. They have breast cancers. One of the

young ladies in her 40s has now passed away from her breast carcinoma. She leaves an 8-year-old child.

So there appears—we were talking about a unit of 40 people coming down with rare, esoteric cancers, and I don't know if the VA is keeping track of any of those records. I know in my case that they have considered them not service connected, but I think if you—it doesn't take an Einstein to know that these are rare diseases that don't occur commonly in the general population, and I have never seen them in my practice of 25 years.

I think there does need to be an adequate information database system to keep track of these malignancies. If the frequency and incidence of these cancers are found to be much higher in the Gulf vet, then there has to be looked for an etiology and a treatment for these veterans.

Thank you.

Mr. SHAYS. Before we go to Lieutenant Colonel Kem, your unit was 40 people?

Dr. CIANFLONE. The unit that we deployed out of Denver was 40. When we mobilized at Fort Dix, we were approximately 800 or 900.

Mr. SHAYS. You don't know about the remaining 800?

Dr. CIANFLONE. I don't.

Mr. SHAYS. Within your own unit of 40, you are saying there are 4 with some form of tumors?

Dr. CIANFLONE. That's correct.

[The prepared statement of Dr. Cianflone follows:]

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May 14, 1998

Congress of the United States
House of Representatives
Committee on Government Reform
and Oversight
2157 Rayburn - House Office Building
Washington, D.C. 20515-6143

Attention: Subcommittee on Human Resources
Christopher Shayes, Connecticut Chairman

Subject: Written Testimony of Alexander Cianflone, M.D.

RE: Concerning his experiences with condition following the Gulf War and DOD's-CCEP and/or VA's Gulf War Health Registry.

Dear Sirs:

My name is Alexander G. Cianflone, M.D. I am board certified in Family Practice, Emergency Medicine and hold a certificate of additional qualification in Sports Medicine. I presently am a Captain Retired from Navy Reserve.

I served in the Persian Gulf with Fleet Hospital VI and was recalled to active duty from a reserve center in Denver, Colorado. I was called on January 2, 1991, and served approximately 2-1/2 to 3 months in the Persian Gulf on the Island of Baharain.

I was released from active duty on June 2, 1991, following recovery for repair of a torn cartilage in my left dominant hand at Fitzsimons Army Medical Center from a fall injury while on active duty in Baharain.

The following is a summary of my medical condition following my Desert Storm experience.

January 2, 1991, I was in a good state of health. I did not have any other previous medical conditions other than having had a right medial meniscectomy following an injury on an aircraft carrier in 1979 that was repaired at NRMC, Jacksonville, Florida.

We were deployed after mobilization in Denver, Colorado. Our total unit was composed of members from many other parts of the United States at Fort Dix, New Jersey. We arrived in Baharain in theater following the onset of the war shortly after January 16, 1991. We remained in theater until the end of March 1991. At that time, I sustained a fall injury requiring an operative repair

of cartilage of my left dominant hand wrist at Fitzsimons Army Medical Center following return to the United States. I was released from active duty on June 2, 1991. I continued to remain with my Primus medical unit in Denver, Colorado until I was found NPQ in June 1995.

In Baharain, my duties were that of a Triage Receiving Medical Officer at Fleet Hospital VI. I was stationed at various times at Shakiza Air Base and at Baharain International providing triage in the event of multiple casualties coming in from Desert Storm.

My exposure was limited to that of some casualties that had been forwarded to a higher tertiary care facility for medical treatment. We did indeed have nocturnal scud attacks, and only on one occasion did a scud land within one mile of our compound. During deployment we did receive the immunizations that were required of us including the Anthrax provided by the military.

Upon my return from Desert Storm, I continued on with my unit and returned to my medical practice. However, I started noticing the onset of headaches, abdominal pain and chronic diarrhea that occurred after ingestion of any meat products. In fact, at one point in time, we thought we might have purchased a tainted cow. We contacted the Department of Agriculture to do an extensive assessment of our meat to see if there was improper processing. We were finally informed by late 1991 that the meat was not tainted and of good quality.

I continued on with intermittent symptoms, and finally by 1993 I developed bloody diarrhea and was eventually hospitalized with the diagnosis of ischemic colitis, rarely seen in anyone of age 39. Usually this is due to either advanced atherosclerosis and/or exposure to some type of environmental toxin. After receiving GI consultation and modification of diet, this problem seemed to have resolved by late 1993.

In May 1994, I started developing suboccipital neck pain. This was eventually diagnosed by MRI in June as a possible herniated disk in my neck, and in July 1994, I underwent a C6-7 cervical decompression and fusion. However, by November 1994, I continued on with pain and it was felt that the repair had developed a pseudoarthrosis and I underwent repair of an additional level and refusion of this area.

However, by May 1995, I was unable to continue work secondary to severe pain. A further diagnostic workup demonstrated a C2 body and odontoid lytic lesion. Following three additional neck surgeries with exposure biopsies and eventual excision, I was found to have an osteoblastoma of C2 body and odontoid process, that closely represented an osteosarcoma. At that time transoral resection was performed with C1-C2 fusion. Complications sustained from surgery included that of a paralyzed vocal cord and esophageal dismotility requiring several months of nasal gastric feedings and a vocal cord repair.

By that time, I had been incapacitated for approximately one year, no longer found to be deployable and I was released from military, nonphysically qualified in June 1995. At that time I did not correlate any of my symptoms as being related to Desert Storm. However, upon my discharge physical, there was another young lady in our unit who had developed a thoracic fibrosarcoma in September 1994 and had spent the last seven months undergoing chemo and radiation therapy. I was also informed at that time that another member of our unit had developed metastatic breast carcinoma and was expected to die from this disease. She subsequently passed away.

After being found to be nonphysically qualified from military duty, I was asked to file with the Department of Veteran's Affair for the Persian Gulf Registry Health Examination Program. Application was acknowledged on July 7, 1995. On July 26, 1995, I was scheduled for an initial physical examination and because of schedule conflicts I was rescheduled for September 20, 1995. At that time, I mentioned my neck problems, wrist problems, knee problems and my ischemic colitis.

Finally, by February 23, 1996, I received a notification from the Veteran's Administration Hospital requesting additional information. Upon forwarding this information on April 2, 1996, I received opinion from the V.A. Hospital claiming that there was no service connected disability concerning the C2 osteoblastoma and the ischemic colitis. These were felt to be non-service connected and no link to my military service.

I wrote an additional letter to the Veteran's Administration claiming that other members had had similar illnesses. They apparently felt that this was still a non-related phenomena, but

May 14, 1998
Congress of the United States
House of Representatives
Committee on Government Reform
and Oversight
Attention: Subcommittee on Human Resources
Christopher Shayes, Connecticut Chairman
Subject: Written Testimony of Alexander Cianflone, M.D.
Page 4

in either event, I was given a second letter on September 13, 1996, again restating the Veteran's Administration position.

On June 20, 1997, the claim was transferred to a new officer, Raymond B. Moore. Again, review of my medical condition was performed January 28, 1998. When I presented myself for examination, they said I was only there to be evaluated for my knee and wrist, and that the conditions of my neck and ischemic colitis were felt not to be service connected and would not be addressed on that visit.

At that time, a very substandard physical examination was performed because the physician examined the joints of concern without direct visualization of the specific joints. Again, he was instructed not to address the other issues, especially those concerning the cervical spine.

A letter was addressed to me on April 2, 1998, again denying any basis for service connected disability.

It is not my intention to collect any compensation for these disabilities. This is not of my concern. What is of more concern is that we had two individuals, myself included, out a unit of 40 individuals who developed rare bone and soft tissue malignancies. These are of rare incidence with only 5,700 new cases diagnosed in the United States in the entire year of 1990, including all types of soft tissue and bony malignancies. There have been two other members who have developed breast cancer, one of whom has died from it.

It appears to me that it would be efficacious for the Veteran's Administration to develop an accurate information data base system documenting the incidences of tumors and other serious diseases among the veterans of the Gulf War. Statistically, if it should be documented that the incidence of these malignancies occur at a much greater frequency with the Gulf veterans as compared with the general population, I think it would be safe to say that illnesses such as the one I have may relate in some way to some type of environmental, toxic exposure during Operation Desert Storm.

Submitted May 14, 1998.

Sincerely,

Alexander G. Cianflone, M.D.

AGC:jr

Mr. SHAYS. Larry Hawkins.

Mr. HAWKINS. My name is Larry Hawkins. I was formerly with the U.S. Marine Corps. I served as a Gunnery Sergeant. I served 1 year in Vietnam, and I stayed in the Reserve, and our unit got called up for Active Duty for the Persian Gulf. We were assigned to Jabaal where, upon arriving in Jabaal, about 2 to 3 weeks after we arrived, I started having these symptoms of diarrhea, stomach problems and nausea.

I went to the medical personnel there, which were the corpsmen, and they informed us it was probably a lack of getting used to the climate and the food that we were eating. After that, they gave us some pills to take care of the problem, which seemed to work at the time, so we went back to performing our regular duties.

After this, about a month or so later, we received an order that we were going to have a company formation which—we were then told that we had these PB pills that we had to take, and these were supposed to bring our immune system up to 100 percent for the biological or chemical warfare that Saddam Hussein might use upon us.

After that—we took the pills and people started having different symptoms from those. They were very erratic. They did stuff that normally wasn't what they were supposed to be doing. After that we—I continued to be sick after that. Then I returned back to the States. Upon that I started feeling a little better, but my condition worsened.

I went to the VA hospital here in Washington, DC, where I met with Ms. Esther Cooper and she informed me—she introduced me to Dr. Murphy, who put me into this program at the VA which seemed to help, but after she left, the problems increased and the VA, I don't know, they just didn't seem to help.

So I went to my personal physician, and that's when I was diagnosed with cancer in my small intestines. I was put on a bunch of lists for CCEP and they sent me forms which I filled out and sent back. I was also put on the DOD Veterans' Gulf war list, and the same thing with them; I filled those forms out, they never really did anything. I guess they were collecting some type of data, and every time I would fill them out and send them back in, I never heard anything back from them.

VA scheduled me for a physical, and I was in there for approximately 1 month, and they really didn't do anything for the problem that I had. They were trying to say that I had stress and other things. That really wasn't what my problem was, and so I left there, and that's when I started going to my personal doctors and that's when I found out that I have the problem that I have now. That's pretty much where I am right now, to date.

[The prepared statement of Mr. Hawkins follows:]

Statement of Larry W. Hawkins

My name is Larry Hawkins. I served as a Gunnery Sergeant in the United States Marine Corps during Operation Desert Storm. I was attached to the First Marine Division in a reconnaissance unit. My unit was based in Jabaal and we were actively involved in the incursion into Kuwait and it's liberation. I am also a Vietnam Veteran.

Prior to my tour of duty in the Persian Gulf I was in very good health but shortly after my arrival in Saudi Arabia I began to experience gastro-intestinal problems. I also had headaches, muscle cramps, and other flu like symptoms. I reported these symptoms to the medic and I was told it was probably a result of my body adjusting to the climate change. I was given medications to treat the symptoms and they would lessen for a while and then return. We had a battalion formation about a month after we arrived and at that time we were informed that chemical and biological agents might be used against our forces. We were instructed to take some pills including P.B. tablets that, we were told, would boost our immune systems and supplement the shot we had previously been given. No information about either the shots or the pills was entered into my shot records.

Once hostilities actually began my unit was subject to frequent Scud alerts during which we had to wear full protective gear. During several of these attacks chemical alert alarms sounded indicating the presence of chemical or biological agents. My unit was also subjected to environmental hazards caused by the oil fires set by Iraqi troops.

After my return to the United States I believed that my health problems would end but they did not. Instead the diarrhea continued and I began to loose weight and miss time at work. I went to the V.A.Hospital in Washington, D.C. for treatment. I was told that I had a parasite and that it would eventually go away without treatment. When I did not get any better I went to a private gastroenterologist, who conducted several tests but was unable to determine the reason for the diarrhea. He did, however, tell me that there was no evidence of parasites in my system. He gave me medications to control the symptoms but could not determine the cause.

I began attending a counseling group at the V.A. facility in Silver Spring, Maryland in the fall of 1993 and they assisted in registering me in the DoD Comprehensive Clinical Evaluation Program, as well as the V.A. Gulf War Health Registry.

The C.C.E.P.'s only action was to send me a number of forms, which I completed and to follow up with a telephone call to verify the data from the forms. About six months later I received another call to update my health condition. I was given no information or other assistance.

The V.A. scheduled me for a number of tests at the Veterans' Hospital in Washington, D.C. in September and October of 1993 . The testing consisted of medical and psychological examinations, blood tests and a neurological test involving electrical stimulation of the muscles. I was not given any type of gastro-intestinal examination, despite the fact that my major symptom was chronic diarrhea. I never received any diagnosis or treatment from the V.A. Hospital and no further action was taken.

Toward the end of 1993 I became very ill, losing over 40lbs in a month and at that time I was

admitted to the V.A. Hospital. They were unable to determine the cause of my illness and I was discharged. At that time I applied for a V.A. Disability Pension and I was awarded a 10% pension payment.

In early 1995 I applied to the Veterans' Administration for an increase in my disability pension because my symptoms had worsened. In addition to the diarrhea I was experiencing leg cramps and chronic insomnia. My appeal was denied because I could not prove that the additional symptoms were service related. My case was reopened in 1996 and again denied.

In August of 1996 I became very ill. I experienced vomiting for several days at a time and lost weight rapidly. I went to my gastroenterologist and he did an endoscopy and a colonoscopy. He was unable to diagnose what was causing my illness and began to treat me for an excess acid condition. Despite the treatment my condition continued to decline and he ordered a C.A.T. scan. On October 8, 1996 I was hospitalized at Prince Georges Hospital and within two days I had surgery to remove a tumor, which was causing a blockage of the small intestines. The tumor was malignant and I was diagnosed with adenocarcinoma of the small intestines. The cancer had spread outside the original site and the lymph nodes were also cancerous. I began a course of chemotherapy in November 1996. I filed another request for an increase in benefits because of the cancer and it was denied.

I continued the chemotherapy until May of 1997, when I was again hospitalized because of recurrent tumor masses in my small intestines and on the abdomen wall. I underwent three surgeries within a two week period. The first was to remove the tumor on the abdomen wall and to resect a section of intestines that had become blocked by a tumor. There was a large number of small tumors throughout the intestines that could not be removed because of their number. The second surgery was done about five days later when one of the remaining tumors caused another blockage. The third surgery was an attempt to save my right kidney which was unable to function because of a tumor on the urethra. The surgery was not successful and the kidney is now nonfunctioning. I was hospitalized for over a month . I began a new type of chemotherapy one week after my release from the hospital. As a result of the cancer and the side effects of the chemotherapy I was no longer able to work. I experienced a great deal of pain and I became fatigued with the smallest amount of activity.

My case was reopened in August of 1997 and I was sent to the V.A. Hospital for a battery of tests including medical and psychological examinations. I filed several forms for the release of medical records from my private doctors to document the cancer and the treatment I had received. My case was originally being handled by the Philadelphia office of the Veteran's Administration but it was then transferred to the Washington, D.C. office . I spoke with the V.A. claims officer assigned to my case on two occasions, once in November and again in January 1998. He would not give me any information other than to say that a decision would be made within a couple weeks. In March 1998 I finally received the decision. My request had been denied because I could not prove that the cancer is related to my service in the Persian Gulf. This type of cancer is very rare and little is known about it's causes but it would seem to be more than a coincidence that I suffered from gastro-intestinal problems beginning during my service and that the cancer developed in my small intestines. The explanation provided by the V.A. for the denial of my claim stated that insufficient evidence was submitted which was particularly frustrating since they failed to obtain any of the medical records for which I had

given them releases. I was very angry and felt betrayed by this denial of my claim and the fact that the V.A. hadn't even made the effort to get the records that could support my claim.

I wrote to Senator Paul Sarbanes and asked for his help with this situation. Within a week of my letter being received and acknowledged by Senator Sarbanes office I received a call from an appeals officer at the V.A. She told me that she was reviewing my case and she admitted that none of my medical records had been obtained previously. I met with her on April 29, 1998 and provided her with copies of the records. She promised that she would write her decision within a week and send the claim to processing. She told me that I should hear from the V.A. within 30 days. I must admit that I am skeptical at this point.

My health has never returned to what it was before my service in the Persian Gulf and for almost two years I have suffered with a cancer that no one can explain. I am in pain a great deal of the time, I have no energy and become fatigued with the slightest exertion. For over 20 years I worked as a Federal police officer, now I cannot hold a job. My illness has put a tremendous strain on my family both emotionally and financially and the Veterans' Administration tells me that I am not entitled to anything more than a 10% disability because I cannot prove that my cancer is a result of my service in the Persian Gulf. Doctors and researchers have been trying to find the cause of this type of cancer for more than 10 years and have been unable to, but the V.A. expects to me to do just that. They have shifted the burden of proof on to me instead of giving me the benefit of the doubt.

I am bitter, not with my Country which I was proud to serve, nor with the U.S. Marine Corps but with the Veterans Administration. They diminish what I have sacrificed to do my duty and, without even making the effort to investigate my claim thoroughly, they tell me that I am not credible. They seem to have lost sight of what their agency was set up to do in the first place, assist veterans not rob them of their dignity. There have been individual employees of the V.A. who have really worked to help me but they are in the minority and their frustration with the limitations and uncaring attitude of the agency as a whole was evident. I served my country when I was called and now all I'm asking for is Justice.

Larry W. Hawkins served in the United States Marine Corps for over twenty years including a tour in Vietnam and the Persian Gulf.

Mr. SHAYS. Thank you. You summarized your testimony. Let me just be clear on a few things before we go to our next witness.

You were at the VA hospital—you went to the VA first?

Mr. HAWKINS. When I came back from the Persian Gulf.

Mr. SHAYS. And you were not well?

Mr. HAWKINS. Right.

Mr. SHAYS. And you did not have a diagnosis of any tumor while you were at the VA?

Mr. HAWKINS. That's correct.

Mr. SHAYS. So you went to your private doctor, who diagnosed you with——

Mr. HAWKINS. Cancer in my small intestine.

Mr. SHAYS. Then you went back to the VA?

Mr. HAWKINS. Yes.

Mr. SHAYS. Thank you. We will ask more questions, but I just wanted to be clear on that. Thank you.

Lieutenant Colonel Kem.

Colonel KEM. Before I get started, I need to preface my statement that I am appearing in uniform at the invitation of the subcommittee. However, I am not appearing in an official capacity, and I'm testifying as an individual about my personal experiences, so this testimony does not necessarily reflect the views of the Department of the Army.

Mr. SHAYS. You are here at our request and the military respects that you are here, and anything you say in response to our questions is something you need to say and the military understands that.

Colonel KEM. In August 1990, I was assigned to the 82d Airborne Division and deployed to Saudi Arabia. While deployed I worked primarily in an office environment and worked 12-hour shifts doing intelligence analysis. During the deployment I was given PB pills as well as other pills and immunizations. I'm not sure what I was given, but there was major concern of an Iraqi attack into Saudi Arabia, so very few questions were asked. Pesticides such as DEET were used because of the persistent flies and other pests.

Our meals varied during the deployment, starting with airline meals, Hardees meals and moving to locally prepared meals. We ate few military meals, such as the Meals Ready To Eat, because of the concern to keep the prepackaged meals for wartime use.

We were also concerned about the availability of bottled water, so the local water supply was deemed safe at times for us to drink, and then it would be declared unsafe. This cycle happened several times during my deployment.

As a result of the diet, differing water supplies and dramatic climate change, many became sick with diarrhea and flu-like symptoms. The medical care in Saudi Arabia was super because of the buildup, but there were shortages of some medicines, such as Imodium, and so we would just drink lots of water and eat crackers and let the diarrhea run its course.

I continued to have this diarrhea after several weeks in Saudi Arabia, and these problems also included a rapid heart rate, blurred vision and weak and dizzy.

As a result, I was redeployed back to the United States in September 1990 for medical reasons. When I returned, I was medically

evaluated and found unfit for duty, but was allowed to stay in the service with a waiver. I remained in the 82d Airborne Division and served as a battalion executive officer on jump status and was able to run 8 to 12 miles.

In 1993, I was assigned to a NATO headquarters in Izmir, Turkey. While in Izmir, I started to have medical problems, most notably persistent diarrhea, losing more than 25 pounds in the first 3 months in Turkey. I also began having more heart problems, which were checked by the physicians in Izmir. During one of these checks in 1993, a Turkish contract physician noticed a bulging over the right heart border which he felt was due to previous surgery. This turned out to be more than just tissue from a previous surgery.

In April 1995, I returned to the United States, and I felt terrible. Immediately upon my return I saw a doctor for shortness of breath, muscle soreness and dizziness, which continued for several months.

In August 1995, I was still having difficulty in running and felt tired all the time, so I requested a chest x ray. This x ray and CAT scan indicated a 7-centimeter mass in my chest. I was then scheduled for surgery at Walter Reed, and in September 1995, the Walter Reed surgeons removed a 6 by 4 by 8 centimeter tumor, which is roughly the size of two bars of soap.

The initial biopsy results indicated a thymoma which appeared to be encapsulated with no evidence of capsular invasion. Based on these results, I was discharged from Walter Reed for what was felt to be a benign tumor, totally encapsulated and noninvasive. Two days after I left Walter Reed, the pathology results were amended to show invasive cells into the surrounding mediastinal fat. This pathology report also stated that such invasions may locally recur without additional therapy and appropriate followup was recommended. I was not told of the amended results and there was no followup.

Over 2 years later, in October 1997, I requested copies of all of my lab reports, so I could have them for my records. This is when I discovered that the pathology reports had been amended. I was greatly concerned over this changed diagnosis because it meant the difference between a benign and malignant tumor. I had been told at Walter Reed 2 years prior that if I had invasive or malignant tumor, I would need both radiation and chemotherapy. When the results showed a noninvasive tumor, this was not considered necessary.

Last month I had a third CAT scan after this, which showed a result code of abnormality, attention needed, and showed a mass of 1.5 centimeters and also two other masses which were seen on previous CAT scans. I am scheduled for another CAT scan in June to see if my cancer has returned.

This tumor has other implications for my health. As a result of the surgery, my phrenic nerve was severed, which has caused a paralysis of my right hemidiaphragm. Additionally, I have been diagnosed with myasthenia gravis, which is a neuromuscular disease. Myasthenia gravis has as much as a 75 percent correlation with a thymoma, the type of cancer I had. Myasthenia gravis is an autoimmune disease which explains some of my other symptoms that I had after the Gulf, including dizziness, double vision, and fatigue.

I entered the medical registry for the CCEP in April 1997. I have gone from Phase I to Phase II, and began Phase II in May 1997. I have had a large number of consults which have resulted in the following diagnoses: myasthenia gravis; migraine headaches; paralysis of my right hemidiaphragm; Raynaud's phenomenon, which is a circulatory disorder; chronic inflammation of my gastrointestinal system, which is possibly colitis; tinnitus in my right ear, which is felt to be autoimmune related; and a persistent skin rash that I have had since the Persian Gulf. Many of these problems appear related to the autoimmune.

I have also had several cardiac consults, as well as two heart procedures for my continued rapid heartbeats. These have not been completely successful, so I still have rapid heartbeats and problems with two of my heart valves, which only complicate the other issues with myasthenia gravis, my lung function and autoimmune.

I would say that my care under CCEP with specific physicians has been exceptional. I received excellent assistance in scheduling these many appointments, and if there is one area of the CCEP that is lacking from my standpoint, it is looking at the correlation of the data and also the lack of any long-term epidemiological studies of Persian Gulf war veterans.

Thank you for this opportunity.

[The prepared statement of Lieutenant Colonel Kem follows:]

11 May 1998

MEMORANDUM FOR: The Honorable Christopher Shays, Chairman, Subcommittee on Human Resources, Committee on Government Reform and Oversight, House of Representatives, Congress of the United States.

SUBJECT: Persian Gulf War Illness Written Testimony

1. In accordance with your May 1, 1998 letter concerning the thirteenth Subcommittee hearing regarding the incidence of tumors and other serious diseases among veterans of the Gulf War, the following testimony is presented:

a. I deployed to Saudi Arabia on 13 August 1990 as part of the initial deployment to Operation Desert Storm with the 82d Airborne Division headquarters. I was assigned as the Chief, Division Intelligence Support Element and was stationed at the base camp known as Champion Main. As a member of the 82d Airborne Division, I had taken most of the required immunizations for world-wide deployment. As a result, the only immunization for pre-deployment that I was given was gamma globulin -- a normal procedure in for.deployments.

b. Prior to deploying to the Gulf, I had several health problems, most notably two heart surgeries for an atrial septal defect in January 1989 and January 1990. Immediately prior to deploying to the Gulf (9 August 1990) I underwent a heart catheterization and several other cardiac tests (including a stress test and pulmonary function tests) that indicated no recurrent problems which cleared me for deployment to the Gulf (no restrictions to duty or activity) on 10 August 1990. During the deployment, I worked primarily in an office building and worked twelve hour shifts doing intelligence analysis and production.

c. During the deployment, there were a number of immunizations and pills that we were given at various times. I was given the PB pills, as well as others. I am not sure exactly what all I was given -- but there was major concern at that time that an Iraqi attack into Saudi Arabia was possible, so there was little question at the time. We were all given immunizations for spinal meningitis, as well, since there had been a report of a case of spinal meningitis in theater. In addition, pesticides such as DEET were used on a regular basis because of the persistent flies and other pests. Our meals varied during the initial deployment; initially, we were given local meals which appeared to be airline meals that were locally purchased. Shortly afterwards, we received meals from a Saudi Hardee's that had been reportedly turned over to the US Military. A week after this, we started eating in a mess hall that served locally purchased meals that were prepared on site. There was great concern about the initial stockage levels of military MRE's, so we were limited to one MRE a day. We were also concerned about the availability of bottled water, so the local water supply was deemed safe at times for us

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to drink -- then it would be declared unsafe so we would go back to drinking bottled water. This cycle happened several times during my tour in Saudi Arabia.

d. As a result of the changing diet, differing water supplies, and dramatic climate change, many of us became sick with gastrointestinal problems. The medical care was super in Saudi Arabia -- the build-up has caused a lot of doctors to be deployed, so we had access to a number of specialists on site. There was, however, shortages of some of the basics, such as immodium, so most of us drank lots of water and ate crackers and let the gastrointestinal problems run its course.

e. On 25 August 1990 I first went to one of the physicians concerning rapid heart rate and gastrointestinal problems. I was started on medication for the rapid heart rate (PSVT) and was returned to duty. On 10 September 1990 I returned for a follow-up, and still had the rapid heart rate, was weak and dizzy, and had blurred vision. Subsequently, I was returned to the United States on 25 September 1990.

f. Upon my return to the United States, I was given a medical evaluation board and physical evaluation board and was found not fit for duty based upon the rapid heart rate (PSVT). I appealed this decision and requested a continuance on active duty, which was granted. I remained in the 82d Airborne Division and returned to a healthy state -- serving as a battalion executive officer in the division. Before leaving the 82d Airborne Division in June 1992, I was again running long distance runs (8-12 miles) and was in excellent physical condition. I also received my Master Parachutist Wings prior to leaving the 82d.

g. My next assignment was as a student at the Air Command and Staff College, which I completed without any medical problems. After completing Air Command and Staff College in June 1993, I was assigned to a NATO headquarters in Izmir, Turkey.

h. While in Izmir, I started to have a number of medical problems, most notably gastrointestinal problems -- which were not unusual in this assignment. During this assignment, I also began having more heart arrhythmia's, which were checked periodically by the American military physicians in Izmir. During one of these periodic checks, I received a chest x-ray on 21 November 1993 which was read by a Turkish contract physician, who noted a "lobulated bulging over the right heart border" which was felt to be due to previous heart surgery.

i. In April 1995 I returned to the United States, and had greatly diminished exercise capacity. Immediately upon my return I saw a military physician at Fort Huachuca. I had shortness of breath, muscle soreness, and dizziness when standing. I was given medication for the muscle soreness (motrin) and for dizziness and returned to duty.

m. I was assigned to Fort Bragg in June 1995 and returned to see a military physician in August 1995. I was still having enormous difficulty in running and felt tired all the time. I requested a chest x-ray. This x-ray indicated a 7 cm intermediastinal mass. A

subsequent CT scan confirmed the mass, and I was scheduled for surgical consult at Walter Reed Army Medical Center.

n. On 11 September 1995 I underwent surgery at Walter Reed. The surgeons removed a 6 by 4 by 8 cm anterior mediastinal mass densely adherent to the mediastinum and the lung. The initial biopsy results on 14 September 1995 indicated a spindle cell thymoma with the following comment, "This thymoma appears to be grossly encapsulated and the histologic sections that have been examined do not show any evidence of capsular invasion. However, additional sampling of the capsule will be undertaken and histologic sections reviewed and reported in an addendum." Based on this diagnosis, I was discharged from the hospital on 16 September 1995. At this time, the thymoma was felt to be totally encapsulated and non-invasive.

o. Two days after I left Walter Reed, 18 September 1995, the final diagnosis was entered by pathology of "Invasive Spindle Cell Thymoma" with the following notes: "Neoplastic cells extend through the capsule of the neoplasm into the surrounding mediastinal fat. Neoplastic cells are present within less than 1 mm of the inked surgical margin. See comment." The comment was: "This neoplasm has all of the microscopic features of a conventional thymoma, however, there is capsular invasion with extension of neoplastic cells into the surrounding mediastinal fat on microscopic sections. Neoplastic cells are present within less than 1 mm of the inked surgical margin. Such invasive lesions may locally recur without additional therapy. Recommend clinical correlation and appropriate follow-up."

p. Over two years later, on 10 October 97, I requested copies of all lab reports from Walter Reed Army Medical Center so I would have them in my records. At this time I discovered that the pathology results had been amended to indicate an invasive thymoma, rather than a non-invasive thymoma as per discharge instructions in September 1995. I brought this to the attention of a pulmonary physician at Walter Reed, who referred the situation to cardiothoracic surgery for resolution of changed diagnosis.

q. I was greatly concerned over this changed diagnosis -- it meant the difference between a noninvasive tumor (benign) and an invasive tumor (malignant). I had been told at Walter Reed prior to being discharged that if I had an invasive tumor, I would need both radiation and chemotherapy. When the biopsy results indicated a non-invasive tumor, this was not considered necessary. As a result, I turned to the internet to find out more information about this specific type of tumor (thymomas). Information from the National Cancer Institute (Malignant thymoma -- 208/01248) as of 12/97 describes the key difference between invasive and non-invasive thymomas:

> "Although there is no standardized staging system, the one proposed by Masaoka in 1981 is commonly employed and shown below:

Subject: Persian Gulf War Written Testimony

Masaoka stage	Extent of disease
I	Totally encapsulated
II	Capsular invasion or invasion into surrounding fat or pleura
III	Invasion into organs (pericardium, lung, great vessels)
IVa	Pleural or pericardial implants
IVb	Hematogenous metastases

Noninvasive (stage I) malignant thymoma is tumor limited to the thymus gland and has not involved other tissues. All of the tumor cells remain within a fibrous capsule that surrounds the tumor.

Locally invasive (stage II) malignant thymoma is tumor that has broken through the capsule and invaded the fat or pleura. Extensively invasive (stage III and IVa) malignant thymoma is tumor that has spread contiguously from the thymus gland to involve other organs in the chest. Spread to organs in the abdomen or metastatic embolic spread (stage IVb) is unusual at the time of presentation."

r. On 13 November 1997, a follow-up CT scan was completed, with the following findings: "A rounded area of soft tissue density is seen in the anterior mediastinum, measuring 1.0 cm, located directly posterior to the sternum. The finding is non specific, and may include neoplasm recurrence and/or postsurgical scarring. Fatty tissue is noted around this lesion posteriorly. There is no evidence of erosion of the adjacent sternum. The muscular and other soft tissue planes are well maintained. There is no evidence of thoracic adenopathy, to include the asilla, remaining aspects of mediastinum, and hila." Subsequently, a tumor board was held in November 97 to determine if there were any changes in the CT scan from preoperative scans. The tumor board findings were no malignant cytology and to follow-up with CT scan every 3-6 months. The final staging decision by the tumor board was "benign path, thymus stage II by cytology."

s. An additional CT scan was completed on 27 January 1998. The report indicated that there were no significant changes from this CT scan compared with the scan in November 1997. I was told that I would not need CT scans except for every year or so for follow-up and that there was no need for any therapy. I frankly had some problems with this report – the CT scan in November 1997 showed a 1.0 cm mass that was thought to be scar tissue; the CT scan in from January 1998 measured the mass at 1.6 X 1.6 cm; additionally, the CT scan from January 1998 indicated "two stable nodular densities" which were not noted on the previous CT scan – even though the report indicated no change. I realize that there could indeed be no change, but the report did not address the inconsistencies.

t. I returned to the pulmonary physician and explained my concern. He subsequently scheduled me for another (third) CT scan, which I had on 3 April 1998. This CT scan came back with the result code of "Abnormality – Attention needed" and indicated the

same mass of 1.5 cm, and indicated "at the anterior aspect of the right middle lobe, there is a new small focus of alveolar density. This finding was not identified on the previous examination." I am scheduled for another CT scan in the next two months to follow-up on this finding.

u. As a result from the initial surgery for thymoma in September 1995, I have had an additional complication. My phrenic nerve was severed as a complication, which has resulted in "right hemidiaphragmatic paralysis secondary to phrenic nerve injury. This problem is not likely to resolve and is expected to get significantly worse. Some lifelong disability is expected...may require MEB for iatrogenic neurologic disorder resulting from phrenic nerve paralysis." Pulmonary function tests and fluoroscopy exams have confirmed this damage to my right lung function.

v. The major complication that I have which is related to the thymoma is that I have now been diagnosed with a neuromuscular disorder, myasthenia gravis. Myasthenia gravis has a close correlation with the incidence of thymomas – as much as a 75% correlation, depending on the source. Myasthenia is an autoimmune disease – which possibly explains some of my other symptoms that I have had after the Gulf. Surprisingly, myasthenia gravis is the only disease that has FDA approval for PB as a treatment.

2. I entered the medical registry for the Department of Defense's CCEP on 16 April 1997. As a result, I entered the Phase I of the CCEP on 8 May 1997 at Fort Bragg, NC, and was referred to the Phase II CCEP. On 20 May 1997 I received my initial consult for the Phase II CCEP at Portsmouth Naval Medical Center. I was transferred to Walter Reed for the Phase II when I was reassigned to Carlisle Barracks, PA, in July 1997. I have still not completed the Phase II evaluation. My evaluation in the Phase II has included:

a. Neurology consults, which have included diagnoses of myasthenia gravis and migraine headaches. I have undergone countless blood tests and electrodiagnostic tests from neurology.

b. Cardiology consults, which have resulted in two heart procedures for my continuing rapid heart beats (PSVTs). These procedures were cardiac radiofrequency ablation procedures, and have not been completely successful in my case. I still have infrequent bouts of PSVTs as a result of a persistent dual atrioventricular node physiology. I also have had several echocardiograms for mild regurgitation of my mitral valve.

c. Pulmonary medicine consults, which have resulted in the diagnosis of paralysis of my right hemidiaphragm secondary to the thymoma surgery in September 1995.

d. Rheumotology consults, which have resulted in a diagnosis of Raynaud's Phenomenon, with "classic triphasic color changes of his hands with cold exposure and

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exertion. He gets these attacks almost daily. He has mild pain sometimes during the reperfusion stage... (and) has significant morbidity from his Raynaud's given the frequency of his attacks."

e. Gastroenterology consults, which have resulted in a diagnosis of a "chronic disorder of uncertain etiology" and possibly colitis or irritable bowel syndrome (IBS). The results of an esophago-gastroduodenscopy (EGD) and colonoscopy indicated mild nonspecific chronic inflammation and pigmented macrophages throughout my gastroenterological system.

f. Otolaryngology consults, which has examined tinitis in my right ear. After numerous tests, it was felt that this was due to possible autoimmune inner ear disease.

g. Dermatology consults, which have examined a skin rash that I have had periodically since my return from the Persian Gulf War area.

3. My care at Walter Reed for the CCEP has been exceptional; I have received excellent assistance in scheduling the many appointments that I have had in the last year. If there is an area lacking for the CCEP from my standpoint, it is in looking at the correlation of my many health problems from a cross-system standpoint and the lack of long-term epidemiological studies for Persian Gulf War veteran. As a non-physician, I have also had the opportunity to speak with many of the physicians in detail concerning my situation and have received an excellent response from many of these physicians.

4. Thank you for the opportunity to provide this testimony. I remain available to provide any documentation or additional information as needed.

JACKIE D. KEM
Lieutenant Colonel, US Army

12 May 1998

MEMORANDUM FOR: The Honorable Christopher Shays, Chairman, Subcommittee on Human Resources, Committee on Government Reform and Oversight, House of Representatives, Congress of the United States.

SUBJECT: Persian Gulf War Illness Written Testimony Disclaimer

1. In accordance with guidance from the Office of Congressional Legislative Liaison, the following disclaimer should accompany my written testimony of 11 May 1998 provided for the thirteenth Subcommittee hearing regarding the incidence of tumors and other serious diseases among veterans of the Persian Gulf War:

> *"I am appearing before the subcommittee in uniform at the invitation of the subcommittee. However, I am not appearing in an official capacity. I am testifying as an individual about my personal experiences. This testimony does not necessarily reflect the views of the Department of the Army."*

2. I request that this disclaimer letter be attached to the written testimony I have provided for the subcommittee hearing.

JACKIE D. KEM
Lieutenant Colonel, US Army

Mr. SHAYS. I am just going to suspend for a second while I talk to my colleague.

Thank you very much. All three of you have tumors and all three of you are not well. I make the assumption that—and I don't want to make the assumption, but is the military and the VA making an assumption that these are not related to your service in the Persian Gulf, or not? And I want each of you to be very clear on that.

Dr. CIANFLONE. The two letters of correspondence that I received back from the VA clearly state that there is no correlation between the tumors and the colitis with the Persian Gulf war service connection.

Colonel KEM. I have been told that there is no way that they can see a correlation between the Gulf and the tumors, but I have been personally told by a surgeon that he thought there was a higher incidence of tumors with those that served in the Persian Gulf; and that is not in writing, and I have not been able to get that officially.

Mr. HAWKINS. I also was told that mine was not related to the Persian Gulf.

Mr. SHAYS. So as long as the VA is not able or willing to calculate the incidence of tumors, they can say to each of you that there is no correlation.

Given that, what incentive is there for you to continue to work with the VA?

Dr. CIANFLONE. I have written a couple letters over the years, and after going through the indignity of another—second and very cursory VA physical and the time involved, I don't think that I'm going to pursue that again.

Mr. SHAYS. Lieutenant Colonel Kem.

Colonel KEM. I'm under DOD, and really that is where I have to receive my medical care as an Active Duty Officer.

Mr. SHAYS. Are you remaining Active Duty?

Colonel KEM. I will be retired from Active Duty because of medical problems in the next month.

Mr. SHAYS. Whose services would you come under after that?

Colonel KEM. I will probably use some options to be able to go to civilian health care.

Mr. HAWKINS. I will never go back to the VA and just stick with my personal physicians. If I stayed with the VA, I would probably not be here today.

Mr. SHAYS. Say that again?

Mr. HAWKINS. I said, if I stayed with the VA, I probably wouldn't be here.

Mr. SHAYS. Because your illness was detected by the private sector, not the VA?

Mr. HAWKINS. Yes, sir.

Mr. SHAYS. Going to the VA, given that they said there is no service-connected relationship, there is no financial incentive for you to go to the VA, No. 1. No. 2, you believe that you are getting better health care in the private sector?

Mr. HAWKINS. Yes, sir.

Mr. SHAYS. Mrs. Hawkins, you are accompanying your husband. I am more than happy to have you make a general comment.

Mrs. HAWKINS. Yes, there is no advantage for us to go to the VA. They treated my husband really shamefully. We got a 10 percent disability for the chronic diarrhea. When we applied to have that expanded, when we found that he had cancer, they denied it. They did not even get the medical records for which we provided them release forms, and they sent him an extremely insulting letter which said that he was not credible.

Mr. SHAYS. Using those words?

Mrs. HAWKINS. Exactly. We have appealed again. I had written to Senator Sarbanes, and after I wrote to him, the VA opened the appeal again, and we are hoping to hear something by the end of this month as to whether they are going to give my husband a higher pension or not.

Mr. SHAYS. Dr. Cianflone, your testimony is that among 40 people that you went in as a unit, 4 of them have tumors.

Now, in your service as a doctor, do you find that unusual, predictable?

Dr. CIANFLONE. I am very surprised. My condition, the osteoblastoma, the aggressive early osteosarcoma and the other soft tissue malignancies, those are the kinds of tumors that you would see with toxic exposure or the Agent Orange kinds of thing. That is extremely rare.

In my entire practice I only remember seeing one sarcoma in 25 years, and that is through a residency training and through the University of Colorado and all my years in private practice.

The breast cancers, I don't know. Breast cancer is a very common thing and we had a lot of women. We were a medical unit. They may be coincidental. I don't know if those were related at all.

Mr. SHAYS. But among a pool of 40 people?

Dr. CIANFLONE. It is a high incidence of cancers.

Mr. SHAYS. The range of ages is 25 to 35?

Dr. CIANFLONE. We were kind of an old unit. There were some up into the mid-50's for physicians and some of the senior nurses.

If you look at the incidence of those cancers, if you take the entire population going into Desert Storm, there should be no more than seven sarcoma-type lesions in the entire Gulf population.

Mr. SHAYS. Of 700,000?

Dr. CIANFLONE. If you look at the national statistics, two out of our unit is quite high.

Mr. SHAYS. And you are saying this as a professional doctor?

Dr. CIANFLONE. Yes.

Mr. SHAYS. Not as somebody who has been researching this issue. This is something that you have some familiarity with?

Dr. CIANFLONE. Right. You can take standard textbooks, which I even brought with me from the American Cancer Society, Clinical Oncology, and this is 1991 data. Those are not like very secretive information; they do have data nationally on that.

Mr. SHAYS. One of the things that it raises is not only would we just look at the benign, the malignant, but what other kinds; and when you have, as you point out, two rare types just within your own unit——Lieutenant Colonel Kem, it is your testimony that you had a tumor that was not diagnosed as being a malignant, or it was, but you weren't told about it?

Colonel KEM. What happened was, the pathology results came back that was a benign, noninvasive tumor. I was discharged. Two days after I left, the pathology results were amended, where it was a malignant invasive tumor. And I discovered that myself 2 years later; I was not told.

Mr. SHAYS. And you discovered it through——

Colonel KEM. I was stationed in North Carolina. My health care had been in the District of Columbia at Walter Reed, and I asked for copies of my records, so I would have them available.

When I asked for those copies of records, that's when I read through them and saw that the pathology results had been amended.

Mr. SHAYS. You obviously were very distraught to find this out. But also you wanted an explanation. What was the explanation?

Colonel KEM. I never received an explanation other than just, systemically, they never followed up on it.

Mr. SHAYS. I make the assumption that if you have a malignant tumor, the sooner you know about it the better.

You have gotten no official response, one, apologizing; two, explaining; and, three, saying "you were not notified, we take responsibility," we being the military?

Have you received any of those three?

Colonel KEM. No, sir. What I have received is follow-up care. I have received a reaction in terms of them doing more CAT scans to see my current status.

Mr. SHAYS. That would happen anyway?

Colonel KEM. Yes, sir.

Mr. SHAYS. I don't usually do this, but I would want our committee to followup on this case, because I need to know how the military thinks in terms of this kind of response. It would seem to me that they have put your life in further jeopardy, and they simply not only owe you an apology, but they owe you extra care. And they hold some liability, it would strike me. So I would encourage you to work with our committee staff on your particular case, in addition to what you are helping us understand.

Mr. Hawkins, you are very credible and that's why you are here and that's why your wife is here. We haven't yet been able to understand why you and other veterans get the kind of response that they get, and that's the purpose of this hearing.

Is there anything that you would like to tell me before I give the floor to Mr. Kucinich?

Mr. HAWKINS. Just on the VA or the system in general?

Mr. SHAYS. Whatever you would like to say.

Mr. HAWKINS. The VA, you are just a Social Security number and they don't look at you as a person. Like I say, it was only a couple of people there, like Mrs. Cooper and Dr. Murphy, that really took any interest in what we were trying to tell them. And after that, you just went somewhere; and it was like, we see you, but we don't see you.

Mr. SHAYS. I may come back, depending on what we learn from further questions. We are joined by Mr. Sanders from Vermont, who has been extraordinarily active on this committee on these issues and knows as much as anyone; and also Mr. Kucinich, who has also been very active.

Mr. Kucinich, why don't we start with you, and then we will go to Mr. Sanders.

Mr. KUCINICH. Thank you, Mr. Chairman, and thank you for your undaunted dedication to the health of veterans who have served this country. I am particularly interested in the testimony of Dr. Cianflone.

Now, most of the people who have been affected by this syndrome have not been medical doctors with the background you have. What occurs to me is that when you first presented symptoms, how would you describe the workups that were done by the VA? Were they pretty conventional?

Dr. CIANFLONE. I never—like I said before, I never correlated my symptoms as being related to my contact in the Gulf until I presented myself for a discharge physical from my Active Duty Reserve unit.

When I did present myself for the physical, as when I registered myself for the Persian Gulf thing, I brought my x rays, I brought all of my medical reports. I brought the fact that there was another person in my unit that had had a fibrosarcoma, and this was in a similar category. I made all of those available to the physician and to the individual that checked me in.

They told me that if they wanted that information, they would request it at a later time. They did not even look at it.

Mr. KUCINICH. They didn't look at what information?

Dr. CIANFLONE. The CAT scans, the physician reports, the operative reports. I brought them for my initial physical as part of that Persian Gulf registry.

Mr. KUCINICH. When that happened? How did you respond?

Dr. CIANFLONE. I was quite surprised. I had given them a statement in my initial application, and I thought perhaps they would respond to that. But the response came months later with a no correlation, nonservice connected, either of those two categories. I brought pathology reports on the ischemic colitis. I brought the pathology report and also Mayo Clinic reports on the osteoblastoma.

They apparently felt—I had other service-connected injuries, and I think that is what they thought I was there for, and that was the knee and wrist injury.

Mr. KUCINICH. You are a medical doctor. Is it your opinion that this was a case—I'm speculating here because so much of this has to involve speculation, that it was just a misdiagnosis, or was there a mind-set that said, you know, buck up, you are not that sick?

Dr. CIANFLONE. I think the latter part was there. I think—if they didn't see it happen to you, then it didn't happen. When I had a fall in Baharain and injured my wrist, I had surgery. But these other nebulous issues it was obvious that they did not want to get into, or the physician that was assigned my case at that time was simply instructed not to address those issues.

Mr. KUCINICH. This is a point, and I think we have gone over this territory at other times—Congressman Sanders and I have had this discussion—the practice of medicine involves certain regimens for treatment, but it doesn't always involve a policy which stands behind that which limits the diagnostic potential or the treatment regimens.

Would you say it is a fair characterization that you and other veterans were put in a situation where the paradigm was such that it would not accept the possibility of some other reason for the illness?

Dr. CIANFLONE. I would agree with that. I think there is so much mentality that the average veteran has a problem of "compensationitis," and that was the only reason that they are there.

I was really there more with the concern that I had with myself and my other fellow member on my unit. I thought there would be a value to the overall veteran serving in the Persian Gulf if I was to register myself as having this malignancy and that would, in turn, help identify other individuals.

Mr. KUCINICH. I think, Congressman Shays, I think this testimony is extremely important because if a medical doctor, who obviously has training and experience far beyond any layperson, presents certain symptoms; and as we look retrospectively, we find out that this system may have been set up to ignore the problems, which means that there was no diligence or attention paid as a matter of policy, this wasn't a matter of doctors who didn't know what they were doing. It almost sounds like a variation of HMOs where people can't get specialized care because it is adverse to the economic interests of the insurance companies.

And we are considering certain laws, and we have passed certain laws which require steps of treatment; and doctors have a duty to disclose, they can't refuse to refer for specialized treatment. It sounds like there was a policy, and the policy said that there is nothing wrong.

The problem with your wrist, yes, we will take care of that; that was obvious. But when it came to something particular, there was a policy not to explore it, probably because there was a concern about the consequences if something was found.

I find this very disturbing, and it is very important to have all of these witnesses here, and I don't think that anyone can understand what you are up against because your lives are on the line with this. As a Member of Congress—and I share this with Mr. Shays and Mr. Sanders—there are Members of Congress who are very concerned about this and that it was ignored as a matter of policy.

You have so many of the symptoms that are present, and each presentation of symptoms provides for a certain type of diagnosis; but then when they kept on expanding with the difficulties, obviously there was something much larger than colitis or whatever, and yet they never got to that. And I don't think that is because we don't have good doctors at the VA. I think we have very good doctors at the VA. I think it was because they were told not to; that's what I think. I hear this testimony, and it continues to be shocking, just shocking.

Thank you.

Mr. SHAYS. I thank the gentleman.

Let me ask you, were any of you diagnosed early on as having posttraumatic stress disorder?

Dr. CIANFLONE. No.

Colonel KEM. No.

Mr. HAWKINS. No.

Mr. SHAYS. Mr. Sanders, you have the floor for 10 minutes.

Mr. SANDERS. Thank you, Mr. Chairman.

I'm not into hyperbole much, but I want to reiterate my thanks to the chairman and his staff for being on the cutting edge in Congress in exposing what the VA has been doing for so many years. I thank you, Chris, and your staff.

I also want to thank the witnesses for coming here today. I know that this is not a happy or easy thing for you to do, but some of us appreciate what you are doing, and it helps us understand the very serious problem that we have got to address. I thank you very much for coming.

I think what this hearing indicates to us, to me, is that the VA and the DOD's handling of Gulf war illness, I think, from a historical perspective will be regarded as one of the most shameful activities of the United States Government's history. From beginning to end, it has been an enormous disaster, and the reason that the chairman just asked if you had been diagnosed with posttraumatic stress syndrome, there are still high officials at the VA who think that the cause of your problems and the illnesses that are affecting some 70,000 or more Americans is stress; and they will tell you that with a straight face. And I apologize for that. We are doing what we can to change that, but that is the reality that exists.

What this hearing tells us not only with regard to the problems that you are having and the horrible misdiagnosis of you, Lieutenant Colonel Kem, and the shameful treatment of you, Mr. Hawkins, is that quite probably the issue of Gulf war illness is far more serious than we think it is; and the people up here think that it is very serious.

What I'm learning from this hearing is that there are probably many, many folks who served in the Gulf war who may not have been properly diagnosed, who may or may not have cancer or other diseases.

I come from Vermont, and we didn't have tens of thousands of men and women going over there. We had relatively few. Don Edwards, who is a former adjutant general from the State of Vermont, went out of his way in the State to find out. We were aggressive, finding out how many folks were suffering from one or another symptom, and we found out, in our small State several hundred Vermonters were suffering from one or another symptom of Gulf war illness. And if that ratio was taken all over the country to the folks that served there, my guess is that the number of people who are ill is much higher than we think.

But people on Active Duty, are they going to say that I'm suffering from one symptom or another and then expect to see that paycheck? I see you smiling, Lieutenant Colonel Kem, and I think you know the answer. They need their jobs. Mr. Hawkins, they need their jobs. They are not going to say, gee, I have short-term memory loss, but I want to stay in the Army. So we think that the problem is probably a lot more severe than we have been led to believe.

I think that, as I have said many times and I know that the chairman and Mr. Kucinich have also felt, the difficulty is that we are dealing with a new medical paradigm, and that is the Gulf war theater was a chemical cesspool. Many of our soldiers were given

bromide. They were given various other drugs, and then they were exposed to a combination of very toxic substances, uranium and God knows what else; and it is, to my mind, very likely that the synergistic effect of all of those chemicals may well have caused many illnesses.

I just want to thank the chairman again for highlighting this issue, and I intend to keep working with him until we find a real resolution.

I think, Mr. Chairman, perhaps the only bright light that I can see, and let me also tell our guests here, that after 7 years, if I were to ask you what the treatment protocol now is, forget even cancer, but for all of the symptoms that are out there, do you know what the VA has for a treatment protocol? They don't have one. Seven years have come and gone and they do not have a treatment protocol. But I think the good news is, at least some people in the VA are moving forward and trying to develop a treatment trial that we hope to get under way in a few months.

I would just like to thank you all very, very much, and I will participate as the discussion flows.

And thank you, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

Dr. Cianflone, you made the point that there were a number of Scud missile attacks and there was an interception.

Dr. CIANFLONE. It was a mile from our fleet hospital.

Mr. SHAYS. You didn't have any symptoms from the Gulf war until you returned home?

Dr. CIANFLONE. That is correct.

Mr. SHAYS. Lieutenant Colonel, do you have any suspicions as everyone goes through the self-diagnosis, any experience that would have made you feel uncomfortable that you might, looking back, have contracted anything? In other words, were you near the Gulf war fires? You took PB. You took other vaccines as well?

Colonel KEM. I was not near the oil fires or Scud attacks. However, I did take the PB pills. I took the PB pills and other medications. The heat and water supply and other environmental factors of that area could potentially be a contributing factor.

Mr. SHAYS. Mr. Hawkins, were you in an environment where you——

Mr. HAWKINS. Yes, I was. We were evacuating the Kuwaitis, and we were in the Gulf oil fires; and one particular night we had a Scud alert, and they sent up a missile, and it blew, and this rain-like substance fell. And I think that's when most of our problems really started.

Mr. SHAYS. Are you aware that Dr. Cianflone has already mentioned 4 people in a group of 40 who have serious illnesses. Are you aware of any of the people that you served with who have found that they have tumors of any kind or any other serious illness, Lieutenant Colonel Kem or Mr. Hawkins?

Mr. HAWKINS. A few of my colleagues have symptoms, but I don't know whether they are cancerous or not, because I haven't spoken to them. They have been to the VA, but I think they have been blown off.

Colonel KEM. I don't know of anybody who has serious illness, but I know most of the people have a persistent skin rash, which is very unusual.

Mr. SHAYS. Dr. Cianflone, you were nodding your head. Do you concur?

Dr. CIANFLONE. Yes, before I came here I called our unit CO to get an update, and she is a nurse that works for the VA hospital. And I asked her if there were any other significant illnesses in our troops, and she said that a few of us have rashes that won't go away. And I asked if she ever had checked into, and she said that she felt reluctant to pursue that through the VA because she worked there.

Mr. SHAYS. Any other comment that the four of you would like to make?

Mr. Towns, would you like to question any of the witnesses?

Mr. TOWNS. No, that is fine.

Mr. SHAYS. Would any of you like to have a closing statement?

Colonel KEM. To draw back on what you said previously and what Mr. Sanders said, we have excellent physicians and I have had excellent care from individual physicians. Most of my problems have been from a systemic standpoint and the way that the system is set up and the administrative overwatch and the tie-in to see if there is an epidemiological reason for it.

Most of the physicians are quite excellent, but the system is where the biggest problems have been.

Mr. SHAYS. That seems to be the continual testimony that we have had throughout our 13 hearings. Good people to work with. Protocols, different questions being answered, data not being kept well. But you can't prove the negative. We can't prove anything if we don't gather the information, but we shouldn't make the assumption in reverse that since we can't prove it, it is not a problem.

Mr. SANDERS. Mr. Chairman, if I could just ask one question very briefly?

Mr. SHAYS. Sure.

Mr. SANDERS. The last time I met with Vermont Gulf war veterans, 60 or so of them, and I asked them if any of them are suffering from short-term memory loss, and they all started to laugh because it was—almost all of them were these were middle-aged, healthy men, hard-working people, and almost all of them had that.

Can I ask any of you if you are aware of your friends or colleagues who were over there also suffering from short-term memory loss?

Dr. CIANFLONE. Well, it would be difficult for me to make an accurate comment on that. I was fairly sick for over 2 years and could not work and was actually on disability there for awhile and on fairly high doses of narcotics, and was entertaining entering a hospice program for terminal metastatic cancer; and so during that period of time I have very little recollection of events. Certainly coming out of that has taken a little bit of a battle to regain my medical acumen and get my medical practice re-established.

Colonel KEM. I have not seen that with the people that I have served with.

Mr. HAWKINS. Me either.

Mr. SANDERS. Thank you.

Mr. SHAYS. Thank you. I would like to just ask this question. We noticed that each of you have been given psychological tests despite the presence of physical illnesses. Have you received any explanation about the reason for the tests and do you believe psychological tests should be given where physical illnesses have been diagnosed?

Were you all given psychological tests?

Mr. HAWKINS. Yes.

Mr. SHAYS. Nodding heads will not get in my record.

Colonel KEM. Yes. Sir, part of the phase II, I had psychological, psychiatric and social work exams as part of the normal protocol.

Dr. CIANFLONE. I have never had any such testing.

Mr. HAWKINS. I have had the testing, sir.

Mr. SHAYS. Thank you very much. Were you puzzled as to why you had those tests?

Colonel KEM. I was a bit surprised why I had those tests and why they were so extensive. The other thing that was surprising was in the CCEP phase II staffing at Walter Reed, the predominant personnel that are permanently there are either psychiatrists or social workers.

The others things that you have taken care of where you go for neurology, whatever, are the normal staff in the hospital. The only permanent staff appears to be related to psychological, social work-types of issues.

Mr. SHAYS. Mr. Hawkins, do you want to make——

Mr. HAWKINS. I was surprised about the test, but I also felt that it was humiliating because some of the stuff that they did was just a little outrageous.

Mr. SHAYS. OK.

I'm happy we have that for the record. It's almost like when you go to some colleges and universities, and you go to undergraduate or graduate and the professors decide what courses to teach, not the administrators, and you find that you end up taking the course that the professor got their training in, not necessarily the right course. They didn't offer the courses they should, and we found that less than a handful of people in the thousands of doctors at the VA have any real background in chemical exposure. We have, as you point out, doctors who have other expertise, and they're going to use their expertise on you whether or not it's helpful. In your cases, you have a physical challenge that is quite serious and one that needed to be diagnosed.

In your case, Lieutenant Colonel, you didn't find out until years after what they already knew; and we need to deal with that, and we will. In your case, Mr. Hawkins, you had to go to the private sector to get a diagnosis and have them take you seriously. Then when you went back, they still do not accept the fact that this illness may be caused by your service.

So I thank all three of you for being here—excuse me, all four of you for being here; and, Mrs. Hawkins, thank you for accompanying your husband.

We will go to our next panel.

Our next panel is Kwai Chan, Director, Special Studies & Evaluation Group, General Accounting Office, accompanied by Dr. John Oppenheim and accompanied by Dr. Sushil Sharma, both from the General Accounting Office.

I'll just have you remain standing because I will swear you in. [Witnesses sworn.]

Mr. SHAYS. Thank you. For the record all three have responded in the affirmative.

I'm going to say, Mr. Chan, before we start, that I hope we can have plain talking, and that I've read your GAO report. I think it's very helpful, but I need to be able to read between the lines; and I need your candidness, and I'm going to do my best to bring it out. The issues are just too serious for us not to get right to the bottom line.

But your testimony I think should be read in its entirety. It's what, six pages?

Mr. CHAN. Yes, sir.

Mr. SHAYS. Let's get the whole testimony in the record.

STATEMENT OF KWAI-CHEUNG CHAN, DIRECTOR, SPECIAL STUDIES & EVALUATION GROUP, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY JOHN OPPENHEIM, Ph.D., ASSISTANT DIRECTOR, SUSHIL SHARMA, Ph.D., ASSISTANT DIRECTOR, AND DAVID G. BERNET, SOCIAL SCIENCE ANALYST

Mr. CHAN. OK.

Mr. Chairman and members of the subcommittee, it is indeed my pleasure to be here today to discuss the results of our recently completed study on the incidence of cancer and other tumors among Gulf war veterans. Specifically, I will report on the accuracy and completeness of available data sources for determining incidence, and implications of our findings based on our analysis of the VA data.

Before turning to the results of our study, let me first introduce my team and briefly provide some background. I have with me here Dr. John Oppenheim and Mr. Sam Bernet. They worked on this study, as well as, next to me, Dr. Sushil Sharma, who is conducting much of our work evaluating Government research on Gulf war illnesses.

As you know, in the past 7 years following the Gulf war, thousands of veterans have come forward complaining of various illnesses, including cancer. Our troops were exposed to many hazardous substances, such as chemical warfare agents, depleted uranium, pesticides, organophosphates and petroleum fuels. Some of these substances have been found to be associated with different types of cancer. As we reported to you earlier, information on exposures to these substances has been either incomplete or nonexistent due to the lack of recordkeeping and measurement before, during and after the war. Without accurate and precise exposure information, it is difficult to form specific hypotheses about what types of tumors might occur. Nevertheless, it is important, in our view, to monitor and assess where the Gulf war veterans may have excess risk.

Mr. SHAYS. Mr. Chan. Would you just suspend for 1 second? I want to make sure that you have the same—OK, this is the docu-

ment that you're reading, and I want to follow word by word the document you're reading. So if you have another copy have someone bring it up to me.

I'm going to have you start with "As you know, in the past 7 years." We're going to have you start right there.

Mr. CHAN. OK.

Mr. SHAYS. We're starting over again basically.

Mr. CHAN. As you know, in the past 7 years following the Gulf war, thousands of veterans have come forward complaining of various illnesses, including cancer. Our troops were exposed to many hazardous substances such as chemical warfare agents, depleted uranium, pesticides, organophosphates and petroleum fuel. Some of these substances have been found to be associated with different types of cancer.

As we reported to you earlier, information on exposure to these substances has been either incomplete or nonexistent due to the lack of recordkeeping and measurement before, during and after the war. Without accurate and precise exposure information, it is difficult to form specific hypotheses about what kinds of tumors might occur. Nevertheless, it is important, in our view, to monitor and assess where the Gulf war veterans may have excess risks in tumors over time so that appropriate outreach and health care can be provided.

Our review of the accuracy and completeness of existing data focused on five types of data sources. These include the VA mortality data, DOD and VA hospital and outpatient medical records, DOD and VA Gulf war health registries, health survey results and national and State cancer registries.

In summary, we found that none of these data sources can be used to reliably estimate the incidence of tumors or other illnesses. The existing data are generally limited by poor coverage of the Gulf war veteran population and problems of accuracy and completeness. As a result, it is not known how many Gulf war veterans have tumors or whether they have different incidence rates than other groups.

Let me now highlight a few details about each of these data sources we reviewed. The VA maintains a large administrative data base which can be used to track the mortality of veterans and provides broad coverage of veterans. However, mortality is only a proxy measure for incidence, because not all cancers result in death. And those that do may take several years to show up. Because of these limitations, mortality data will systematically underreport overall cancer incidence.

The DOD and VA medical records have two major limitations. First, a large majority of Gulf war veterans do not use DOD and VA hospitals and there has been hardly any effort to determine the health status of this hidden population. In addition, until recently, these data systems do not include coverage of outpatient care where more diagnosis and treatment of many types of tumors have been occurring.

Second, we found that the DOD and VA hospitalization data are inaccurate and incomplete. We found that miscoding of discharge diagnoses had been common in these systems.

As far as DOD and VA health registries are concerned, the suitability of these registries for assessing cancer incidence is extremely limited. Only veterans who voluntarily complete a medical exam are included. In addition, the registry data captured information about a veteran's health only at one point in time. Furthermore, VA medical facilities have not reported Registry examination information consistently.

VA is currently using a survey approach to study the general health status of Gulf war veterans. The overall response rate to the survey had been relatively low, at around 57 percent. Furthermore, the sample size of the VA survey is also too small to identify elevated incidence of most cancers. VA has acknowledged that "The study may provide inadequate statistical power to detect a small increase in risk for rare, adverse health outcomes in a particular subgroup of veterans."

Finally, a national cancer registry called SEER, which was established by the National Cancer Institute, reports incidence rates for the general population in key subgroups. While the Registry closely represents the United States population, it is not designed to access specific groups such as the Gulf war veterans. To assist cancer among Gulf war veterans, available State registries could be used, which contain the necessary Social Security numbers to identify them.

Following completion of our report, at the committee's request, we conducted some analyses to determine the nature and extent of tumors among Gulf war veterans. Specifically, we obtained information on tumor cases reported from the following five VA databases: the Persian Gulf Health Registry, inpatient and outpatient medical records, active disability benefits, and divided on inactive disability claims.

These databases do not cover Gulf war veterans who remain on Active military duty or who have separated from the service and use non-VA medical facilities. As a result, a significant portion of the Gulf war population are not included in these databases. Nevertheless, VA and DOD have not combined information from these databases to show a larger picture of the health condition of Gulf war veterans.

We were able to merge the VA data at an aggregate level to estimate the total number of tumors. Based on our analysis of these data, we identify over 14,500 Gulf war veterans with tumors of which about 20 percent are malignant cases. Although we have not determined whether this is higher or lower than an appropriate comparison group, it is important to know that this number is more than twice the number previously reported. Further, this number could be significantly larger if information on veterans who are not in the system is included. We also found that a large majority of these veterans tend to have several other diagnosed illnesses as well.

In conclusion let me point out some key implication of this analysis. First, studies using these databases will underestimate the incidence of tumors among Gulf war veterans. Second, while none of these databases are suitable for determining the incidence of tumors or other illnesses in Gulf war veterans, nevertheless, both DOD and VA have used some of these databases to conclude that

Gulf war veterans do not have excess mortality, morbidity, or birth defects. I believe such conclusions are misleading and send a wrong message to our veterans, policymakers and the public at large.

Mr. Chairman, this concludes my prepared remarks. My colleague and I will be happy to answer any questions you or other members of the subcommittee may have.

[The prepared statement of Mr. Chan follows:]

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the results of our recently completed report, at the Subcommittee's request, on the (1) reliability and utility of existing data for determining the incidence of tumors among Gulf War veterans and (2) uses of the data by the Departments of Defense (DOD) and Veterans Affairs (VA) to monitor tumors in the Gulf War veteran population.[1] Our review focused on five types of data sources: mortality data, DOD and VA hospital and outpatient medical records, DOD and VA Gulf War health registries, survey results, and national and state cancer registries. It is important to point out that most of the data sources we reviewed were not designed for medical research purposes but rather for other uses, such as the administration of records or veteran outreach. Nevertheless, researchers have used some of these data sources to assess the nature and extent of Gulf War illnesses. Our intent was to see if the data could be used to determine the frequency of tumors and to examine the appropriateness of using the data in other applications.

I will first summarize our study results. Then, I will present some preliminary observations on subsequent data analysis, requested by the Subcommittee, to assess the numbers and types of tumors that are reported for Gulf War veterans in available VA

[1]Gulf War Veterans: Incidence of Tumors Cannot Be Reliably Determined From Available Data (GAO/NSIAD-98-89, Mar. 3, 1998).

health and benefits disability databases. Following this, I will provide more details on our findings.

RESULTS IN BRIEF

Based on our completed study, we found that none of the data sources providing information on the health of Gulf War veterans can be used to reliably estimate the incidence of tumors or other illnesses. Existing government data systems are generally limited by poor coverage of the Gulf War veteran population and problems of accuracy and completeness. As a result, it is not known how many Gulf War veterans have tumors or whether they have a higher incidence of them than other veterans. DOD and VA have begun efforts to improve these data systems but have not developed the capability to effectively link information from different sources to assess tumors or other illnesses among Gulf War veterans. DOD and VA also recently funded a few research studies that should provide additional information on tumor cases in the future. However, these studies are not the product of a systematic effort to study the incidence of tumors, and limitations to the studies will prevent them from providing reliable and valid estimates of Gulf War veterans' tumors.

Following completion of our report, we conducted additional work to assess the feasibility of linking data from different sources and determining the number of tumors among Gulf War veterans. Based on our preliminary analysis of only VA health and

disability benefits databases, we identified about 14,700 Gulf War veterans with tumors. Although we have not conducted appropriate analyses to determine whether the total we computed translates into a higher or lower rate of cases as compared to other groups of veterans, it is a larger number of cases than that reported in other studies of Gulf War veterans. These data reflect cases that are reported in VA data systems and do not include Gulf War veterans who are still on active duty or those who use non-VA medical facilities. While we were able to merge VA data at an aggregate level to estimate the total number of tumors, detailed analysis involving the combination of cases by type of tumor will be more difficult to conduct because of different diagnostic coding systems used in the different data systems.

GAO'S REVIEW OF EXISTING DATA SOURCES TO DETERMINE INCIDENCE OF TUMORS AMONG GULF WAR VETERANS

Background

Although casualties were relatively light during the Gulf War deployment, thousands of veterans have come forward complaining of various illnesses, including cancer, in the years following the conflict. During the Gulf War, American troops may have been exposed to several potentially hazardous substances. These include chemical warfare agents, depleted uranium from munitions, smoke from oil-well fires, infectious diseases, pesticides, petroleum fuels, and vaccines. Some of these substances have previously been

associated with different types of cancer through animal laboratory studies and other epidemiological research investigations. For example, combustion products from petroleum include polyaromatic hydrocarbons, benzene, and carbon disulfide, some of which are known to cause lung cancer when inhaled. Exposure to certain pesticides has also been linked to lymphatic and lung cancers. In addition, exposure to radioactive particles has been tied to higher rates of respiratory and other cancers. Information on exposures that took place during the Gulf War, however, has been either incomplete or nonexistent due to the lack of record-keeping and measurement before, during, and after the deployment of troops; loss of key records; poor recall by veterans; and other factors.

The development of cancer is usually characterized by a latency period of many years from initial exposure to a harmful agent to a definitive medical diagnosis. Depending on the nature and extent of the exposure, type of cancer, and characteristics of different individuals, the latency period may be as long as 30 years or more. The most common types of cancers have a latency period of 15 years or more, but in certain situations cancer can develop more quickly (e.g., in cases where the immune system is compromised).

Given that there is a lengthy latency period for most tumors, it may be too soon to detect any increase in tumors among Gulf War veterans. Also, since cancer is a relatively rare

event,[2] large population groups may need to be observed over several years to assess incidence and determine whether it has changed over time. Furthermore, without credible exposure information, it is hard to form specific hypotheses about what kinds of tumors might grow in what individuals. Although such constraints exist, it is nonetheless important to begin monitoring Gulf War veterans to assess whether they are suffering from an increase in tumors so that appropriate health care and treatment can be provided where needed. With many types of tumors, early detection is important to more effective treatment outcomes.

Mortality Data

One source for estimating the incidence of cancer among Gulf War veterans uses mortality as an indicator. The VA maintains a large administrative database, the Beneficiary Identification and Records Locator Subsystem (BIRLS), which can be used to track the mortality of veterans. The system's strength is its broad coverage of the veteran population (estimated to be 80 to 90 percent of the deceased veteran population, according to VA and other researchers) and its cost-effectiveness for ascertaining vital status and causes of death. However, mortality is only a proxy measure for incidence because not all cancers result in death, and those that do may take several years to show

[2]The average age-adjusted incidence rate for all types of cancer combined was 400 cases per 100,000 population in the United States in 1990-91 (National Cancer Institute, Cancer Rates and Risks, 1996, p. 17). Among the age group that served in the Gulf War, incidence is lower (fewer than 100 cases per 100,000 population for the ages 15-44).

up. Mortality data provide good estimates of incidence for cancers that have a high mortality rate (such as lung and liver cancers), but they are less useful for cancers with lower rates of mortality (such as prostate and breast cancers). Because of these limitations, mortality data will systematically underreport overall cancer incidence.

In one published study using data from BIRLS, the VA assessed whether mortality from a range of diseases (including cancer) was different for Gulf War veterans compared with a sample of veterans who were not deployed to the Persian Gulf.[3] The study, which covered deaths occurring in a 2-year period after the war, found that there was a small but significant excess of deaths among Gulf War veterans compared with nondeployed veterans and that the excess was due mainly to accidents and not disease. Of the 1,765 Gulf War veterans who died during the study period, 119 died from cancer, showing no statistically significant difference compared with the cancer death rate among nondeployed veterans. One key limitation of this portion of the study is the relatively short time period for assessing veterans that died from cancer.

Another limitation of the study, which the authors acknowledged, is whether the study's comparison groups were appropriately matched. Military personnel who were ill or recovering from an illness would not have been deployed to the Gulf War area. However, these personnel were included in the comparison group of nondeployed veterans. This

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[3]Kang, H. K., and Bullman, T. A., "Mortality Among U.S. Veterans of the Persian Gulf War," New England Journal of Medicine, vol. 335 (1996), pp. 1498-1504.

meant that the comparison group may have been less healthy than the deployed veterans group. The extent to which a higher rate of prior illnesses among nondeployed veterans resulted in a different rate of mortality (or cancer mortality in particular) and thus biased the study findings is unknown.

VA is now updating the study, extending the period to be studied through 1995, and the results should be published later this year.

DOD and VA Medical Records

Both DOD and VA maintain an automated database containing detailed medical and demographic information on patients discharged from their respective hospitals. Both data systems contain millions of records, but they do not represent the entire active duty and veteran population. DOD's data include most hospitalizations of active duty personnel, in large part because DOD medical care is free and readily available to active duty personnel; however, some veterans' groups have reported that Gulf War veterans are seeking medical care outside DOD. VA also has an extensive network of medical centers across the country, but the overwhelming majority of veterans who have separated from the military use non-VA hospitals and medical facilities. A survey conducted by VA in the late 1980s, for example, estimated that only about 20 percent of veterans had ever used a VA hospital.

Another weakness of these data systems has been the lack of coverage of outpatient medical care. Coverage of outpatient care is important because more patients have been diagnosed and treated for many types of tumors in outpatient facilities in recent years. DOD currently has no centralized reporting system for its outpatient facilities, although an automated system is under development. In October 1996, VA established an automated system that includes diagnostic information, but consistent and reliable outpatient reporting may not be available for several years.

In addition to limitations in terms of population coverage, there are also issues regarding the accuracy and completeness of hospitalization data reporting. Miscoding of diagnoses has been problematic in the past, as shown by VA researchers in previous assessments of certain types of cancer among Vietnam veterans. For example, in one case-control study of over 400 Vietnam veterans identified in VA's hospitalization database as having malignant tumors of connective and other soft tissue, close to 40 percent of the records were found to be miscoded or misclassified when hospital pathology reports were subsequently collected and independently reviewed by an expert pathologist.[4]

In a large DOD-funded study published in 1997, the hospitalization experiences of all active duty Gulf War veterans during the period 1991-93 were compared with a sample of

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[4]Kang, H.K. et al, "Soft Tissue Sarcomas and Military Service in Vietnam: A Case Comparison Group Analysis of Hospital Patients," Journal of Occupational Medicine, vol. 28 (1986), pp. 1215-1218.

other active duty military personnel who were not deployed to the Gulf region.[5] Overall, the authors found there was no excess in hospitalizations among Gulf War veterans compared with other military personnel. However, Gulf War veterans had higher rates of hospitalizations in certain years for mental disorders, diseases of the blood, and diseases of the genitourinary system. Hospitalization rates for tumor cases were also higher for Gulf War veterans, but the differences were not statistically significant and most involved benign conditions.

A major strength of this study is its large size and statistical power to detect differences in rates of hospitalizations between deployed and nondeployed military personnel. However, a key limitation of the study, which influences the interpretation of the results, is that it excluded hospitalizations of Gulf War veterans who separated from the services and hospitalizations of active duty personnel who used non-DOD hospitals. Another important limitation of the study is that the time frame was far too short for detecting any diseases resulting from possible exposures during the war, such as tumors, which have lengthy latency periods.

The same researchers have underway a related follow-up study to examine hospitalizations of Gulf War veterans in military and nonmilitary hospitals in California. Although the study results cannot be generalized to the entire Gulf War population, it is

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[5]Gray, G.C. et al, "The Postwar Hospitalization Experience of U.S. Veterans of the Persian Gulf War," New England Journal of Medicine, vol. 335 (1996) pp. 1505-13.

large and one of the first to systematically combine military and nonmilitary hospitalizations. The study period is longer (1991-95); however, the problem of detecting diseases with a lengthy latency period is still an issue, and outpatient data will be excluded.

Gulf War Health Registries

Both DOD and VA have established separate programs that provide medical examinations and diagnostic services, free of charge, to Gulf War veterans. The VA began its Persian Gulf Health Registry Examination Program in 1992, and DOD started its Comprehensive Clinical Evaluation Program in 1994. An existing health problem is not necessary for participation in the programs; any Gulf War veteran with health questions or concerns is eligible to enroll on a voluntary basis. Close to 100,000 veterans have completed either the VA or DOD registry examination. Of that number, less than 1 percent of veterans have received a primary diagnosis of a malignant or benign tumor.

The suitability of the registries for assessing cancer incidence is extremely limited. As designed, the registries are not intended to be used to determine the frequency and causes of illnesses among the general Gulf War veteran population, but rather to diagnose and treat voluntary participants' symptoms. Because the participants were not selected based on a random sample, there is no way to know whether their health problems are similar to those of the general population of Gulf War veterans. In addition, because

there is no ready comparison or control group for the registry participants, the significance of the data reported cannot be determined. A further limitation of the registry data is that they capture information about the health of veterans only at one point in time. Thus, if a veteran develops cancer or another illness later on, the registry data will not reflect this.

Data quality concerns also have been raised in a previous review of the VA registry by the Institute of Medicine. The Institute found, for example, that there was a considerable delay between the collection of the examination data and their entry into the registry database.[6] We also found that VA medical facilities have not reported registry examination information consistently. It appears that a large number of case records submitted for input into the registry database have been returned to the medical facilities due to coding errors. At the same time, effective quality assurance procedures have not been in place to ensure that rejected records are corrected and reentered into the database. Thus, data coverage even for those who participate in the registries may be incomplete.

Survey Data

[6]Institute of Medicine, Health Consequences of Service During the Persian Gulf War: Initial Findings and Recommendations for Immediate Action, 1995.

Another data approach involves developing information about the incidence of tumors using survey methods such as a questionnaire administered to a sample of veterans. Significant advantages to using the survey approach include the ability to draw a random sample of Gulf War veterans and an appropriate comparison group. A survey also permits researchers to gather other information, such as information about exposures and family history, that might shed light on the causes of a disease. Limitations of this approach include the possibility of response bias (individuals who complete the survey not being representative of the sample as a whole) and the subjectivity of self-assessments. The extent to which response bias is a factor, however, can be estimated through a special survey of nonrespondents, which may be conducted by telephone or personal interviews. The results of the nonrespondent survey can then be compared to the results of the principal survey to gauge the degree to which respondents are typical of the overall sample. Subjectivity of the assessments of cancer or other illnesses can also be gauged to a degree through an independent medical review of a subsample of respondents. A further concern in implementing large population surveys is that they tend to be much more costly than the other approaches. In addition, the type and number of questions must be restricted, or the response rate will be low.

VA is currently using a survey approach to study the general health status of Gulf War veterans. The National Health Survey of Persian Gulf War Era Veterans was mailed to a random sample of 15,000 Gulf War and 15,000 nondeployed veterans. The questionnaire includes a checklist of illnesses, including skin cancer and "any other cancer," and a

checklist of symptoms such as "coughing" and "skin rashes." In addition to questions about current health status, respondents were also asked to report about their exposure to a list of agents, including nerve gas, depleted uranium, and smoke from oil-well fires, while they were in the Gulf War region. The overall response rate to the survey has been relatively low (57 percent). VA is conducting a survey of nonrespondents in order to evaluate nonresponse bias. VA is also addressing the limitation imposed by subjective assessments through an independent review of medical records and the "comprehensive physical examination" of a subsample of 2,000 respondents (1,000 in each of the Gulf War veteran and nondeployed veterans groups). The sample size of the VA survey, however, may be too small to identify an elevated incidence of most cancers. VA has acknowledged this possible limitation.

A population-based survey to assess the prevalence of self-reported symptoms and illnesses among Gulf War veterans was also conducted in Iowa from September 1995 through May 1996.[7] By telephone, a random sample of about 3,700 Gulf War and non-Gulf War veterans from Iowa were surveyed. Overall, the study found that Gulf War veterans reported a significantly higher prevalence of a wide range of medical and psychiatric conditions compared with military personnel who were not deployed to the Gulf War. The primary conditions on which differences were reported included depression, posttraumatic stress syndrome, chronic fatigue, cognitive dysfunction, and respiratory

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[7]The Iowa Persian Gulf Study Group, "Self-Reported Illness and Health Status Among Gulf War Veterans," Journal of the American Medical Association, 277 (1997), pp. 238-245.

diseases. The rate of cancer reported among these Gulf War veterans was generally low (an estimated rate of about 1 per 100 subjects), but it was slightly higher than that of the comparison group.

Cancer Registries

Another source for estimating the incidence of cancer is population-based cancer registries that compile standardized reports of cancer cases directly from medical facilities (typically hospitals) on an ongoing basis. A national cancer registry (the Surveillance, Epidemiology, and End Results (SEER)) established by the National Cancer Institute reports incidence rates for the general population and key subgroups but cannot be used to identify the Gulf War population. Many available state registries could be used to identify Gulf War veterans, but the registries vary in terms of data quality and reporting consistency and coverage. For example, many states require only hospitals to report on cancers and do not capture cases diagnosed by private physicians, laboratories, and health maintenance organizations.

The VA has provided initial funding for a study to assess cancer incidence among Gulf War veterans in New England, based on cases reported in the state cancer registries in the region. Cases will be identified by matching the registries against a roster of all veterans who were deployed to the Gulf War conflict. The first phase of the study has been funded to develop a framework for merging data from the individual state registries.

The next phase of the study, to begin by 1999, will involve an assessment of cancer incidence and mortality. Although this study is several years away from completion, it should provide a useful means for obtaining information about cancer incidence. Some of the strengths of the study are that it will use existing data systems, identify and assess a large cohort of Gulf War veterans, and can be readily updated over time. One key limitation of the study, however, is that the results cannot be generalized to the entire Gulf War population, since only the New England states will be included. Also, there is likely to be an underreporting of cases in the state registries, particularly cases diagnosed outside of the hospital setting and cases from border areas that may be reported in other state registries outside the New England area.

Conclusions and Recommendation

No direct link has been established between potential exposures that occurred during the Gulf War and the development of tumors among veterans. Yet, concerns have been raised because many of the exposure agents in question have previously been associated with certain cancers. This has led to interest in determining whether the cancer incidence rate among Gulf War veterans is higher than the rates within other appropriate comparison groups. If there is a higher rate that indicates an emerging health problem, then outreach efforts could be conducted to target appropriate diagnosis and treatment to those potentially at risk. The existing data and research applications we reviewed, however, provide very limited information about the incidence of tumors or other illnesses.

To more effectively evaluate the incidence of tumors and other Gulf War illnesses over time, we recommended in our report that the Secretaries of Defense and Veterans Affairs improve existing monitoring capabilities. Attention should be directed toward strengthening the utility of existing data systems and particularly in developing cost-effective ways to make data systems more compatible with one another so that information from different sources can be linked. In addition, steps should be taken to address the data quality concerns we identified. While we believe such improvements can lead to more effective monitoring capabilities, the existing data systems are likely to be insufficient to answer the question about cancer incidence or other illnesses among Gulf War veterans. Therefore, further research efforts will be needed to supplement the available data systems. For example, little is known about the health status of veterans who receive medical care from sources other than DOD and VA facilities. Practical approaches should be developed to determine whether health problems among these veterans may be emerging.

In response to our report, DOD and VA concurred with our overall findings regarding the inadequacies of existing data systems for assessing the incidence of tumors among Gulf War veterans and our recommendation to improve monitoring capabilities. They emphasized, however, that they have several initiatives underway to strengthen the reporting of health information and the linkage of data from different sources. While we recognize that these efforts will lead to some improvements, we are concerned that the

available data sources will continue to be insufficient to assess Gulf War illnesses such as tumors.

GAO'S PRELIMINARY ANALYSIS OF INFORMATION IN VA DATABASES ON TUMORS AMONG GULF WAR VETERANS

Following completion of our report, we conducted further work, at the Subcommittee's request, to determine the nature and extent of tumors among Gulf War veterans that are included in DOD and VA data systems and demonstrate the feasibility of linking data from different sources. As a first step, we analyzed data from VA's disability benefits and health care reporting systems. Specifically, we requested information on Gulf War veterans who from July 31, 1991 to March 31, 1998, had filed a disability claim based on the presence of one or more malignant or benign tumors or were diagnosed with a tumor at a VA hospital or outpatient medical facility. We obtained cases from five databases maintained by VA: (1) Persian Gulf Health Registry, (2) Patient Treatment File, (3) Outpatient, (4) Compensation and Pension Masterfile, and (5) Beneficiary Identification and Records Locator Subsystem.[8] As shown in table 1 in appendix I, these databases represent different subpopulations of Gulf War veterans, periods of coverage, and levels of diagnostic information. For example, the Compensation and Pension Masterfile

[8]The BIRLS data cover denied and inactive disability claims. The data we obtained from VA, however, do not indicate the reasons claims were denied (e.g., due to lack of service connection, insufficient medical support). As a result, these cases should be viewed as potential tumor cases.

includes up to 6 different diagnoses for an individual, whereas, the Outpatient database records as many as 15 diagnoses.

The data from these reporting systems do not cover Gulf War veterans who remain on active military duty or who have separated from the services and receive non-VA disability benefits or health care. As a result, a significant portion of the Gulf War population will not be included in these data.[9] In addition, VA omitted from the disability data files they provided to us a number of codes for tumors, including those for leukemia, Hodgkin's disease, non-Hodgkin's lymphoma, and benign tumors of the gynecological system and mammary glands. Consequently, there is some degree of underreporting in the VA data. Nonetheless, these VA data have not been previously combined to show a larger picture of health conditions, such as tumors, among Gulf War veterans. We have completed some preliminary analysis of the VA data at an aggregate level, which are presented in tables 2-5 (see appendix I). A more detailed analysis, which involves combining cases with similar tumor types, will be more difficult to complete because

[9]According to VA, of the 697,000 servicemembers who participated in the Gulf War conflict, about 568,000 separated from the services, while 128,000 remain on active duty. The majority of veterans separated from the services do not use VA hospitals and medical facilities.

different diagnostic coding systems are used for the health and disability benefits data.[10] VA has not developed a linkage between these different coding systems.

As shown in table 2, a total of 16,226 cases of tumors were reported for Gulf War veterans across all five databases; the vast majority of the tumors were benign. When we removed duplicate cases by matching social security numbers, the total is reduced to 14,676 veterans with tumors. The fact that a relatively small amount of records (about 10 percent) are duplicated reinforces the need to use multiple data sources to obtain greater coverage of the veteran population. Use of only selective data may lead to an undercount of cases and incomplete information about the health condition of veterans. Although we do not know whether the total we computed is higher or lower than other appropriate comparison groups, it is a larger number of cases than that reported in other studies of Gulf War veterans. In May 1996, for example, VA provided some information, at the request of the Subcommittee, on the number and types of tumors among Gulf War veterans. In estimating the total number of veterans with tumors, VA used information from three databases: Persian Gulf Health Registry, Patient Treatment File, and Compensation and Pension Masterfile. The total number of tumor cases reported by VA was 6,397 as compared to the 14,676 cases we identified. Our total is much higher because of 2 additional years of data and the inclusion of the BIRLS and outpatient data.

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[10]The International Classification of Diseases, Version 9 (ICD-9), which is used in VA's Persian Gulf Health Registry, Patient Treatment File, and Outpatient data systems, is ordered by groupings of diseases; VA's disability coding, which is used in the Compensation and Pension and BIRLS data systems, is structured generally by the part of the body affected by the disability or disease.

As shown in table 3, a large majority of the Gulf War veterans with tumors also tend to have other diagnosed illnesses as well. This is in line with other published studies of Gulf War illnesses that have noted multiple symptoms and illnesses among the Gulf War veteran population. Further details on the different types of tumors reported from each database are also presented in tables 4-5. Here, it is clear that a broad range of different tumors has been reported for these veterans.

Mr. Chairman, this concludes our prepared remarks. We will be happy to answer any questions you or other members of the Subcommittee may have on our completed and ongoing work.

APPENDIX I

Table 1: Characteristics of VA Databases Used to Assess Information on Tumors Among Gulf War Veterans

VA databases	Description	Relevant time period covered	Diagnostic information
Persian Gulf Health Registry (PGR)	Gulf War veterans completing voluntary medical examinations	Late 1992 to present	Up to 10 diagnoses, coded by ICD-9[a]
Patient Treatment File (PTF)	Veterans receiving inpatient treatment at VA hospitals	Gulf War to present	Up to 10 diagnoses, coded by ICD-9[b]
Outpatient Database	Veterans receiving outpatient treatment at VA medical facilities	1996 to present	Up to 15 diagnoses, coded by ICD-9
Compensation and Pension (C&P) Masterfile	Veterans with 1 or more service-connected disabilities[c]	Gulf War to present	Up to 6 diagnoses, coded by VA disability categories
Beneficiary Identification and Records Locator Subsystem (BIRLS)	Veterans denied and/or no longer receiving disability compensation[d]	Gulf War to present	Up to 9 diagnoses, coded by VA disability categories

[a]International Classification of Diseases, Version 9. Up to 1994, only three diagnoses were recorded.

[b]Individuals may have multiple records in the PTF and outpatient files as a result of multiple visits to a VA medical facility. Thus, the number of diagnoses reported for an individual may be larger when multiple records are merged.

[c]Includes veterans whose illnesses are service-connected but who are receiving no compensation as well as veterans receiving pensions. Does not include pending claims.

[d]For veterans whose claims were denied, the database has no information to indicate reasons for denial (e.g., due to lack of service connection, insufficient medical documentation). Diagnostic information reflects what veterans submitted on claim applications. Therefore, these should be viewed as potential cases of veterans with tumors.

Table 2: Number of Gulf War Veterans with Benign and Malignant Tumors, by VA Database

Database	Benign tumors[a]	Malignant tumors	Total veterans with tumors
PGR	837	280	1,117
PTF	681	606	1,287
Outpatient	2,696	1,902	4,598
C&P	4,938	709	5,647
BIRLS	3,179	398	3,577
Total tumors	12,331	3,895	16,226
Total number of unique cases[b]	11,550	3,126	14,676

Note: A number of codes for tumors, including those for leukemia, Hodgkin's disease, non-Hodgkin's lymphoma, and benign tumors of the gynecological system and mammary glands, were omitted by VA when it created the C&P and BIRLS databases for our analysis.

[a]Veterans with one or more tumors diagnosed as malignant within all possible tumor diagnoses were placed in the "malignant" category. Veterans with only benign tumors were categorized as "benign."

[b]Given that the BIRLS data may reflect potential rather than diagnosed cases of tumors, there is a total number of 11,333 unique cases when the other 4 databases are combined and the BIRLS records are excluded from the analysis (8,502 benign and 2,831 malignant).

Table 3: Number of Gulf War Veterans with Tumors and Other Diagnoses

Database	Tumor cases				Total veterans with tumors
	One tumor, no other diagnoses	One tumor plus other diagnoses	Multiple tumors, no other diagnoses	Multiple tumors plus other diagnoses	
PGR	260	830	10	13	1,113
PTF	233	775	20	259	1,287
Outpatient	1,671	2,016	212	697	4,596
C&P	136	5,276	7	196	5,615
BIRLS	464	2,982	20	110	3,576

Note: Table does not reflect 39 missing cases of unspecified tumors. As a result, the numbers in the column for total veterans with tumors will differ somewhat from the numbers in the same column in table 2.

Table 4: Number of Tumors in Gulf War Veterans, by VA Health Administration Databases

Diagnostic code	Type of tumor	PTF	Outpatient	PGR
	Malignant			
140 - 149	Lip, oral cavity and pharynx	91	206	8
150 -159	Digestive organs and peritoneum	341	814	17
160 -165	Respiratory and intrathoracic organs	357	821	13
170 - 176	Bone, connective tissue, skin and breast	323	1,531	112
179 - 189	Genitourinary organs	389	1,159	45
190 - 199	Other unspecified sites	2,645	1,170	36
200 - 208	Lymphatic and hematopoietic tissue	702	1,848	58
	Benign			
210	Lip, oral cavity and pharynx	23	122	11
211	Other parts of digestive system	137	753	56
212	Respiratory and intrathoracic organs	31	60	5
213	Bones and articular cartilage	32	42	22
214	Lipoma	176	901	296
215	Other connective and other soft tissues	31	128	26
216	Skin	68	1,439	206
217	Breast	16	57	3
218	Uterine leiomyoma	136	342	30
219	Other, uterus	10	15	
220	Ovary	8	5	1
221	Other female genital organs	3	15	
222	Male genital organs	2	69	9
223	Kidney or other urinary organs	3	20	3
224	Eye	2	63	1

Diagnostic code	Type of tumor	PTF	Outpatient	PGR
225	Brain and other parts of nervous system	30	94	6
226	Thyroid gland	15	23	2
227	Other endocrine glands and related structures	40	87	4
228	Hemangioma and lymphangioma, any site	43	80	38
229	Other and unspecified sites	9	107	13
	Carcinoma in situ			
230	Digestive organs	5	28	
231	Respiratory system	2	24	1
232	Skin	1	40	3
233	Breast and genitourinary system	19	91	4
234	Other and unspecified sites	1	28	1
(235 -238)	Neoplasms of uncertain behavior			
235	Digestive and respiratory organs	33	35	2
236	Genitourinary	13	57	10
237	Endocrine glands and nervous system	33	76	21
238	Other and unspecified sites and tissues	63	432	32
239	Unspecified nature	46	387	46
Total		**5,879**	**13,199**	**1,141**
	Number of other diseases	444	459	269
	Number of other diagnoses	8,621	8,677	1,745

Table 5: Frequency of Tumors in Gulf War Veterans, by VA's Benefits Administration Databases

Diagnostic code	Type of tumor	BIRLS	C&P
5012	Bones, new growth, malignant	30	34
5015	Bones, new growth, benign	229	657
5327	Muscle, new growth, malignant - excludes soft tissue sarcoma	4	4
5328	Muscle, new growth, benign	26	45
5329	Soft tissue sarcoma	1	12
6014	Eyeball, new growth, malignant	2	3
6015	Eyeball, new growth, benign	43	82
6208	Ear, new growth, malignant	1	
6209	Ear, new growth, benign	12	46
6819	Respiratory system, new growth, malignant	57	85
6820	Respiratory system, new growth, benign	145	237
7343	Digestive system, any specified part, new growth, malignant	67	57
7344	Digestive system, any specified part, new growth, benign	80	187
7528	Genitourinary system, new growth, malignant	51	148
7529	Genitourinary system, new growth, benign	194	297
7627	Gynecological system, new growth, malignant	34	65
7628	Gynecological system, new growth, benign	9	18
7818	Skin, new growth, malignant	156	248
7819	Skin, new growth, benign	2,740	3,742
7914	Endocrine system, new growth, malignant	11	52
7915	Endocrine system, new growth, benign	20	60

Diagnostic code	Type of tumor	BIRLS	C&P
8002	Brain, new growth, malignant	36	53
8003	Brain, new growth, benign	20	75
8021	Spinal cord, new growth malignant	7	9
8022	Spinal cord, new growth, benign	3	20
Total		**3,978**	**6,236**
	Number of other diseases	448	530
	Number of other diagnoses	12,620	22,576

Mr. SHAYS. Thank you very much. This was a very clear statement, and I appreciate having you present it to the committee.

I don't want to be facetious, but I have to get it out of my system: So this took you years and years to determine?

Mr. CHAN. For the analysis, once we received the data, I think it took us about 3 weeks to do it.

Mr. SHAYS. So the VA in 3 weeks could have done what we asked you to do, correct?

How many people, 100 people helped you do this?

Mr. CHAN. I have one staff behind me, Mr. Bernet.

Mr. SHAYS. So now you have five databases in 3 weeks' approximate time. I'm going to assume that you have hard-working people who work 60 hours a week. But in 3 weeks you accumulate and you put together the five different databases into one. I would imagine you use something like Social Security to make sure you don't double-count.

Mr. CHAN. Yes.

Mr. SHAYS. And your report says that the number of Gulf war veterans with tumors—and this is a specific area. In other words, they're benign or they're cancerous; they're malignant, but of the total you had 14,500. Let's go through the chart. Let's use the exact number. You had 11,550 benign tumors, you had 3,126 malignant tumors and you had total tumors of 14,676.

Mr. CHAN. Yes.

Mr. SHAYS. OK.

Now what was the number that you had been told and have been documented by the VA?

Mr. CHAN. I think the numbers given to you in your request, Mr. Chairman, back in 1996, if I recall, signed by Secretary Brown, I believe, on May 30, 1996—I believe that was the date—ranged between 1,600–1,700 to 6,000.

Mr. SHAYS. OK, and we had an in-between. We didn't have an exact number then.

Mr. CHAN. They gave you two sets of numbers, though, and based on different databases they use.

Mr. SHAYS. All right, and admittedly time has elapsed, so you were able to collect more. I'm not comparing apples to apples exactly here, and there's a significant difference. It's not your suggestion that it is. First off, explain to me again why we didn't have a precise number, whatever their number was, the 1,600 to 6,000 or whatever range.

Why did they give me two numbers? Why didn't they just give me one number?

Mr. CHAN. If you look at——

Mr. SHAYS. Let me just say, Mr. Chan, I have no need to have you answer a question if you have someone whom you prefer—I mean, so feel free.

Mr. CHAN. Sure.

I think it's really a question of using selective databases to present the results. If you look at—on my written statement, page 22, table 2 there, what you find is—that the 1,600 or 1,700 that they came out with is really taking the first two databases——

Mr. SHAYS. Which page am I on?

Mr. CHAN. Page 22.

Mr. SHAYS. Hold on 1 second. Yes.

Mr. CHAN. So if you add that up, we end up with about 2,300–2,400, and that's a comparable piece of information to the 1,700 that was given to you back in 1996.

Mr. SHAYS. So——

Mr. CHAN. So the 2 years may have increased by that number.

Mr. SHAYS. The 2 years would not have doubled the amount?

Mr. CHAN. For 2 years it could have gone up, you know, from 16-something to 20——

Mr. SHAYS. To 23 or something.

Mr. CHAN. Yes, right.

So what I'm saying is that they did report to you, but using these two sets of databases and combine them, send them to you.

Mr. SHAYS. OK, and they left that outpatient——

Mr. CHAN. At the time, outpatient data was not available, but they did that——

Mr. OPPENHEIM. In their analysis they used three data bases, the Persian Gulf Registry, the PTF, which is the hospitalization data, and also the compensation and pension data bases. Based on those three data bases, they came up with about 6,400 cases. Our number 14,000 differs because we also include the BIRLS data, the outpatient data, plus we have 2 extra years of data, because theirs is 1996 and ours is 1998.

Mr. SHAYS. So you bring all these data bases into one.

Now my understanding is that many of these data bases are geared toward accounting and claims. They're not geared toward wanting to assess the different kinds of illnesses that we have and then draw some conclusions.

What I'm troubled by is—and I may be unfair to the VA, and they will be testifying afterwards—that they take your report and turn it around to say, we can't draw a conclusion because there is a disproportionate number.

But I'm going to try something out on you, and then you respond to it, and then the VA, who is here, can also respond to it. We don't know this pool is a limited pool. With all the data bases, it's not 700,000 of the men and women who serve in the Persian Gulf. Do we have a sense of how large that number is, what that pool size is?

Mr. CHAN. These five sets of data represent, at best—about 570,000 of those who are no longer in Active Duty. So it doesn't include DOD data.

Mr. SHAYS. OK. So we do have DOD data right now that we could add to it?

Mr. CHAN. Yes, we do.

Mr. SHAYS. Except, with all due respect, our Active Duty participant, the lieutenant colonel, is in this data base—oh, he's not in this data base. The other two are, but he is not in this data base. So whatever your number—your number 14,676 is only within the VA.

OK, let's just take the VA, this number. We're talking of an age group that's somewhere in their twenties up to their fifties, but the median is somewhere in their thirties, twenties? Where is it?

Mr. CHAN. Mm——

Mr. SHAYS. You know what I'm going to do? And if you won't mind who did this report, actually did the 3 weeks of the report? Would you identify the individual's name?

Mr. CHAN. Sam Bernet.

Mr. SHAYS. I'd like to swear him in and I'd like him to come and share in this, if that's all right with you. Is that all right with you, Mr. Chan, swear him in and have him participate?

[Witness sworn.]

Mr. SHAYS. I just—the last question—maybe identify yourself for the record, please.

Mr. BERNET. My name is Sam Bernet.

Mr. SHAYS. Mr. Bernet, if you would, the question——

Mr. BERNET. There is a large cluster in what would be now roughly the 25- to 45-year-old age range. We do have some breakdowns, there really wasn't anything surprising when you broke it down that way. You would expect the distribution to be a large bubble there because during 8 years previous, those would have been the people who were largely the infantry out there fighting.

Mr. SHAYS. But the bottom line to this is that these aren't senior citizens?

Mr. BERNET. No.

Mr. SHAYS. They're pretty healthy men and women. They were in the service and they had physicals and they were pretty healthy people?

Mr. BERNET. Presumably.

Mr. SHAYS. Presumed.

If I were to assume all 700 were in our five data bases, Mr. Chan, all 700, would I be able to draw any conclusions if I made that assumption about incidence, 14,676 compared to the general population? What kind of conclusion could I begin to draw, not have it be definitive, but would we find in the general population in that age group that it would be likely to be higher or lower?

Mr. CHAN. Well, I was going to answer your first question, which is on the distributions of age.

Mr. SHAYS. OK, let's do that first.

Mr. CHAN. We did calculate——

Mr. SHAYS. Let's do yours first.

Mr. CHAN [continuing]. With the cases, and if I can just go through them very quickly. Just on the malignant cases, we found that between ages 25 to 34, over 1,000 cases in the—and between 35 and 44, about 940 cases; 45 to 54, 800 cases; and then 55 to 64, 200 cases, and so on. So it trailed down, clearly. The age group really is between 25 and 44, at least, from a very general comment here that you asked me.

Mr. SHAYS. So the larger group is in the younger age groups?

Mr. CHAN. Yes. Because they also have much higher incidence. That means—in fact, they are much more represented——

Mr. SHAYS. See, I was just giving you time to gather that information. I was just trying to help you out.

Mr. CHAN. Thank you.

And if I may, then, answer your second question about the prevalency and so on, unfortunately I don't have the general data in back of my head. But if I recall correctly for the general popu-

lation between—around the age 30 to 40 you would find maybe 100–150 cancerous cases per 100,000.

Mr. SHAYS. Cancerous or malignant tumors?

Mr. CHAN. Malignant tumors.

Mr. SHAYS. OK.

Mr. CHAN. I mean, someone may want to correct me later because that's what I have in my memory.

Mr. SHAYS. OK.

It would seem logical to me that this is a question that I will want an answer to pretty quickly. I'm not going to wait until we get 700—I'm going be able to draw assumptions that I'm very comfortable drawing that if, in fact, with a pool of 550,000 people, we have 3,126 malignant tumors and 11,550 benign tumors, that adds up to 14,676; and that if the pool were 700,000, we should only have a total number of tumors of 10,000 for the larger or 9,000 or 12,000 or 7,000. We got a problem and we don't need to wait for a rocket scientist to say that. So we can't draw some conclusions, but we can draw some other conclusions.

Then we can say, of the 550 to 700—of the 550 to 700, we don't know who hasn't come forward and who chooses not to, one, who doesn't know they may not be well, or two, who simply says why go to the VA? It's going to be deemed as not service related, so forget it.

What I'm going to do is go there and just have them tell me that I'm not credible, or that it's simply that I have no right to expect that it would be service connected. So I make that assumption pretty easily, and I'm very willing to have a dialog with the VA about this, and the DOD.

Mr. Sharma, thanks for your patience.

Mr. SHARMA. Yes, I just want to make a comment about the general population. The presumption that, you know, the rates are no different than the general population is also faulty, because what we are talking about is a much healthier group.

Mr. SHAYS. A much what?

Mr. SHARMA. Much healthier group, people who——

Mr. SHAYS. In the military?

Mr. SHARMA. Who are in the military. And by all means, you know this is, you know, a challenge, this hypothesis, that there should be no difference. As a matter of fact, if anything, we should expect a lower incidence. So if you find that there are incidents, there is no difference; to me, that is a finding. I mean, why is it that the healthier group is experiencing the incidence of cancer at the same rate. But what we're finding, on the contrary, is that it seems to be slightly higher than the general population.

Mr. CHAN. If you—when you are asking a question about, let's make that leap and make the assumption compared to the overall population, I mentioned something like this, I remember, if I'm correct, about 150 cancerous cases per 100,000 in the general population.

Then you take that number and then try to say, look, for the 3,000 cases we have, if they're indeed, you know, the maximum you have, whenever you want to include, that's the max you have. OK, take that first, and you say, this represents, let's say, 700,000 of our soldiers out there, OK? That would give you about 400 per

100,000, that, compared to 150 per 100,000; that's the ratio you have.

Mr. SANDERS. For the same age group?

Mr. CHAN. Yes.

So this is only on cancer. So what one can say then is that, at the very least, a very straightforward analysis suggests to us that there might be more to it than no problems.

Mr. SHAYS. Thank you very much.

You have the floor and you don't have any clock. Unless you——

Mr. SANDERS. Mr. Chan, in your report, you note that the DOD and VA agree with the basic conclusions of your study and have begun actions that would address your concerns. Have you had an opportunity to review their plans for future action? If so, do you believe that those actions will provide a data base which will be better able to answer questions about the incidence of illnesses which may be linked to service in the Persian Gulf?

Mr. CHAN. We have received some of the comments that they had in terms of what they plan to do and so on. Recently, they had a meeting, I think on May 7, in which we did not participate, to examine how best to improve the information, and that's best to ask of them to do that.

I think generally we all agree that these data bases that we are using are really not intended to be a single data to be combined to examine, you know, about this particular population, because the intent of these data bases, I wanted to make sure people understand, is for other reasons—for claims, for benefits, for, you know, tracking mortality rates and so on, all the other stuff.

So they have hospitalization data and whatnot, but really it does not represent the overall population.

Now let me turn the other way around. Given that we know, let's say, that the VA data doesn't include overall population, it seems to me that we can in fact find out about this hidden population, those who are now participating in this—the hospitals and use the VA facility. What does this say of their health? So those are additional information one can obtain.

So I think we generally agree that we need to bring the DOD information together with the VA information, but I don't know the detail enough to comment on it.

Mr. SANDERS. Your report finds that the data-gathering activities of the VA and DOD will not yield information about the incidence of specific illnesses. Given this conclusion, what can you say about denials of disability claims based on the finding that they are not service connected?

Mr. CHAN. It's extraordinarily difficult to, and what we have demonstrated so far with our analysis is that you can count the number of cases of tumors in the aggregate. But you cannot do it down to the level where, how many cases of soft tissue cancers we have, be it benign or malignant, and that was the problem when we say we couldn't do it in terms of incidences.

Now, we did present them with two sets of data bases, combined them on page 24 and all the way to 27, and you can see right away the diagnostic codes themselves are different, so that's why we can't combine them. Hopefully, VA at least would be able to do that, to bring those together, because as I said, the intent of those

data bases for hospital—hospitalization and benefits are different because one looks for the body systems rather than the ICD code, you know——

Mr. SANDERS. Mr. Chan, we live in what we are told, every day on television, the Information Age, right, the age of high technology. I know the first major piece of legislation I passed here in Congress was the National Cancer Registry Act, and the reason I did that is that I thought it would be important for researchers to have an understanding of the relationship of the incidence of cancer and the kinds of cancer to where people lived and where people worked; and I thought that would be an important tool, and I think it is.

But given all of the technology out there, why in your judgment has the VA been so slow in using it in an appropriate way to give us some better understanding of the kind of illnesses that were developed—Gulf war veterans and the incidence of those illnesses?

Mr. CHAN. Well, let me say that when we were first engaged in starting this study and we talked with the agency there, generally the comment to us was that we don't understand why you're doing this because it's not very important——

Mr. SANDERS. It's not important to understand the kinds of illnesses and the amount of illnesses the veterans——

Mr. CHAN. On cancer.

Mr. SANDERS. That's not important?

Mr. CHAN. Yes. And this is not of high enough priority. But I think the next question one should ask is, do we have any data base that's been combined on other illnesses, as well, if this is not important; and we haven't found that either. So I think you have to pose that question to agencies.

Mr. SANDERS. I mean, in this day and age, should it be very difficult for us to say what percentage of folks who served in a particular area today are coming down with this illness or that illness and the severity of that illness? I mean, should it really be that hard?

Shaking your heads, but as the chairman says, that doesn't quite get into the record.

Mr. CHAN. I don't believe so, and I think it could be done, it should be done; and as they're saying now that they're beginning to look into it——

Mr. SANDERS. Well, this is 8 years after the war. I mean, but how do we make the judgment? Some of us think that we have a serious health problem related to the folks who served in the Gulf war, but how do we make that case if we don't have accurate information? I mean, isn't it somewhat difficult?

We see it anecdotally, we see it through 13 hearings that have been held here, we see it in the State of Vermont when I talked to dozens and dozens of people who, to any objective observer, would say, These folks are not malingerers, they are not liars, they are not suffering from stress, they are ill.

So based on that reality, the chairman and I and other Members say, we have a problem, but obviously it makes it more difficult for us to go forward if we don't have objective, analytical statistics. And some of us feel the frustration that 8 years after the war in

this great era of modern technology on the Information Highway, we're still not getting that information.

Mr. CHAN. If I may answer your question in the following way, I think, given the nature of these illnesses that people talk about and given the fact that we do not know precisely, by individual, what level of exposure they received, what kind of shots they received and how long they were there; we don't have dose—dose response information; we don't know where they were generally and so on, that in fact their health status is really the only accurate piece of information you can obtain unless there are bio-markers on them in terms of, you know, hydrocarbon, whatever they have in their bloods. So, if anything, you know, you've got to work backwards.

Now the important thing about what you're saying in obtaining that set of data is, it allows you at least through lots and lots of providers, inside and outside a system, to come out with their diagnosis, bring them together so that when you compare them with a comparable—and when I say the word "comparable," I mean non-deployed, but deployable soldiers, then those people can allow you to say clearly, what and where do we have excess risks? If you can identify that, then it can help you to say, what would be the common themes that bring these people together?

Let's say all these people with this illness, were they together, did they get the same shot, did they fight in the same area, did they recover the same tank or whatever? So it allows you to begin to say, OK, let's go backward now to determine the condition that might have—even though it may not help you to answer the cause of the illness, but at least helps you to group the people. And if that kind of information is available for the general public, particularly with the veterans, then they would say, I have that, too, let me bring my information in to help, too.

So fundamentally it is that, yes, you're right. You know, this is one approach you can take to get to, one, not only open this thing up, but also allow the veterans to have a certain degree of trust on this system.

Mr. SANDERS. Mr. Chairman, anyone else who is up there, from what I'm hearing you say, what we've learned today is, it's your judgment that the incidence of tumors is far greater, significantly greater than we have previously thought; is that correct?

Now this pattern of underestimating——

Mr. SHAYS. If the gentleman would suspend, he said, is it correct? You kind of nodded your head, and I need an answer to that question.

Would you ask the question again?

Mr. SANDERS. Yes. What I would like to ask Mr. Chan and other members up there is, I think one of the conclusions of your work is that the incidence, the amount of tumors for Gulf war veterans, is significantly higher than we have previously been led to believe; is that correct?

Mr. CHAN. Yes.

Mr. SANDERS. OK.

It seems to me that almost from the very beginning of the discussion of Gulf war illness, the VA and the DOD have consistently underestimated the problem; in fact, in the beginning, there was no

problem. Then maybe the problem was in folks' heads, psychological problem; and after years, we evolved to the fact that it was a stress problem. And I think behind the situation of consistently underestimating the problem is the fervent hope, consciously or unconsciously, that there is no problem. Why would you want to look? You asked—when we spoke a moment ago, you were saying, well, they didn't think that—why would you want to look at the amount of tumors? It's not a very serious problem, is basically what you said.

I suppose if you start off by believing that there is no problem or maybe a few folks have some stressful problems, then why the hell would we waste all of our time looking at issues like tumors and various forms of cancer and other types of illness? But would you agree that from the very beginning of this whole discussion, and till today, that the record has shown that the VA has consistently underestimated the problem, as well as the DOD, that time after time new revelations come out that suggest that the problem is a lot more serious than we had believed the day before?

Mr. CHAN. Well, I don't know the intent, but I do know that they recognize the limitations of the information they have. But nevertheless I think they went ahead with the research and drew conclusions on the basis of that research, and if I may say that upon receiving that kind of conclusion, they believe that hypothesis is over, they don't need to look at it any further.

That's clearly a problem that I find because, you know, the population issue is a difficult one, but at the same time I think you know it could be addressed and obtain the information and, you know, really try to represent this population as well as you can.

Mr. SANDERS. Let me ask you or let me take you a bit off of your report today to ask you a question, because you have been following this issue very closely and the folks from the VA will be testifying in a few minutes, but is it your understanding that the VA still holds that the cause of Gulf war illness is stress? Is that still the official party line?

Mr. CHAN. You need to ask them that.

Mr. SANDERS. All right.

I noticed there was a line in your report on page 6 which I found very interesting, and that is, you say, "We also found that a large majority of these veterans who had tumors tended to have several other diagnosed illnesses as well," and I found that to be an interesting point of observation. It suggests that you have a cluster of folks who are ill, and among other symptoms, you have tumors.

Can you talk about this? Is that significant?

Mr. CHAN. We analyzed the information, and we don't know if it's significant, but certainly let me try to explain to you what we did, OK; and there lies, you know, you may get some different answer to the problem of bringing multiple diagnoses together and trying to figure it out, what's wrong with the veterans.

On page 25 in my written statement here, we attempt to do that in some way. Essentially, what we did is the following: We obtain all the individuals with tumors from the VA and then, given that piece of information, we try to so-called "computer match" them so that we don't have double counts and triple counts. And with that in mind we then look at what other diagnosis they have and try

to count those, and we end up with multiple other illnesses they have diagnosed they have. And the best way to present that is on page 23 of our table 3. Here on the left-hand column you see those five data bases again.

The first one is that we have a number of people with one tumor and no other diagnosis, those are the numbers. Second is one tumor plus other diagnosis, multiple tumors with no other diagnosis and the multiple tumors with others. And you can see that there's quite a few people, if you look at the second column, one tumor plus others, as well as multiple plus others. So, you know, it's a huge number.

Mr. SANDERS. Obviously I'm not a physician or an expert on the area, but doesn't this suggest to us that you have some folks whose organisms are in pretty bad shape? I mean, in other words, it's not just that they have a tumor, but they are suffering individuals and, among other things, they have tumors. They also have other problems which might well suggest—understand that we don't know the cause of cancer that their body was subjected to something of which tumors is one of the symptoms.

Mr. CHAN. I think you're raising a very—my own belief now—a very important question in terms of how do you go about testing hypotheses. If we try to compare as we just did, making assumptions about overall population and all that, comparing one illness at a time, you may find there may not be any significant difference; but you start comparing a person with multiple tumors in their body, and you say, where is that coming from?

Then you compare the control group, you find other people with the same kind of distribution of illnesses. So I guess I've stated before that you really have to look at the individual as a unit of analysis, not by body parts, and do the analysis one at a time; and if you do that, then I think it may help to understand some of these combinations you need that you don't find in the normal population. And I think that's where we're heading to in this kind of analysis.

Mr. SANDERS. This information, I think, is extremely important, has the VA itself come up with information like this at all?

Mr. CHAN. I'm not aware——

Mr. SANDERS. In other words, you are giving us for the first time——

Mr. CHAN. I'm sure they can do it though, sorry.

Mr. SANDERS. That gets back to utilization of the information that is out there, but you are saying, which I think is very important—I mean ultimately what the chairman and I, and I think everybody in America wants to know is, what in God's name happened to the folks who were over there. That's what we want to know, what kind of—and then we can perhaps better understand the cause of the problems and then we can hopefully develop a treatment, right? That's not very complicated; it's what we want to do.

But what you are telling us, importantly, is that we have to go beyond, symptom by symptom, right; and if we find out that there are a significant number of folks who are suffering from multi symptoms, including tumors, we can perhaps, or our scientists perhaps, can learn something from that. Is that correct?

Mr. CHAN. Yes.

Mr. SANDERS. Well, again, I have mixed feelings, Mr. Chairman, because I want to applaud and thank these people for giving us this information; and yet we would—and this information you gave you did based on 3 weeks' work. Was that——

Mr. BERNET. Plus or minus.

Mr. SANDERS. And yet the VA and the DOD have yet to come up with this information.

OK, well, I would just like to thank you very much for that.

Mr. SHAYS. I thank the gentleman.

How would you assess the value of the VA's national health survey in terms of identifying rates of cancer and other illnesses among Gulf war veterans?

Mr. OPPENHEIM. I think the National Cancer Registry provides very useful information on incidence, but it's for the general population and key demographic subgroups. It's not designed to track cancer rates in other population groups such as Gulf war veterans. To do that, I think you have to go back to individual State registries where you can get the kind of identifiers, Social Security numbers, for instance, to be able to match that with a roster of Gulf war veterans, and then do some kind of analysis to assess what those rates look like in some mix of different State registries.

Mr. SHAYS. Let me ask the question this way as well. Will the VA get us closer to a valid conclusion about tumor incidence by their research?

Mr. OPPENHEIM. I think there are a couple of studies under way which will get us closer. There is one study they funded which will look at cancer registries in the New England States, for instance, which will give some useful information on cancer occurring in those States. However, that's not generalizable to other veterans in other States.

Similarly, there is a study that DOD and VA have funded to look at hospitalization rates in the State of California, and that's going to be an effort to try and combine VA, DOD and California hospitals together to get a picture of hospitalization rates. So that, too, will provide some useful information, although it's limited to only one State.

Mr. SHAYS. Mr. Chan, one of the things you pointed out is that we weren't able to include a data base from the DOD, correct? So we need you to do that, combine it with your study; and then we need to do the line of questioning that you and Mr. Sanders got into which is people who are—and I realize that tumors are just one part, but the interesting thing is that we can kind of nail down that area. But to know where they're happening, if they're happening in clusters with different units and so on, I don't know how we go about doing that, but it seems to me that's a logical step. We had testimony from our first panel and we learned of two rare forms of cancer in a unit of just 40 people.

Mr. CHAN. Yes. Let me comment on what Dr. Oppenheim just said.

One of the problems, if you take a selective sample of—such as the New England study or the California study, I think in a certain way, it's useful to understand the general health status of those people; but if you are really looking for a needle in a haystack like

one in a million chance for that to occur, you're not going to find those there.

So unless—the prevalency is very high. So on one hand I think it helps to do studies of that kind; on the other hand we have to start looking at this population as a very unique population. It's different than the general population, and by taking some of these subgroups in little pieces and so on, you may not be able to find anything, and then it's a wasted effort. And I'm concerned that if we continue to pursue in this way, you're going to keep having these kind of answers that we don't know. You know, to me seems like, why don't we just look at the whole thing and do it once and for all? If there aren't any, then so be it; if there are, then find out what's behind it.

Mr. SHAYS. Kind of just stares us in the face, doesn't it, Mr. Chan?

Mr. CHAN. Right.

Mr. SHAYS. Is there anything that any of the four of you would like to say? I know that I brought you from the back row and your boss is sitting at the table, but you did do this study.

You did the research on the three during the 3 weeks. Is there anything you would like to say here?

Mr. BERNET. No, I think everything has pretty much been covered from the analysis point. Like we said, 3 weeks; it really wasn't difficult to do, but out at the aggregated level, that's simple, benign versus malignant.

If you're going to try and put it down and compare the ICD 9 and the other coding, the different coding, the VBA and the VHA use, I think that is something that really needs to be done on the entire scale not just for tumors. That would open up all these data bases to systematic analysis.

Mr. SHAYS. Let me just put it in my words to make sure I understand you. You're saying what we did for tumors we should do for everything else?

Mr. SANDERS. If I may? Is the VA capable of doing that, in your judgment?

Mr. BERNET. They are right now leading a new effort in their Office of Policy that looks very promising, and I believe they will be talking a little bit about that today. The Office of Policy is who we largely dealt with and was very helpful in us doing this study.

Mr. SANDERS. Any guesses as to why it took them 7 years to get around to doing that?

Mr. BERNET. No. Considering I just started in this subject field in January, I don't know.

Mr. SHAYS. Listen, we brought him to the front table, we don't want to get him fired.

Dr. Sharma do you have any closing comment?

Mr. SHARMA. I wanted to make a comment that for most cancer, there is a long latency period. What we're seeing is just the tip of the iceberg. With the progression of time, we're going to see more and more cases, and therefore it's extremely important to monitor this population over time. As we said in our June report when we testified to you, monitoring this population is extremely important over time. We are going to see perhaps very unique kinds of combinations in this population, and it's not for just one specific thing,

body system, as Mr. Chan said, but we have to look at these individuals as individuals and convey to them that we really care about them.

Mr. SANDERS. So in other words, what you are saying is that as a result of what may have happened to them over there that—10 years or 15 years later, we may see a surprisingly large number of one ailment or another. Is that what you're saying, and that's why we have to monitor that so closely?

Mr. SHARMA. Right.

Mr. SHAYS. Dr. Oppenheim.

Mr. OPPENHEIM. I would just say in closing comment that this is—our analysis was really just a first step, and in some sense, it was kind of a crude analysis, it was a very quick sort of analysis. I think much more could be done with resources and time. One thing, as Sam Bernet mentioned, was VA developing some kind of crosswalk so the different coding systems that are used for disability and for hospitalization diagnosis can be combined together.

Second, as Chairman Shays suggested, combining the DOD data into what we did would give even a larger picture.

I think, third, trying to come up with an appropriate comparison group to compare our analysis to something would be a lot more meaningful as well.

And, finally, I think it's also important that there needs to be some effort to address the veterans who are not captured by these systems; that is, this so-called hidden population of veterans who use public and private medical facilities around the country.

Mr. SHAYS. And Mr. Chan, any comment?

Mr. CHAN. No.

Mr. SHAYS. OK. I think you were very helpful and very forthcoming, and your written statement was easier for me to understand, your shorter version, though I know that the longer version probably had more to it. Thank you very much.

We'll get to our last panel.

Our third and last panel is Dr. Susan Mather, Chief, Public Health and Environmental Hazards Officer, Department of Veterans Affairs, accompanied by Dr. Frances Murphy, Director of Environmental Agents Service, Department of Veterans Affairs; and Dr. Han Kang, Director, Environmental Epidemiology Service, Department of Veterans Affairs.

Also, Gary Christopherson, Acting Assistant Secretary of Defense, Health Affairs, Department of Defense, accompanied by Dr. John Mazzuchi, Deputy Assistant Secretary of Defense, Clinical and Program Policy, Department of Defense.

Finally, Dr. Richard Miller, director of Medical Follow-Up Agency, Institute of Medicine, National Academy of Sciences, accompanied by Dr. G. Marie Swanson, director, Cancer Center, Michigan State University.

Can we fit everybody at this table? I want to make sure that we do this. We have testimony from one, two and three people, so we want to make sure they're definitely at the desk. And we will be starting with Dr. Mather, and then we will be going to Gary Christopherson, and then we will be going to Dr. Richard Miller.

I think what I'm going to do is have Dr. Miller, maybe—I think we can make it. Could we just slide down a little to my right and your left just a little bit? Thank you very much.

Sorry, I'm not trying to play musical chairs here. If you can slide down. Thank you.

I'm going to say something. I have not sworn them in yet. Now that you're all comfortably seated, get up, and we'll swear you all in, and if there's anyone else who might be responding, if everyone would stand please, just in case you respond. Thank you.

[Witnesses sworn.]

Mr. SHAYS. I'm sorry my colleague from Cleveland isn't here because I agreed with most of his comments. The one thing that I want to make sure is that no one, either as a guest or a witness or even on the transcript would doubt that I believe that everyone who is coming to testify before this committee cares about our veterans and is doing their best as they see it to help our veterans. I believe that. Where my differences lie is the collective wisdom of certain organizations and if, in the end, we are truly helping our veterans.

But I believe that, first and foremost, all of you are very patriotic Americans. You are all serving this country to the best of your ability in either the public or private sector, and you care deeply about our veterans. I do want that to be part of the record, and I appreciate that you're here. We obviously have our disagreements and we'll have our disagreements be part of the public record, and we'll let time determine when we are right and when we are wrong, because I know we're not always right on this side and I know also that sometimes we are.

So we'll start with you, Dr. Mather. It's nice to have you here.

STATEMENTS OF SUSAN MATHER, M.D., CHIEF PUBLIC HEALTH & ENVIRONMENTAL HAZARDS OFFICER, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY FRANCES MURPHY, M.D., DIRECTOR, ENVIRONMENTAL AGENTS SERVICE, AND HAN KANG, Ph.D., DIRECTOR, ENVIRONMENTAL EPIDEMIOLOGY SERVICE; GARY CHRISTOPHERSON, ACTING ASSISTANT SECRETARY OF DEFENSE, CLINICAL & PROGRAM POLICY; RICHARD MILLER, M.D., DIRECTOR, MEDICAL FOLLOW-UP AGENCY, INSTITUTE OF MEDICINE/NATIONAL ACADEMY OF SCIENCES, ACCOMPANIED BY G. MARIE SWANSON, M.D., DIRECTOR, CANCER CENTER, MICHIGAN STATE UNIVERSITY

Dr. MATHER. Thank you for your words, Mr. Chairman and members of the subcommittee.

I'm pleased to be here today to represent the Department of Veterans Affairs. I'm accompanied by Dr. Frances Murphy and Dr. Han Kang. VA has testified before the subcommittee at seven previous hearings, most recently on February 24, 1998, and we have provided information on our Gulf war health care and research efforts on those occasions. I have provided some background information in our full statement, but I refer you to our previous testimony for a more detailed discussion and to the annual report to Congress for federally sponsored research on Gulf war veterans illnesses, which was released April 22, 1998.

The Department of Veterans Affairs began planning to provide health care and benefits to the service members deployed in Operations Desert Shield and Desert Storm as soon as the first soldiers entered the theater of operations. VA's Gulf war programs encompass a comprehensive approach to health services, addressing relevant medical care, research, outreach and educational issues. To date, almost 67,000 Gulf war veterans have completed Registry examinations, 226,530 have made almost 2.7 million visits to ambulatory care facilities, more than 23,000 have been hospitalized at VA facilities and there have been almost 500 admissions to specialized referral centers, and more than 83,000 Gulf war veterans have been counseled at the VA's vet centers. VA is committed to continuing to provide and improve health care services available to Gulf veterans.

Concerns have been raised about the government's ability to track the health of Gulf war veterans. As a result, VA and the Department of Defense have contracted with the National Academy of Sciences Institute of Medicine to provide advice on the optimal methods to do this. In order to get the best assessment of the health status of Gulf war veterans a carefully designed and well executed research program is necessary. Under the auspices of the Persian Gulf Veterans Coordinating Board Research Working Group, 121 federally sponsored research projects are pending, under way or have been completed. More than half of these projects are being carried out by non-Federal investigators. Federally funded researchers have, to date, published approximately 60 papers in the peer-reviewed literature, including nearly 40 from VA investigators. VA projects a cumulative expenditure of research dollars from fiscal year 1994 through fiscal year 1998 of approximately 27 million.

I am pleased to report that there has been significant progress on a number of key VA studies. Phase III of the National Health Survey of Gulf war veterans has begun with preliminary site selection for physical examinations; 2,000 will be invited along with their family members to participate in a comprehensive protocol conducted at 17 VA medical centers nationwide. Completion of data collection is anticipated in late 1999. This study will provide the most comprehensive picture to date of the prevalence of symptoms and illnesses among veterans who served in the Gulf war.

VA's environmental epidemiology services carried out a mortality study of all Desert Shield and Desert Storm veterans and the comparison group, who were not deployed to the Gulf war, using data from VA, Social Security and the national death index. The results through December 1995 have not revealed an increased risk of death for medical conditions, including neoplasms. This result is not surprising since most cancer has a long latency for development after exposure to carcinogens. VA will continue to update this data, which is a valid mechanism to provide surveillance for development of serious, life-threatening cancers in veterans.

The mortality study did find elevated rates of death from external causes, primarily accidents, in Gulf war veterans. Two other studies of interest to the committee are in the planning stages. First is a multisite randomized clinical trial to assess the effectiveness of treatments for chronic fatigue syndrome and fibromyalgia

in Gulf war veterans. Such a study is possible because these conditions have case definitions and proposed treatments. A second treatment trial is under development to examine the effectiveness of antibiotic treatments in ill Gulf war veterans. These studies will be carried out in collaboration with DOD and in consultation with the National Institutes of Health, the university community and international experts. A general invitation to VA clinicians and scientists who propose additional multisite trials to evaluate the effectiveness of treatment strategies for other symptom-based conditions has also been issued.

The Department has received and reviewed the GAO's report of "Gulf War Veterans: Incidence of Tumors Cannot Be Reliably Determined from Available Data." The report discusses the strengths and weaknesses of the available data for assessing neoplasms among Gulf war veterans. The GAO concludes that no direct link has been established between potential exposures and development of tumors among Gulf war veterans.

GAO raises concerns that many of the potential hazardous exposures of these veterans are potentially carcinogenic. GAO states that existing data sources provide limited information about the incidence of tumors or other illnesses among Gulf war veterans, and recommends that the Secretaries of Veterans Affairs and Defense continue to develop comparable data bases and strengthen existing data systems.

Finally, GAO points out neither Federal nor civilian medical data sources currently provide adequate information on the health conditions of Gulf war veterans to allow a reliable estimate of the incidence of tumors. We concur.

VA also agrees with GAO's conclusion that cancer incidence among Gulf war veterans cannot be determined using existing Federal, State or private data sources. As was discussed in our previous testimony before this committee on June 25, 1996, these data sources have important limitations that preclude drawing scientifically valid inferences about the risk of developing a neoplasm among Persian Gulf veterans.

First, Gulf war veterans have authorized special eligibility for both inpatient and outpatient treatment at VA medical facilities. The same special eligibility is not authorized for other veterans who did not serve in the Gulf making the comparisons between the two populations difficult.

Second, many Gulf war veterans are identified as having neoplasms through a participation in the Persian Gulf War Registry health examination program data base. No similar program exists for other veterans who served during that time.

Both the above factors introduced a selection bias that makes comparison of the rates of neoplasm in these two groups invalid. Furthermore, incidence of cancer cannot be determined because VA and DOD data bases do not account for individuals who sought care from non-Federal medical facilities.

VA agrees with the GAO recommendation that data sources and information systems should be strengthened. The Department has taken several actions to improve its information technology and management. As noted in the GAO report, for the first time, in fis-

cal year 1997, outpatient diagnostic information was reported in the ambulatory care data base.

As GAO points out in their testimony, this data was not available and was not included in our 1996 analysis. The outpatient diagnostic information tends to include working diagnoses that have not been verified.

In fiscal year 1998, VA initiated a Gulf War Veterans' Information System to compile timely and consistent data on Gulf war veterans from VHA and VBA data sources. VA and DOD have begun development of a joint computerized patient record that will enable seamless record transfer between the two departments. VA is committed to continue improvement of its information systems into the next century.

While we are confident that these information technology and management initiatives will improve our ability to assess the medical condition of individuals who use Federal health care, they will not allow us to accurately access the incidence of nonfatal cancers in Gulf war or other Gulf-era veterans.

Deficiencies in the data sources are neither limited nor unique to VA or DOD. Cancer registries and reporting of civilian medical communities are incomplete as well. The best U.S. cancer incidence data—and incidence is new cases of cancer per year—comes from the National Cancer Institute's SEER program. This uses 13 population-based cancer registries generally thought to be the best in the Nation, which cover approximately 14 percent of the U.S. population. We note that a U.S. National Cancer Registry has merits for many reasons, as does a VA Cancer Registry. For this reason, Dr. Kizer is committed to the Department's developing a cancer registry and we are currently working on that.

Improvements in future data sources will enhance our ability to access the health status of Gulf war veterans. However, it is our opinion that well-executed epidemiologic studies will be necessary to supplement these efforts and give us a complete assessment of Gulf war veterans' health. The VA is committed to pursuing these avenues.

Mr. Chairman, that concludes my prepared statements. We are available to answer questions.

Mr. SHAYS. Thank you very much, Dr. Mather.

[The prepared statement of Dr. Mather follows:]

STATEMENT OF
SUSAN H. MATHER, MD, MPH
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
SUBCOMMITTEE ON HUMAN RESOURCES
OF THE
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT
HOUSE OF REPRESENTATIVES
MAY 14, 1998

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to represent the Department of Veterans Affairs (VA) Gulf War veterans program. You requested that we provide testimony on the General Accounting Office report "*GULF WAR VETERANS: Incidence of Tumors Cannot Be Reliably Determined From Available Data.*" The Subcommittee requested this report because of Gulf War veterans' concerns that they may be at higher risk of neoplasms as a consequence of their service in the Gulf War.

TREATMENT OF AND RESEARCH ON GULF WAR VETERANS' ILLNESSES

Mr. Chairman, as you are aware, VA has testified before the Subcommittee at seven previous hearings—most recently on February 24, 1998---and we have provided information on our Gulf War health care and research efforts on those occasions. Specifically, at those hearings we have provided updates on VA's Gulf War veterans' health care, research, education, outreach, and benefits programs. Therefore, while I will provide some background information, I refer you to our previous testimony for a more detailed discussion of VA's Gulf War programs and to the *Annual Report to Congress for Federally Sponsored Research on Gulf War Veterans' Illnesses*, which was released on April 22, 1998.

Background

The Department of Veterans Affairs began planning to provide health care and benefits to the service members deployed to Operations Desert Shield and Desert Storm as soon as the first soldiers entered the theater of operations. VA's Gulf Registry Health Examination Program was the first component of VA's comprehensive Gulf War response. VA developed the Registry in 1991, and Congress passed authorizing legislation in 1992. The Gulf War Registry was established primarily to assist Gulf War veterans to gain entry into the continuum of VA health care services by providing them with a free, complete physical examination with basic laboratory studies and to act as a health screening database. VA staff are instructed to encourage all Gulf War veterans, symptomatic or not, to get a Registry examination. The Registry's database not only allows VA to communicate with Gulf War veterans via periodic newsletters, but also provides a

mechanism to catalogue possible exposures and prominent symptoms and to report diagnoses present at the time of the examination. This record of symptoms, diagnoses and exposures makes the Registry valuable for health surveillance purposes; however, the voluntary, self-selected nature of the database means that the experiences, illnesses and health profiles of those in the Registry cannot be generalized to represent those of all Gulf War veterans.

Since the Registry examination program was initiated, VA's Gulf War programs have grown to encompass a comprehensive approach to health services, addressing relevant medical care, research, outreach and educational issues. In 1993, at the request of VA, Congress passed legislation later enacted as Public Law 103-210, giving Gulf War veterans special eligibility (priority) for VA health care. This law gave VA the authority to treat Gulf War veterans who have disabilities that may have resulted from exposure to a toxic substance or environmental hazard during Gulf War service. We are also pleased that Congress passed legislation subsequently enacted as Public Law 105-114, which expands Gulf War veterans' eligibility for health care for any disability that might be associated with service in the Gulf War. VA now provides Gulf War Registry health examinations and hospital and outpatient follow-up care at its medical facilities nationwide, specialized evaluations at four regional Referral Centers, and readjustment and sexual trauma counseling at Vet Centers and VA medical facilities nationwide to Gulf War veterans. To date, almost 67,000 Gulf War veterans have completed Registry examinations; almost 2.7 million ambulatory care visits have been provided to 226,530 Desert Shield/ Desert Storm Conflict veterans; more than 23,000 Gulf War veterans have been hospitalized at VA medical facilities; there have been almost 500 admissions to specialized Referral Centers; and more than 83,000 Gulf War veterans have been counseled at VA's Vet Centers. VA is committed to continue to provide, and improve, health care services available to Gulf veterans.

IOM Workshop on Assessment of Health Outcomes and Treatment Effectiveness

Concerns have been raised about the government's ability to track the health of Gulf War veterans. As a result, VA and the Department of Defense (DoD) have contracted with the National Academy of Sciences, Institute of Medicine (IOM), to provide advice on the optimal methods to assess the health status of Gulf War veterans and the effectiveness of treatments being delivered by the Department. On May 7, the IOM held a workshop in Washington, and IOM will next produce an interim report.

Status of Gulf War Veterans Research

In order to get the best assessment of the health status of Gulf War veterans, a carefully designed and well-executed research program is necessary. VA, as presidentially-designated coordinator for Federally sponsored Gulf War research, has laid the foundation for such a program. Under the auspices of the Persian Gulf Veterans Coordinating Board Research Working Group, VA, DoD and the Department of Health and

Human Services have developed a structured research portfolio to address the currently recognized, highest priority medical and scientific issues. 121 Federally sponsored research projects are pending, underway or have been completed. More than half of these projects are being carried out by non-Federal investigators. Thirty-nine of the 121 projects are completed. Seventy-eight projects are ongoing, and four have been awarded funds but are pending start-up.

Federally funded researchers have, to date, published approximately 60 papers in the peer-reviewed literature, including nearly 40 from VA investigators alone. VA's own research programs related to illnesses of Gulf War veterans include more than 40 research projects, amounting to a cumulative expenditure of research dollars projected from FY 1994 through FY 1998 of approximately $27 million. The research portfolio of VA encompasses a variety of research approaches, including epidemiology, basic research, clinical research, and applied research, applied to a vast array of potential exposures and health outcomes. In addition, VA research is embarking on some important steps toward the assessment of effective treatments for Gulf War veterans' illnesses.

I am pleased to report that there has been significant progress on a number of key VA research studies. The VA Office of Research and Development has awarded funding for Phase III of the National Health Survey of Gulf War Veterans, and preliminary site selection has begun. It is expected that physical examinations will begin in the near future. As you may recall, the National Survey is designed to determine the prevalence of symptoms and illnesses among a random sampling of Gulf War veterans across the nation. The Survey is being conducted in three phases. Phase I was a population-based mail survey of the health of 30,000 randomly selected veterans from the Gulf War era (15,000 Gulf War veterans and 15,000 non-Gulf War veterans, males and females). The data collection phase is complete and analysis of the data continues. Phase II consisted of a telephone interview of 8,000 non-respondents from Phase I (4,000 deployed and 4,000 non-deployed veterans) to assess any response differences between respondents and non-respondents to the mail survey. Additionally in Phase II, 2,000 veterans from each of the deployed and non-deployed groups (1,500 mail respondents and 500 telephone interview respondents) will be selected to validate their health questionnaire responses (mail or telephone) against their medical records. Phase II is nearing completion. In Phase III, 2,000 veterans who responded to the postal survey or underwent a telephone interview will be invited, along with their family members, to participate in a comprehensive physical examination protocol. These examinations will be conducted at 17 VA medical centers nationwide and involve specialized examinations, including neurological, rheumatological, psychological, and pulmonary evaluations. Completion of data collection is anticipated in late-1999. This study will provide the most comprehensive picture of the prevalence of symptoms and illnesses among veterans who served in the Gulf War.

With respect to mortality, VA's Environmental Epidemiology Service has carried out a mortality study of all Desert Shield and Desert Storm veterans and a comparison group of military service members who were not deployed to the Gulf War. The results of the study through September 1993 and a follow-up through December 1995 did not reveal an

increased mortality risk of medical conditions, including neoplasms in Gulf War veterans. With respect to cancer, this result is not surprising since most cancer has a long latency for development after exposure to carcinogens. VA will continue to update this data on five-year intervals. This is a valid mechanism to provide surveillance for development of serious, life-threatening cancers in veterans. I would note that the mortality study did find elevated rates of death from external causes (primarily accidents) in Gulf War veterans as compared to the non-deployed control group.

Two other studies of interest to the Committee are in the planning stages. The VA Office of Research and Development is developing a multi-site, randomized clinical trial to assess the effectiveness of treatments for Chronic Fatigue Syndrome (CFS) and Fibromyalgia (FM) in Gulf War veterans. Such a study is now possible because these conditions have case definitions along with proposed treatments. A second treatment trial is under development that will examine the effectiveness of antibiotic treatment in ill Gulf War veterans. These studies will be carried out in collaboration with DoD and conducted at multiple VA and DoD health care facilities. Each department is investing up to $5 million to conduct these trials. Additionally, because of its experience and research on the characteristics of these diseases, we are consulting with the National Institutes of Health (NIH), the University community, and international experts in the development of these research protocols.

In addition, the VA Office of Research and Development has issued a Program Announcement, or general invitation to VA clinicians/scientists, to propose additional multi-site trials to evaluate the effectiveness of treatment strategies for other symptom based conditions. The planned treatment trial, along with any trials proposed in response to the Program Announcement, will undergo rigorous scientific peer review by VA's Federally chartered Cooperative Studies Evaluation Committee. These treatment trials are in response to the mandate in Public Law 105-114 to establish demonstration projects to test new approaches to treating and improving satisfaction with treatment of Gulf War veterans who suffer from undiagnosed and ill-defined disabilities.

GAO Report

The Department has received and reviewed the GAO's report "*GULF WAR VETERANS: Incidence of Tumors Cannot Be Reliably Determined From Available Data*". The report discusses the strengths and weakness of the available data for assessing neoplasms among Gulf War veterans. GAO concludes that no direct link has been established between potential exposures and development of tumors among Gulf War veterans. GAO raises concerns that many of the potential hazardous exposures of these veterans are potentially carcinogenic. GAO states that existing data sources provide limited information about the incidence of tumors or other illnesses among Gulf War veterans and recommends that the Secretaries of Veterans Affairs and Defense continue to develop comparable databases and strengthen existing data systems. Finally, GAO points out neither Federal nor civilian medical data sources currently provide adequate information on the health conditions of Gulf War veterans to allow a reliable estimate of the incidence of tumors. We concur.

VA also agrees with GAO's conclusion that cancer incidence among Gulf War veterans cannot be determined using existing federal, state, or private data sources. As was discussed in our previous testimony before this Committee on June 25, 1996, these data sources have important limitations that preclude drawing scientifically valid inferences about the risk of developing a neoplasm among Persian Gulf veterans. First, Gulf War veterans have been authorized special eligibility for both inpatient and outpatient treatment at VA medical facilities. The same special eligibility is not authorized for other Gulf War era veterans who did not serve in the Gulf, making comparisons between the two populations difficult. Second, many Gulf War veterans are identified as having neoplasms in the PGW Registry health examination program database. No similar database exists for other Gulf era veterans. Both of the above factors introduce a selection bias that makes comparison of the rates of neoplasms in these two groups invalid. Furthermore, incidence of cancer cannot be determined because VA and DoD databases do not account for individuals who sought care from non-federal medical facilities.

VA agrees with the GAO recommendation that data sources and information systems should be strengthened. The Department has taken several actions to improve its information technology and management. As noted in the GAO report, for the first time in FY 1997 outpatient diagnostic information was reported in the ambulatory care database. In FY 1998, VA initiated a Gulf War Veterans' Information System to compile timely and consistent data on Gulf War veterans from VHA and VBA data sources. In addition, VA and DoD have begun development of a joint computerized patient record that will enable seamless record transfer between the two Departments. VA is committed to continue improvement of its information systems into the next century.

While we are confident that these information technology and management initiatives will improve our ability to assess the medical condition of individuals who use Federal health care, they will not allow us to accurately assess the incidence of non-fatal cancers in Gulf War or other Gulf Era veterans. Deficiencies in the data sources are neither limited to nor unique to VA or DOD. Cancer registries and reporting in the civilian medical community are incomplete as well. The best U.S. cancer incidence data (new cases of cancer per year) comes from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program. This uses 13 population based cancer registries (Atlanta, Detroit, Seattle/Puget Sound, Oakland/San Francisco, Connecticut, Iowa, New Mexico, Utah, Hawaii, Rural Georgia, Arizona, Los Angeles, and San Jose/Monterey) generally thought to be the best in the nation. SEER data cover approximately 14% of the U.S. population. We note that, beyond SEER, a U.S. National Cancer Registry has merit for many reasons, as does a VA Cancer Registry. With respect to the latter, Under Secretary for Health, Kenneth W. Kizer is committed to the Department's developing such an effort.

Improvements in future data sources will enhance our ability to assess the health status of Gulf War veterans. However, it is our opinion that well-designed and well-executed epidemiologic studies will be necessary to supplement these efforts and give us

a complete assessment of Gulf War veterans' health. VA is committed to pursuing these avenues.

CONCLUSION

Mr. Chairman, that concludes my prepared statement. My colleagues and I will now be happy to respond to any questions Committee members may have.

Mr. SHAYS. Mr. Christopherson, it is nice to have you back as well.

Mr. CHRISTOPHERSON. Let me start in the same place I started before, which is that we both care about the same thing, which is taking care of our troops. It is our obligation. We intend to do it, and we intend to do it well. We all agree that we have a lot of Gulf war veterans who are ill. That has never been the question. The issue is how we better understand what they are ill from and trying to do the most we can about that. Dr. Mazzuchi will do more specifics about the cancer issue, but let me do brief overview remarks.

As I have indicated in the past, there were mistakes during the Gulf war. Those were mistakes to be avoided in the future, and we need to work hard to be sure that is the case. We are going to continue to keep searching for the sources of the illnesses and try to better understand it. We are going to continue our care and research programs, continue our work with VA on research and a wide range of other efforts. We are going to continue our efforts with the Institute of Medicine to make sure we are getting the best independent advice we can out there as to how best to approach this issue now and for the future.

One of the major lessons that comes out of this is essentially our need to have a stronger health protection program generally. The President has signed up for that and everybody has been very supportive. It deals with both the issue of medical surveillance, and that is key because no matter what we may find out here, whether it is in the cancer registry or our data bases, it still comes back to the question of, how does that associate itself back to what happened during the Gulf war or any future wars? So we need good data to associate itself with the clinical kinds of conditions that we find in some of our people.

We are working very hard to develop a better data system to support that effort. We put into operation an ambulatory data system which gives us individual information about cancer diagnosis. It is helpful, combined with other kinds of analyses, to learn more about that. We have a number of other efforts as well, data sources that have been going over there, to war, with the troops, and our ability to combine our data bases together allows us to do a much more aggressive analysis.

And as indicated by Dr. Mather, there is an effort to combine our two systems which allows us to share data back and forth with cross-analysis between the two different departments in the two different parts of our beneficiary population.

We understand, by the way, that cancer is very difficult. It is difficult because it is hard to figure out when it began, when the exposure was that began the cancer, its onset. The diagnosis is not always easy, and to trace back the cause is extremely difficult.

I think, again, for the future, forced health protection, and obviously you have heard of our anthrax vaccination program, part of our trying to do something very different than we did 7 years ago; medical surveillance, that is different than what it was a number of years ago; the clinical evaluation and care program is ready and in place for any future efforts. There again, the research program is now well tuned, the coordination between us and VA is well

tuned to make sure that is ready for any kind of future that comes along.

Our missions are clear. Protect the health of the troops. Our other mission is take care of our people and take care of them well.

With that, let me turn to Dr. Mazzuchi.

Mr. MAZZUCHI. Thank you, Mr. Chairman. It is my pleasure to be here and discuss the GAO views on the report on the incidence of tumors in Gulf war veterans. In general, the report highlights both the strengths and weaknesses of available data for assessing cancers and other tumors, and the Department generally concurs with the GAO's findings on the limitations of existing Federal and State data systems available to study the incidences of cancer and benign tumors among population subgroups, including our Gulf war veterans. However, we believe that the picture is not quite as bleak as the report may lead one to believe.

Nearly 8 years after the fighting has ceased, objective data available to this date still suggests no major differences in cancer rates among our Gulf war veterans and our Gulf-era veterans.

However, it is obviously premature to make any final conclusion since the development of cancer is usually characterized, as Dr. Mather said, by a long latency period and it is certainly too soon to detect whether or not there is an increased incidence of tumors among our Gulf war veterans.

Many of the weaknesses noted in the reporting systems available for study of cancers and benign tumors are not unique to DOD or to the VA health care systems. Establishing a National Cancer Registry with standardized reporting of cancers would certainly address many of the data problems noted in the GAO's report. We agree with the GAO recommendation that the State registry systems may indeed provide further avenues of research, and we have previously used State registries for some of our analysis of Gulf war veterans' health concerns.

We differ from the GAO in our view, however, whether the data from cancer registries can be linked to subpopulations of Gulf war veterans. The data from States with the National Cancer Institute's SEER registries can be cross-referenced with Gulf war veteran demographic and self-reported data to validate self-reports and provide incidence data for comparative analysis. We agree that the ongoing improvements in current and future health information systems still may not allow us to answer all of the questions about specific health conditions in specific military members or veterans, and that further research efforts will be needed to supplement available data systems. In such cases, well-designed epidemiologic research studies will be needed to assess the accuracy and prevalence of cancer or other illnesses among Gulf war veterans or other veteran populations.

As the GAO authors mentioned, the VA National Health Survey of Persian Gulf-era veterans will be a very useful cohort to follow. Currently, DOD is surveying the Navy construction workers population that might also be used as a good cohort study. In fact, the study design already includes provisions to provide for the ability to do long-term followup. Other opportunities also exist with similar prospective analysis of existing cohorts. A study that comes to mind is the CDC Iowa study.

As noted by the GAO, DOD and VA have contracted with the National Academy of Sciences Institute of Medicine to provide advice on the optimal methods to assess the health status of Gulf war veterans. In addition, VA has been working with the Congress to establish a permanent scientific advisory committee through the National Academy of Sciences to review scientific literature and determine whether a statistically significant and biologically plausible association exists between Gulf war service and illnesses suffered by Gulf war veterans.

These efforts will be important both for the evaluation of health outcomes among veterans and the generation of hypotheses for future studies looking at Gulf war experience in association with increased instances of adverse health outcomes, including tumors.

I think it needs to be emphasized that there is no one system that will give us all of the answers, but I think we need a multifaceted approach to answering these questions that will combine both cohort studies, as well as registries, as well as other kinds of research.

With the help of all of our partners, including this subcommittee, I am confident that we can get a greater understanding of the health concerns of our Gulf war veterans and conduct adequate research to address the health outcomes which may have resulted from Gulf war deployment, as well as future deployment of our military.

Again, we appreciate this opportunity to testify before this committee and look forward to answering any of your questions.

Mr. SHAYS. Thank you very much. I think we are with you, Dr. Miller.

[The prepared statement of Mr. Christopherson follows:]

Mr. Chairman and members of the Subcommittee, I am Gary Christopherson, Acting Assistant Secretary of Defense for Health Affairs. I am pleased to be here today to provide testimony before this subcommittee on the General Accounting Office (GAO) final report "GULF WAR VETERANS: Incidence of Tumors Cannot Be Reliably Determined From Available Data," dated March 3, 1998. This report was requested in response to the Committee's concerns about whether Gulf War veterans have an increased risk of developing certain cancers as a result of their exposures to hazards in the Persian Gulf.

The Department of Defense (DoD) remains engaged in a comprehensive, coordinated effort to respond to the health concerns of Gulf War veterans (GWV). We hope our testimony today will help alleviate concerns and fear among veterans regarding our ability to address the health outcomes that may have resulted from participation in the Gulf War. Our testimony today will cover:

- Current initiatives to strengthen health information reporting systems and transfer of data from DoD to the Department of Veterans Affairs (VA);
- Our commitment to work in a productive and cooperative manner to use each Department's scientific strengths and unify these capabilities into a productive, responsive and fully integrated research effort;
- Our genuine concern and recognition of the magnitude and consequences of the challenges before us;
- Analysis of the GAO's findings and our current and future research efforts addressing health outcomes among Gulf War veterans.

As we have testified before, DoD and VA are working to enhance and amplify current health information systems for military members while they serve on active duty and when they subsequently receive care in the VA system. Improved health information data are inherent in the DoD and the Joint Staff Force Health Protection initiatives. On November 8, 1997, the President supported those initiatives and directed "...the Departments of Defense and Veterans Affairs to create a new Force Health Protection Program. Every soldier, sailor, airman and marine will have a comprehensive, life-long medical record of all illnesses and injuries they suffer, the care and inoculations they receive and their exposure to different hazards."

Through a joint DoD/VA executive committee, a number of initiatives are underway to improve the transfer of health information between DoD and VA. One is to establish procedures for the transfer of a wide range of health information, regardless of whether or not the respective data systems are compatible. A second initiative is to agree upon common physical examination criteria, which can be used for both the DoD discharge examination and as a VA compensation examination. The third is to develop jointly a computerized patient record system that would be used by both DoD and VA.

As highlighted in the GAO report, the lack of exposure information leads to difficulty in formulating specific hypotheses about what kind of tumors for which exposed individuals may be at greater risk. Key to identifying any increase in adverse

health outcomes when no particular exposure or disease is the target is a comprehensive health information system. The Composite Health Care System II (CHCS II) is an ongoing development program which will ultimately provide a computer-based patient record. CHCS II consists of incremental deliveries of increased functionality supporting the President's November 8, 1997, memorandum and the Departments' Force Health Protection (FHP) program. The Preventive Health Care System (PHCS) and the Personal Information Carrier (PIC), both integral to improved medical tracking capability, are functional components of CHCS II. PHCS and the PIC in the near term will be deployed as a stand-alone system in FY 99, pending identification of funding. The long-term plan, however, is to fully integrate PHCS and the PIC functionality into CHCS II. The end product is a computerized patient record system that would be used by both DoD and VA, providing a comprehensive health information system from which data for epidemiological studies could be obtained.

The Research Working Group of the Persian Gulf Veterans' Coordinating Board ("Research Working Group") was formed less than five years ago to coordinate Federal research into the health consequences of service in the Persian Gulf War. The genuine concern and recognition of the magnitude and consequences of the challenges before us are reflected by our commitment to work in a productive and cooperative manner that utilizes our individual Department's scientific strengths and unifies them into a productive, responsive and fully integrated research effort. The path of science is difficult, challenging, expensive and time consuming. Easy and complete solutions to complex health problems are exceptionally attractive and extremely rare. This truth is especially disappointing to those of us who see those veterans and non-veterans who suffer the consequences of prolonged, often incapacitating illnesses of uncertain or unknown origins and for whom medical science offers little in the way of long-lasting relief or a cure.

The Federal research effort addressing illnesses among Gulf War veterans involves scientists in Federal, academic, and private institutions, both in the United States and abroad. It involves research sponsored by DoD, VA and the Department of Health and Human Services (DHHS). The coordination and management of this extensive, international research effort on Gulf War veterans' illnesses have required the establishment of an overall research policy framework linking each Department's research management hierarchy. This essential linkage is provided through the Research Working Group.

Over half of the research projects have involved non-government scientists who received Federal funding for their research through rigorous, competitive peer review processes. In their final reports of extensive reviews of the research programs managed by the Research Working Group, the Institute of Medicine and the Presidential Advisory Committee on Gulf War Veterans' Illnesses endorsed the research directions of the Research Working Group.

We are committed to sustaining a sound and responsive working plan, against which scientifically meritorious proposals will be evaluated for relative programmatic

merit. Historically, the match of scientific merit and program relevance has been the basis for establishing research priorities. There are no more reliable means to progress of which I am aware.

The DoD is working closely with the VA regarding our preparations to protect the health of our U.S. forces during future deployments, and prepare for their health needs upon their return home. The senior health leadership of both organizations meets regularly. We have active interagency working groups addressing health care, medical record keeping, risk communication, and deployment and re-deployment health programs.

We must be ready to address health concerns of veterans and their families when our service men and women return from a conflict. Our Comprehensive Clinical Evaluation Program (CCEP) for Gulf War veterans remains active. To date, over 32,000 veterans and their family members have been provided CCEP health evaluations. As appropriate, and in close coordination with the VA, we will use that program to address any health issues that may arise out of current or future deployments.

The Department remains engaged in a comprehensive, coordinated effort to respond to the health concerns of Gulf War veterans; our veterans and their families deserve no less. DoD, VA, and DHHS are committed to finding answers to Gulf War veterans' questions. To address these complicated issues, we will continue to solicit advice from independent scientists and experts. The challenges are great and while there may be no quick solutions, we are committed to responsible and aggressive pursuit and resolution of these problems.

We appreciate the interest this Committee and others have shown in the health of the men and women who serve and have served this nation in our armed forces. The health and fitness of military personnel have long been concerns of those responsible for ensuring troop readiness and effectiveness. The Military Health System wants to achieve its goal to take care of those men and women and their families, and protect their health. We recognize that our commitment to keeping our veterans healthy does not end when they leave active service. We will continue to work with you and the VA to ensure the government meets its commitment to our veterans.

I appreciate the opportunity to testify before this Committee, and look forward to answering your questions. Dr. John Mazzuchi will now address some of the specifics of the GAO's report and our current research efforts.

Mr. Chairman and distinguished members of the Subcommittee, thank you for this opportunity to discuss the findings reported in the GAO's final report *"GULF WAR VETERANS: Incidence of Tumors Cannot Be Reliably Determined From Available Data."* I am Dr. John Mazzuchi, Deputy Assistant Secretary of Defense for Health Affairs, Clinical and Program Policy. Today, I will focus my testimony on the findings and recommendations of the GAO and our current research initiatives to address the concerns of the Subcommittee, the GAO, and our Gulf War veterans.

The Department has reviewed the GAO's final report, noting that many of the suggested changes from DoD's review of the draft report were incorporated. In general, this report highlights strengths and weaknesses of the available data for assessing cancers and other tumors among Gulf War veterans, and we generally concur with the GAO's findings on limitations of existing Federal and State data systems available to study incidence of cancers and benign tumors among population subgroups, including Gulf War veterans. However, the picture is not as bleak as this report may lead one to believe. Nearly eight years after the fighting ceased, there have been no objective data to suggest that Gulf War veterans are more likely to develop cancers than their nondeployed peers. In fact, the objective data available thus far suggest no difference in risk. But, we continue to monitor our Gulf War veterans, and as I note later, it is really too soon to detect definitively whether there is or is not an increased incidence of tumors among Gulf War veterans.

As the GAO authors note, the majority of the completed research focuses only upon hospitalization data, registry data, and self-reported survey data. Preliminary analysis examining nonfederal hospitalizations, however, also indicates that there is no suggestion of an increased incidence of cancers among Gulf War Veterans. The ongoing validation of survey data from both the VA's *National Health Survey of Persian Gulf War Era Veterans* and the University of Iowa *Illnesses Among Persian Gulf War Veterans: Case Validation Studies* will address the limitations imposed by previous subjective assessments. The VA Office of Research and Development has awarded funding for Phase III of the National Health Survey of Gulf War Veterans, and preliminary site selection has begun. Publication of results from the DoD sponsored nonfederal hospitalization study is expected later this year.

The DoD expenditure for Gulf War veterans' illnesses specific research from FY94 through FY98 totals $62.6M. DoD established a dedicated program element for GWV illnesses' research beginning in FY99 with FY98 being the transition year. From FY98 through FY02, the Department estimates investing approximately $20M per year in Gulf War related illnesses' research, thereby bringing the total since FY94 through FY02 to $142.6M. DoD has further incorporated review of DoD-sponsored research on Gulf War veterans' illnesses in the annual Technology Area Review and Assessment process. This review is utilized by DoD to obtain advice and recommendations on its science and technology programs and utilizes the expertise of independent technical experts.

The entire Federal research portfolio currently consists of 121 projects with a total research specific investment to date of approximately $115 million. Of these 121 projects, 39 have been completed, 78 are ongoing, and 4 have been newly awarded and are awaiting startup. We have just completed merit review needed to award nearly $8M of new research funds. Additional research projects are at various stages of planning. There are 14 identified research focus areas ranging from the effects of service in the Gulf War on the brain and nervous system to the potential health consequences of low-level exposure to chemical warfare agents. Approximately one-third of the projects are epidemiological, one-third are clinical, and one-third are basic research. This funding

profile does not include related funds for health care delivery or our investments in highly relevant, core science and technology programs (e.g., medical, chemical, and biological warfare defense) which are established, continuing programs that will likely have direct benefits for the Gulf War veterans' illnesses research program.

This investment has been effective in providing new information on the impact of military service in the Gulf War on health-related problems, providing new areas of research exploration, and prompting new force protection initiatives that provide for medical surveillance during future operations. With specific reference to Gulf War veterans' illnesses, the investment and findings have highlighted the need for improved prevention, intervention, and treatment approaches. The national program has responded to these needs both in its approaches for veterans' health care and in the Research Working Group's emphasis on its research investment strategy.

The development of cancer is usually characterized by a long latency period and it is too soon to detect definitively whether there is or is not an increased incidence of tumors among GWVs. The importance of latency effects as well as other time-related factors, such as age at exposure, in determining cancer risk has long been recognized. Often, either because of poor exposure assessment or the desire to report a simple summary measure of association, measures of exposure such as ever/never exposed or cumulative exposure are used to summarize exposure histories. Although such measures can be useful for detecting whether there is or is not an association between exposure and disease, it is well-known that the timing of exposure plays an important role in determining when and how much the eventual disease risk is increased (or decreased) by the exposure. Because the rate of most cancers increases dramatically with age, it is also true that for a given study group, the expected number of cancers per unit of time will increase with time since exposure, simply because the study group is aging. Thus, examination of absolute numbers of cases as time since exposure increases would be misleading. One would expect to see an increase even if there were no change due to the exposure. Biologically, cancer is most probably the end result of a complex multistage process and therefore may be due to a sequence of exposures to different agents at each of these stages.

Many of the weaknesses noted regarding the data systems available for the study of cancers and benign tumors are not unique to the DoD or VA health care systems. We agree that establishing a national cancer registry with standardized reporting of cancers would address many of the data problems noted in the GAO's report. Generally, cancers are reported to hospital, State and national cancer registries — benign tumors and non-melanoma skin cancers are not reported. A person with a cancer may not be entered into a cancer registry, since this is frequently a voluntary activity for civilian medical centers, may have less emphasis in ambulatory medical care settings, and is subject to varying quality control from institution to institution. DoD administers its own cancer registry (the Automated Central Tumor Registry - ACTR) for active duty military, retirees, family members, and others who use DoD medical facilities. This registry was established in 1986 to compile track, and report cancer patient information from military medical treatment facilities. While the reporting system is designed to capture all cancer cases

treated at DoD facilities, it is subject to the same limitations as other cancer registries: accuracy, timeliness, and completeness of reporting.

DoD agrees with the GAO recommendation that State registry systems may provide another avenue of research and we have previously used State registries such as birth defect registries for epidemiologic analysis of Gulf War veterans' health concerns. We differ, however, from the GAO, in that we believe data from State or national cancer registries such as the National Cancer Institute (NCI) Surveillance, Epidemiology and End Result (SEER) Cancer Registry can be cross-referenced with State specific Gulf War veteran demographic data to validate self-reports of cancer.

Both DoD and VA have health registries that provide medical examinations and diagnostic services to Gulf War veterans. The programs are open to all active duty, National Guard, Reserve Components, separated, retired military personnel and others who participated in the Gulf War deployment. The number of registry participants with a primary diagnosis of a malignant or benign tumor is very small, less than 1 percent. Although the suitability of the registries for assessing cancer incidence is limited, they do serve as a primary source for case series, which can be used for hypothesis generation and further study using analytical epidemiologic methods. Case reports and case series represent an important interface between clinical medicine and epidemiology.

The DoD concurs that the ongoing improvements in current and future health information systems (including the Composite Health Care System, the Ambulatory Data System, and the Computerized Patient Record) still may not allow us to answer all questions about specific health conditions, such as cancers, in specific populations of military members or veterans and that further research efforts will be needed to supplement the available data systems. In such cases, well-designed epidemiological research studies will be needed to assess accurately the incidence and prevalence of cancers (or other illnesses) among veterans of the Gulf War or other veteran populations suspected to be at increased risk for a specific health outcome.

Epidemiologic studies provide valuable information about the response of humans who have a unique exposure (the science of epidemiology is concerned with the distribution and determinants of disease frequency in populations). Descriptive epidemiologic studies are useful in generating hypotheses and providing supportive data, but can rarely be used to make a causal inference. Analytical epidemiologic studies of the case-control or cohort variety, on the other hand, are especially useful in assessing risks to exposed individuals. (Analytic epidemiology focuses on the determinants of a disease by testing the hypothesis formulated from descriptive studies, with the ultimate goal of judging whether a particular exposure causes or prevents disease). Many cohort studies are designed to allow for periodic reexamination or resurvey of the members of the cohort. The periodic requestioning of cohort members also allows data to be collected on health

outcomes, exposures or risk factors that were not recognized to be of interest at initiation of the study.

Criteria for adequacy of epidemiologic studies are well recognized. They include factors such as the proper selection and characterization of exposed and control groups, the adequacy of duration and quality of follow-up, the proper identification and characterization of confounding factors and bias, the appropriate consideration of latency effects, the valid ascertainment of the causes of morbidity and death, and the ability to detect specific effects. Where it can be calculated, the statistical power to detect an appropriate outcome should be included in the assessment. Negative results from such studies cannot prove the absence of carcinogenic action; however, negative results from a well designed and well-conducted epidemiologic study can serve to define the upper limits of risk.

Evidence of carcinogenicity from human studies comes from three main sources:

- Case reports of individual cancer patients who were exposed.
- Descriptive epidemiologic studies in which the incidence of cancer in human populations is found to vary in space and time with exposure.
- Analytic epidemiologic (case-control and cohort) studies in which individual exposure is found to be associated with an increased risk of cancer.

Three criteria must be met before a causal association can be inferred between exposure and cancer in humans:

- There is no identified bias that could explain the association.
- The possibility of confounding has been considered and ruled out as explaining the association.
- The association is unlikely to be due to chance.

In general, while a single study may be indicative of a cause-effect relationship, confidence in inferring a causal relationship is increased when several independent studies show the same association, when the association is strong, when there is a dose-response relationship, or when a reduction in exposure is followed by a reduction in the incidence of cancer.

Epidemiologic studies are initiated from clinical observations, from geographic and temporal analysis of mortality data or from general hypotheses based upon our overall knowledge of exposures.

The GAO authors argue that not all cancers would be detected in a mortality study but certainly many of the most serious cancers would be detected. The GAO authors argue that true cancer incidence would be underestimated and GWVs rates could not then be compared with civilian cancer rates. A more valid argument would be that military

personnel are often healthier than their civilian peers and the military/civilian rate comparison is inappropriate anyway. Instead, what would seem more appropriate would be to compare cancer mortality risk ratios between GWVs and their nondeployed military peers, which can be done with current ongoing mortality studies.

As the GAO authors alluded, a second more costly methodology would be to follow large cohorts of GWVs and control groups for 20 to 30 years. To do so, it would seem more efficient to use the large study cohorts now identified by recent surveys. These populations could be followed with periodic mailings for cancer incidence and other chronic diseases during the next 10 or 20 years. The GAO authors mention the VA's National Health Survey of Persian Gulf War Era Veterans (30,000 persons), which would be a very good cohort to follow. Additionally, DoD is currently surveying a population of 19,000 Navy construction workers (Seabees) which might also be used. In fact, the DoD study design already includes provisions to provide for the ability to do long term follow up.

As noted by the GAO, DoD and VA have contracted with the National Academy of Sciences (NAS), Institute of Medicine (IOM) to provide advice on the optimal methods to assess the health status of Gulf War veterans and the effectiveness of treatments being delivered. The IOM held a Workshop in Washington, DC on May 7 and an interim report of the workshop findings is expected in the next 30 – 60 days. In addition, VA has been working with Congress to develop legislation to establish a permanent scientific advisory committee, through the National Academy of Sciences, to review scientific literature and determine whether a statistically significant and biologically plausible association exists between Gulf War service and illnesses suffered by veterans. These efforts will be important both for the evaluation of health outcomes among veterans and the generation of hypotheses for future analytical epidemiological studies looking at the Gulf War experience and an association with increased incidence of adverse health outcomes including tumors.

With the help of all of our colleagues in the Executive Branch, as well as this Subcommittee, I am fully confident that we can better protect the health of our troops during deployment and in garrison and conduct and fund an adequate research enterprise to address health outcomes which may have resulted from the Gulf War deployment or future deployments of our military forces.

Again, we appreciate the opportunity to testify before this Committee, and look forward to answering your questions.

Dr. MILLER. Thank you, Mr. Chairman and members of the subcommittee. I am Dick Miller, director of the Medical Follow-Up Agency at the National Academy of Sciences. Our organization has been carrying out research on veterans health for more than 50 years.

I am pleased that Dr. Marie Swanson who participated in the preparation of this statement could be present with me today; Dr. Swanson is professor of medicine and director of the cancer center at Michigan State University. She is a cancer epidemiologist and is in charge of one of the surveillance epidemiology and end-result programs, SEER programs, mentioned in the GAO report. She is also a member of our board of advisers and has served on two Institute of Medicine committees studying Persian Gulf war illness.

The GAO report is generally correct in its conclusion that the incidence of tumors cannot now be readily, routinely and reliably determined in Persian Gulf war veterans. The report's description of the strengths and limitations of studies completed and existing data sources are, for the most part, correct. One error of fact crept into the report concerning the SEER program. While it is true that the data are reported to the National Cancer Institute in aggregated anonymous form, each Registry site does have identifier information which can be linked to individuals.

Thus, it is possible to link all 697,000 Persian Gulf war veterans and a suitable number of Persian Gulf war-era veterans as controls at each of the 10 SEER sites. This would allow comparisons of the incidence of tumors of Gulf war veterans with the incidence in era controls and with comparable U.S. populations.

As you have heard this morning, obtaining data of this type is a complex undertaking fraught with potential errors. If it is decided that a long-term evaluation of the incidence of tumors in Persian Gulf war veterans is necessary, in spite of the fact that, to date, there are no data that convincingly indicate excess risk, this effort needs to be done very well to avoid errors that could have far-reaching implications. Expert advice from outside the Government may be required if credible results are to be produced. The objectives of a system to address this question of whether Persian Gulf war veterans are experiencing excess cancers, excess tumors and mortality should have four objectives.

First, to provide alerts if tumor rates exceed population norms.

Second, to conduct targeted, and by that I mean cancer- and exposure-specific, studies when indicated by the alerts or by new exposure information.

Third, to have a credible system in which the Persian Gulf war veterans can have confidence.

Fourth, to keep costs within reasonable limits.

The combination of a low-cost sentinel system with more definitive, elaborate studies to followup on alerts from that sentinel system would seem to meet all of the objectives, if done correctly. The sentinel system would need to have adequate sensitivity to detect possible departures from expected tumor rates, would use existing or projected data bases and would require periodic reassessment of cancer incidence and mortality.

To have more than a general surveillance system, specific exposures that are known to increase the risk of specific forms of can-

To have more than a general surveillance system, specific exposures that are known to increase the risk of specific forms of cancers must be identified and linked to well-defined subsets of veterans who are thought to have had these exposures.

Similarly, should the surveillance systems identify subsets of veterans with higher than anticipated risks of specific cancers, studies could be designed to assess relevant exposures or at least to improve the monitoring system during future deployments.

I do not know if there is excess risk of tumors in Persian Gulf veterans. If, however, it is decided that determinations of cancer incidence and tumor incidence are necessary, we suggest that your subcommittee consider having an independent expert panel formed to design a master plan to address the question in Persian Gulf war veterans and in the veterans of future deployments.

Mr. Chairman, Dr. Swanson and I will be happy to answer questions.

[The prepared statement of Dr. Miller follows:]

Mr. Chairman, Members of the Subcommittee:

I am Dr. Richard Miller, Director of the Medical Follow-up Agency, at the National Academy of Sciences. Our organization has been carrying out research on veteran's health issues for more than 50 years, since our founding by Dr. Michael DeBakey in 1946. I am pleased that Dr. Marie Swanson, who participated in the preparation of this testimony, could be present with me today. Dr. Swanson is Professor of Medicine and Director of the Cancer Center at Michigan State University. She is a cancer epidemiologist in charge of one of the ten SEER programs mentioned in the GAO report. She is also a member of our board of advisors and has served on two Institute of Medicine committees studying Persian Gulf War Illness. However, we are speaking for ourselves today and not for the Institute of Medicine, since there has been no official IOM review of the report, Gulf War Veterans: Incidence of Tumors Cannot Be Reliably Determined from Available Data.

In my opinion, the report is generally correct in its conclusion that, on the basis of methods currently employed, the incidence of tumors cannot be readily, routinely, and reliably determined in Persian Gulf War Veterans. The report's descriptions of the strengths and limitations of studies completed and existing data sources are for the most part correct. One error of fact crept into the report concerning the Surveillance, Epidemiology, and End Results (SEER) Program. While it is true that the data are reported to the National Cancer Institute in aggregated, anonymous form, each registry site does have identifier information, which can be linked to individuals. Thus it is possible to link all 697,000 Persian Gulf War Veterans and Persian Gulf War era controls at each of the SEER registry sites, permitting comparisons of the incidence of tumors of Persian Gulf War Veterans with the incidence in era controls and with comparable U.S. populations.

Obtaining data of this type is a complex undertaking, fraught with potential errors. If it is decided that long term evaluation of the incidence of tumors in Persian Gulf War Veterans is necessary – in spite of the fact that to date there are no data that convincingly indicate excess risk of tumors in Persian Gulf War Veterans – the effort needs to be done very well to avoid errors that may have far reaching implications. Expert advice from outside the government may be required if credible results are to be produced.

The objectives of a system to address the question of whether Persian Gulf War Veterans are experiencing excess cancer incidence and mortality are:

- to provide alerts if tumor rates exceed population norms in the entire Persian Gulf War Veteran group or subpopulations that may be at greater risk
- to conduct targeted (cancer specific, exposure specific) studies when indicated by alerts or by new exposure information
- to have a credible system in which Persian Gulf War Veterans have confidence
- to keep costs within reasonable limits

The combination of a low cost sentinel system with a more definitive, elaborate, and expensive studies to follow up on alerts from the sentinel system would seem to meet all of the objectives if done correctly. The sentinel system would need to have adequate sensitivity to detect possible departures from expected tumor rates, would use existing or projected databases, and would require periodic reassessment of cancer incidence and mortality.

For general cancer incidence surveillance, linkage of the 697,000 Persian Gulf War veterans' files with regional, population-based cancer registries can be carried out periodically, e.g., every five years. Cancer mortality surveillance would be a useful complement to the incidence system and is being done by the Environmental Epidemiology Service of the Department of Veterans Affairs using the BIRLS records, supplemented with data from the National Death Index. Mortality surveillance is more efficient and less expensive than incidence surveillance and is a reasonable approximation of incidence for certain forms of cancer that are known to have chemical and environmental etiologies, such as lung cancer and liver cancer. Five-year survival is just 3% for liver cancers and 14% for lung cancers. Therefore, for certain forms of cancer, 5-year mortality studies, which can be carried out more rapidly than the incidence studies, will provide more rapid surveillance. Mortality surveillance would be best conducted as a supplement to incidence surveillance, rather than as the sole endpoint evaluated. These methods would provide accurate assessment of general patterns of cancer incidence and mortality among Persian Gulf War veterans and the general population. It also would be appropriate to consider comparison with a comparison group selected to remove the "healthy soldier" effect from the analyses.

To have more than a general surveillance system, specific exposures that are known to increase the risk of specific forms of cancer must be identified and linked to well-defined subsets of veterans who are thought to have had these exposures. Similarly, should the surveillance systems identify subsets of veterans with high risks of specific cancers, studies could be designed to assess relevant exposures, or at least to improve the monitoring systems during future deployments.

I would reiterate that to date there are no data that convincingly indicate excess risk of tumors in Persian Gulf War Veterans. If, however, it is decided that determinations of cancer incidence are desirable, we suggest that the subcommittee consider having an independent expert panel formed to develop a master plan to:

- Conduct mortality surveillance, including cancer, on a schedule, such as every five years – now being done by the VA.
- Conduct cancer incidence surveillance utilizing other inexpensive, records based studies that can be repeated routinely as part of a sentinel system.
- Assess the organization best qualified to conduct the incidence and mortality studies. For example, the VA could contract with individual regional cancer registries.

- Determine which population-based cancer registries should be selected to supplement the SEER sites in order to have the most complete cancer surveillance system.

- Evaluate changes in the medical information and health surveillance systems underway for both active and veteran populations to determine whether other records systems may be useful or preferred for cancer surveillance in the future.

- Recommend a process for updating cancer surveillance activities over time, as new sources of information become available.

- Recommend general approaches to cancer surveillance that can be used to monitor cancer occurrence in any past or future deployed populations.

Mr. Chairman, Dr. Swanson and I will be happy to answer questions.

Mr. SHAYS. Thank you very much.

Basically, the GAO fulfilled the request we made. That was to take the five data bases that existed within the VA and put them all into one. They spent approximately 3 weeks and came forward with information that says something to me. It doesn't seem to say anything to anybody else.

It says to me that of the five databases, we have 14,684 total tumors; 11,558 benign, 3,126 malignant. We could add one more malignant tumor from the gentleman who came and testified today; he is on Active Duty, but he too served in the Gulf war.

Admittedly, 2 years of additional data and two other data bases were used, but the number is double, and I need you to address with me as to why all of you seem to want to state basically that it just shows there is no difference, that we don't have any documentation that says we see any difference between the population that served in the Gulf war and the general population. Or maybe you want to respond in some other way to say, "Even if we did see a difference, it doesn't matter?"

For me, I look and I say these gentlemen and ladies had to have been healthier, and I want you to tell me that we have the same number in the public sector, and I'm going to assume that we are dealing with a base of 700,000. I'm going to make an assumption that we got everybody. So why don't you go right down the line here and tell me how you react to that.

I know what you wrote in your document here.

Mr. CHRISTOPHERSON. I think the answer is, we don't know. I'm not sure that we have it either way at this point.

What we are looking at here, and I have talked to the VA, and John has as well, we have a lot of numbers. We have a lot of different diagnoses. We are not sure how many stand up and are comparable to the data that you see in the private sector when you actually set up the incidence rate that you are talking about there.

I think the answer is that we need to look at this. We need to figure out what this data really signifies, and I think we need to continue monitoring and see if we can learn more about it. But I think the conclusion is uncertainty more than one way or the other.

Mr. SHAYS. I want to know where we agree and where we disagree.

Mr. MAZZUCHI. I think one of the ways that you want to look at it—to me, there are two questions that really need to be answered when you look at whatever illness it happens to be, cancers today with Gulf war vets.

Are the incidence rates among Persian Gulf war veterans different from veterans of the same era who did not deploy to the Gulf? And we would like to draw the comparison between military who served in the Gulf versus military who served at the same time, not in the Gulf.

Mr. SHAYS. I would like to do that too, Doctor, but I have waited too long for that to happen.

Mr. MAZZUCHI. That's really the only way I know of, of how to answer the question.

Mr. SHAYS. I'm not where you are at, and so you need to know where I'm at and then work with me from that point.

I'm not asking for something definitive. I'm not asking for something that will take away all of your uncertainty. I'm asking for something that will help give an indication that we may or may not have a problem, and that there may in fact be a greater rate, a greater incidence; and I think what I'm going to do is ask that question in a second.

Why didn't the VA do what the GAO did?

Dr. MATHER. I think that we could have done it. I don't think that it answers the question that you are asking. You are asking, is the incidence of tumors in Gulf war veterans higher than the incidence of tumors in the general population that is expressed by the SEER data. This is prevalence data. This isn't new cases in a given period of time. This is cases that have ever occurred. We can't deal with the validity either without looking further into the data bases.

For example, the outpatient data base involves working diagnoses. They are not validated diagnoses, they are not tissue-validated diagnoses.

At any given time—I have, for instance, fibroadenoma, which is a disease of the breast. Every time I go in for a repeat mammogram, the doctor writes, "rule out cancer." I have not yet been shown to have cancer despite the biopsies and the sonograms, but the working diagnosis until the biopsy comes back negative is "rule out cancer." That accounts for a lot of the neoplasms, the malignant tumors that you are seeing in the outpatient file.

Mr. SHAYS. I want you to make your point, then we have to dissect it, because I want to establish with all of you—and I am not looking for certainty yet; I guess what I'm looking for is just a basic response, first, to this question.

You told me in so many words why it doesn't answer the question I want, and you went on and explained more than one reason why. I want to know, first and foremost, why if you have these data in five different areas, you wouldn't combine them into one?

Dr. MATHER. Because they are not comparable data sets, and it is like——

Mr. SHAYS. So the answer is, it is not comparable data.

Dr. MATHER. The data in the——

Mr. SHAYS. And the second question: Is it your testimony that in the case of the 14,000, that they don't represent tumors?

Dr. MATHER. They represent tumors, but I think they fail to differentiate adequately between benign and malignant tumors. There is nobody in this room who doesn't have one benign tumor. At least the people I have looked at, I can see moles on their faces, I can see skin tags; these are benign tumors.

Mr. SHAYS. So let me understand. Your testimony before this committee is that in your various data bases that some of the benign tumors are insignificant, irrelevant and simply not important?

Dr. MATHER. That is true of the benign.

I would like to be on record as disagreeing with the gentleman from the GAO who said that the VA didn't take neoplasms seriously. In any given individual, a malignant neoplasm is a very serious matter. What we are talking about is the need to look at incidence scientifically. As we are prioritizing whether we look at ef-

fects of chemicals or incidence of cancer first, how are we going to spend our limited resources in the right away?

And I think the problem is that there is a latency period that you would expect for cancer. We are beginning to move into that latency period, but up until now we have not been in that latency period for cancers, which might have resulted from the carcinogenesis that occurred in the Persian Gulf.

Mr. SHAYS. I'm going to let you establish all of the information that you want in the record. I'm on a different wavelength because I'm trying to understand attitude. I'm trying to understand direction, and I'm trying to understand why certain things aren't happening.

And I can tell you, this is a story we are just really going to get into and we are going to have more hearings about this, so it is important that you be clear as to my interest, and your interest as well, and I want you to make sure that you establish that on the record. I don't want to intimidate you by my impatience in responding to what you want, but I do want you to be responsive to this.

First, tell me, what do the five different data bases tell us? Run down each one and tell me what they tell us.

Dr. MATHER. The Persian Gulf Registry includes the people who show up for voluntary examinations, Phase I and Phase II; we know that over 60,000 have shown up for that.

Sometimes the patients confuse these with C&P examinations, which are the compensation and pension examinations where a patient, a veteran comes in with a specific problem that he or she feels is due to her service in the military, and that examination looks at specifically that.

But the Gulf War Registry program tries to look at the total health of the individual at that point in time and registers that.

The Patient Treatment File deals with patients who have been discharged from the hospital and the working diagnosis or the diagnosis at the time they were discharged from the hospital. For the most part these are better diagnoses than some of the others, because they are based on a very intensive diagnostic workup.

The outpatient file includes people who come for outpatient visits. In any one visit, they may be dealing with one specific problem; the outpatient record may reflect past problems that they have had, and if someone has had cancer, that tends to be an important problem for a lifetime, whether it is in remission or cured or not. So it might well list a cancer that occurred several years ago.

The compensation and pension file only deals with those diagnoses that those people have expressed an interest in as service connected.

And BIRLS deals with all of the people who have applied for any kind of benefits at all, including those that have been turned down.

Mr. SHAYS. You made reference to benign tumors and you said almost everyone in this room has benign tumors.

Does almost everyone in this room have malignant tumors?

Dr. MATHER. No.

Mr. SHAYS. You want to focus on benign. Why didn't you want to focus on malignant?

Dr. MATHER. I think we have to make a distinction between the two.

Mr. SHAYS. Should I make the same assumptions about malignant tumors?

Dr. MATHER. No.

Mr. SHAYS. This is the way that I feel you approach it. You want to always give me the contrary. Why didn't you jump in and say, "You know, where this is helpful is malignant tumors."

In malignant tumors is it helpful?

Dr. MATHER. It may be.

Mr. SHAYS. I'm sorry, I did interrupt you, but can I believe under the PGR that the 280 who have malignant tumors have malignant tumors?

Dr. MATHER. I believe they do.

Mr. SHAYS. Can I believe under the PTF that the 606 who are cited under your records have malignant tumors?

Dr. MATHER. That is the assumption. However, I would want to do a review, and in fact when the GAO did the review they said that some 25 percent, I believe, were misdiagnoses, even in the PTF. There is a——

Mr. SHAYS. So you say 25 percent. Under the outpatient 1,902, would you say they have malignant tumors?

Dr. MATHER. I have very little faith in the data in the outpatient file.

Mr. SHAYS. Is the outpatient your own hospital?

Dr. MATHER. Yes, but I am not certain whether or not the diagnosis that was recorded on the chart on the day that the patient visited is, in fact, a verified diagnosis.

Mr. SHAYS. Let me understand something.

Dr. MATHER. The physician's job in that outpatient clinic is to design a diagnostic plan, and he or she will put in a lot of diagnoses that——

Mr. SHAYS. Let me understand something. If someone comes in as an outpatient and is told they have a malignant tumor, you're telling me that this is not accurate and that the person would leave—let me finish. Let me finish.

Dr. MATHER. OK.

Mr. SHAYS. I'm going to deal with what you said.

You're telling me that we shouldn't take that all that seriously.

Dr. MATHER. I'm not saying that at all, sir. I'm saying that when a patient presents with a certain symptom complex or a certain group of symptoms, a lump somewhere, the physician looks at the symptom or the thing, the lump, and says this looks very much like a lipoma, let's just watch it. A lipoma is a benign fat tumor.

However, if it is a skin lesion that looks suspicious, the physician will say this may be cancer, we can't tell until we do a biopsy. The physician will enter that into the record. The physician will say, we are going to have to do some blood tests to make sure that you don't have diabetes or some other conditions which might complicate the biopsy, so we will call you in for another appointment in a week or 2 weeks. We will write on the record "rule out cancer."

That record is at some point counted.

Mr. SHAYS. I missed your last point. As a malignant tumor, it is not necessarily cancer?

Dr. MATHER. It may or may not be cancerous. We don't know until we take the biopsy. The doctor writes "rule out," which

means, "That might be cancer, I'm not sure, I'm going to do some other studies."

Mr. SHAYS. So in the outpatient, the 1,902 that are down as malignant tumors, how many would be "rule out"?

Dr. MATHER. I have no idea. Some will be suspicious lesions that will turn out not to be tumors.

Mr. SHAYS. How about under C&P?

Dr. MATHER. These are claims that the patients have made. They may or may not relate to tumors, so I have less knowledge of the C&P data base.

Mr. SHAYS. So, bottom line, of the 3,126 that you all record as malignant tumors, what percent should I take seriously?

Dr. MATHER. I have no idea without doing a more in-depth analysis of that data base.

Mr. SHAYS. What would it take to do a more in-depth analysis?

Dr. MATHER. It would take chart review.

Mr. SHAYS. So you would have to contact the different hospitals. Could you do it in a week, 2 weeks?

Dr. MATHER. It takes a long time.

Mr. SHAYS. For 3,126 people, you mean to tell me we do not have the ability——

Dr. MATHER. At one point I did a chart review of the 35 cases—I believe it was of melioidosis in Vietnam veterans—and it took me approximately 8 months to get all of those charts in. And then the review took—depending on the thickness of the chart, it took a day or two for each chart.

Mr. SHAYS. I'm sorry, I guess what I don't understand, it took you a day or two. Why don't you disseminate the request out to all of the hospital outpatient clinics at the same time, and you get them all back?

Dr. MATHER. This is not a research study, sir.

Mr. SHAYS. Is this mutually exclusive? You do the first and you wait before you do the second?

Dr. MATHER. No, you ask for them, but it takes a varying amount of time to get charts back.

Mr. SHAYS. My clock is off. I'm going to pursue this.

I want to understand why, if we have 3,126 people who under different data bases are assigned malignant tumors, how you can't tell me whether they have a tumor that has been written off as not malignant or one that truly is malignant? I just don't understand that.

You have to walk me through this a little better. I'm not asking you to review the chart. I'm asking you to have the people at the hospital get back to you and tell you the status of each one.

Dr. MATHER. It does take time.

Mr. SHAYS. Tell me how much time.

Dr. MATHER. I don't know how much time.

Mr. SHAYS. That's not good enough. Give me a range?

Dr. MATHER. Months, I would assume.

Mr. SHAYS. OK, tell me why it takes months.

Dr. MATHER. Because you have to identify all of the patients. You have to identify the hospitals that have these charts. They have to pull the charts. Some of the charts are being used for patient visits. They are in the outpatient clinic being reviewed by the

physicians. It takes time to get these, and someone has to call over 200 facilities and give them the names. That takes time.

Mr. SHAYS. If we had 3,126 malignant tumors, is that a high rate or not?

Dr. MATHER. I have no idea.

Mr. SHAYS. Why not?

Dr. MATHER. The number of tumors we have, but we don't know what time period they occurred in and we don't know what the overall population we are looking at is.

To do a rate, you have to know a numerator, the number of tumors, and you have to know the denominator, the number of people at risk in that group, and then you have to know the period of time in which those tumors were diagnosed or in which they occurred. I wouldn't know any of that from these figures.

Mr. SHAYS. Dr. Kang, do you want to say something? Would you use your microphone, please?

Mr. KANG. We are looking at the numbers, but we are discussing the accuracy of the diagnoses. Whether the numbers actually mean that——

Mr. SHAYS. Could you just suspend 1 second?

Let me say that I'm going to be coming back afterwards, but I'm not sure if Mr. Sanders is, so I'm going to let Mr. Sanders ask some questions.

Mr. SANDERS. Thank you, Mr. Chairman.

Let me begin by concurring with the chairman's opening remarks. Anything that I said about you, I don't want you to take personally. I know that people's patriotism is without question and your hard work is understood.

I happen to believe that you have failed. After 8 years, you have very little to show for the efforts and the millions of taxpayer dollars that have gone into your efforts. I say that not on a personal level; that happens for whatever reason, and that is not a personal criticism.

I think that an objective look at the role of the VA would show an abysmal record, and we should get a new team in there to work with a sense of urgency similar to what the Government has done on AIDS, where we can be proud of the achievements that have been made. I don't mean that to be personal, but I mean it in a professional sense.

A couple of months ago there was a program on National Public Television and the conclusion was, I think somebody from the VA made a remarkable study that things similar to Gulf war illness occurred after every war from the Civil War on. People had illnesses, felt bad, hard to understand it.

My question to you is, is there really such a thing as Gulf war illness? Are veterans who served in that war actually suffering? Do you believe that? That's my first question.

Do you actually believe that or is that something that happens after every war? The conclusion, if you saw that program, God knows there is enough stress in every war, there are illnesses.

My first question, after 8 years, do you actually believe there are people who are suffering as a result of their service in the Gulf?

Mr. CHRISTOPHERSON. There is still information missing, so I need to be somewhat cautious here.

Again, are people ill, yes. There is no confusion about that. The question is, did some of them receive illness based upon their service in the Gulf war. The answer is, probably, yes. How big a number is a much more difficult question to come to a conclusion on.

Is it different from previous wars? There is no indication that it is much different than it was in previous wars. We don't know yet.

Mr. SANDERS. You are saying, based on your studies and analysis, there are people who are ill. You think it may be attributable to service in the Gulf?

Mr. CHRISTOPHERSON. In some cases.

Mr. SANDERS. But this has probably occurred after every war and what we are seeing now is not necessarily different?

Mr. CHRISTOPHERSON. We don't know that for sure.

Mr. SANDERS. After 8 years, we don't know that. Thank you.

The President's Commission on Gulf war, was that the official title?

Again, in a general sense, I believe that they kind of concluded that to the degree there is a problem, the problem is caused by stress. Is that a fair—I know that they did not rule out other things, they wanted to look at other things, but wasn't that their major conclusion?

Dr. MURPHY. No. The Presidential Advisory actually said that stress may be a major contributor, but they never said that all of the illnesses could be explained by stress.

Mr. SANDERS. Let me rephrase. They said that stress may well be a major contributory factor?

Dr. MURPHY. I think that it is clear from both the research that has been done and from our clinical work with Gulf war veterans that they are suffering from a wide variety of illnesses. There is not one single exposure, whether it is stress or an environmental exposure that I believe can explain all of those illnesses.

Mr. SANDERS. You are not quite answering my question.

Dr. MURPHY. Do I believe stress can cause serious physiological——

Mr. SANDERS. We all believe that. That's not what I'm asking.

There are a lot of people who are ill. Do you believe from the conclusion of the President's Advisory Commission that stress is a major contributing factor to Gulf war illness? Is that your judgment?

Dr. MURPHY. I don't think that we have enough scientific information to say that stress is in fact causing Gulf war veterans' illnesses or that it is the major factor contributing to Gulf war veterans' illnesses. I believe that it could be, and I think we need to look at that in addition to a number of other important issues.

Mr. SANDERS. But we have been looking at that for 8 years. We have heard that a cause of Gulf war illness is a combination of the drugs that our soldiers were given as a result of exposure to chemical warfare agents and a variety of other toxins that they were exposed to in the Gulf.

I'm asking you a very simple question. The chairman and I concluded this many years ago: Do you think that chemicals may have played a role as a cause of Gulf war illness? Is that something, after millions of dollars, that we have reached a conclusion on?

Mr. CHRISTOPHERSON. There is no clear conclusion. Very honestly, I think there are research projects going on to look at that, but there is not a clear answer. I don't think that you can completely rule it out.

Mr. SANDERS. After 8 years and many millions of dollars, we still don't know the answer?

Mr. CHRISTOPHERSON. It is a tough one to work through.

Mr. SANDERS. So after 8 years, you don't have a cause of Gulf war illness? You have several hypotheses?

Dr. MATHER. Are you saying illness or illnesses?

Mr. SANDERS. If you are exposed to certain toxins, you can end up with various types of symptoms, true?

Dr. MURPHY. We don't treat causes, sir.

Mr. SANDERS. I know that you don't treat causes.

Dr. MURPHY. We would certainly treat any one of the illnesses that——

Mr. SANDERS. You treat people who have symptoms.

Dr. MURPHY. In some cases, you treat the illness itself.

Mr. SANDERS. What is your protocol? Do you have a protocol?

Dr. MURPHY. We have treatments that are known to work for individual diseases, and we provide those to the veterans who have those illnesses.

Mr. SANDERS. If we were to continue going at the pace we are going now, how long before you folks would come up with an understanding of the cause of Gulf war illness? Do you have any idea, 3 years, 20 years?

Mr. CHRISTOPHERSON. The difficulty is, I don't think that anybody is quite sure what the end is. If the end is that these are illnesses a lot like we have seen in other places, we may have a lot of the answer already. If the answer is that it is something that affects a relatively small number of people, that is hard to find based on the data available. The exposure data which helps you with this equation is not very good, and that is a great difficulty when trying to stay on top of this.

Mr. SANDERS. We have a vote. I would just conclude. I want to thank you for all of your work. I don't mean to be rude.

I see people in my State who are hurting bad. If this thing were on C–SPAN, they would be very upset at the lack of progress that you have made. And I would hope that you have the understanding that you haven't done a particularly good job. Eight years have come and gone. You are looking at this and that. You haven't told us anything. You haven't developed treatment protocols and given us a better understanding of the cause of the problem.

I think you are barking up the wrong tree. I think we need folks in there who are going to take us in a new direction and develop a sense of urgency, and using the analogy of AIDS, are going to help us move forward.

Dr. MURPHY. I have to disagree with that. I think there has been a well-designed plan to investigate this problem. It has been looked at by a number of very eminent outside scientists who have said you are headed in the right direction, continue the studies that you've outlined—the Presidential Advisory Committee, numerous IOM committees. We have done studies which have provided important answers to Gulf war veterans and their families on the

mortality, the Iowa study done by CDC, the hospitalization study done by DOD; and I think we know a lot more about Gulf war veterans' illnesses, and I say that in the plural rather than in the singular that you use.

Mr. SHAYS. Dr. Murphy, we have a vote so we are just recessing. We will come back. My big concern is that the only time that we will have any statistics is when we have the mortality, and we are trying to beat the mortality statistic.

Mr. CHRISTOPHERSON. I do disagree with Congressman Sanders. There is no lack of effort here. It is a very strong effort.

Mr. SANDERS. I did not suggest there was not. That is why I strongly concurred with what the chairman said.

Mr. CHRISTOPHERSON. The key in——

Mr. SANDERS. But you have failed.

Mr. CHRISTOPHERSON. We do not know that yet.

Mr. SANDERS. By definition after 8 years, I suggest that indicates you have.

Mr. SHAYS. We are recessing at this time. We have 15 minutes if you need to use the facilities and so on.

[Recess.]

Mr. SHAYS. OK, thank you very much.

I want to accomplish two goals. I want to allow everyone here to feel that they have been able to express their opinion about what the GAO has done, and I want to try to understand why the VA has not done what we asked the GAO to do.

Dr. Mather, you began your criticism of the GAO statistics by pointing out that benign tumors really didn't tell us anything because everyone in this room has some benign tumor, which is news to me. And the inference I took is that a lot of the benign tumors in these various registries must be rather insignificant.

So I accepted for the moment, at least for this hearing that—and we will get doctors and experts to have them comment on the GAO report, as well as at a further hearing, but you are on record and the record will speak for itself.

When we talked about malignant tumors, you called into question the very data that the VA has, and—I'm sorry we will have another vote, but let's see how far we get. You called into question the validity of my drawing inferences about malignant tumors from the various data that are there.

Would you tell me, Dr. Mather, and then I would like each of the others who have testified and anyone else, when we will know and when we will have data that you feel are comparable, and when we can draw conclusions so that I don't continually read responses that there is no objective data to suggest that?

See, my problem with no objective data proves what, a lack of evidence or a lack of inquiry. I suspect that you all believe that it proves a lack of evidence, and I believe it proves a lack of inquiry. That is the biggest difference between us.

We will start with you.

Mr. CHRISTOPHERSON. The data sets that I was describing earlier in my remarks are not all in place. At this point we do not have enough historical data.

Mr. SHAYS. I need you to talk more slowly.

Mr. CHRISTOPHERSON. The data sets that we are putting into place, which will have, like, ambulatory data, are not yet in place; and therefore we do not have the numbers there. They are not operational. We will have more information in the next 12 months as the data starts to roll into the system.

Other than that, you are really down to doing the studies that Dr. Mazzuchi talked about earlier, of doing cohorts, subgroups of, like, California and other kinds of populations.

Mr. SHAYS. Dr. Mazzuchi, I would like you to respond. I don't feel that I have a handle based on your answer, Mr. Christopherson. I feel like you just said that we will know more when those studies are done.

I didn't mean it facetiously when I talked about mortality rates. It seems to me that the only real data that is going to satisfy any of us is when we get to mortality rates.

Mr. MAZZUCHI. The California study is a study of hospitalizations of all Gulf war veterans and Gulf war-era veterans, a comparable cohort of veterans from California, both treated in the DOD hospital system as well as the VA system as well as in the private system within the State.

A manuscript is being submitted on that research study which will look at a comparison of cancer incidences among the Gulf war veterans and Gulf-era veterans. That should be out this year. That is one of the first studies that will look not at mortality data, but at hospitalizations.

Now, it does not answer everything.

Mr. SHAYS. Slow down a little bit, please, when you are talking.

Mr. MAZZUCHI. The hospital study does not answer everything, but it does give you a sense of whether there are more serious tumors among Gulf war veterans and Gulf-era veterans in the State of California. In addition, that cohort is a large piece of the Persian Gulf veterans in that it is about 12 percent of our Gulf war veterans, so it certainly gives you a good picture.

What we are trying to develop are pictures of whether or not the cancer incidences are higher in Gulf war veterans versus Gulf-era veterans, and this is a first piece. One of our first studies was a DOD hospitalization study internally to look at people seeking treatment for cancers.

The second piece of that is hospitalizations in the State of California because it is a large block.

The third piece of that study is hospitalizations outside the DOD because again the point has been made that many people don't seek their care at the DOD or VA, especially if they have left, they just may go into the private system.

So that will give us, I think this year, an indication of whether or not we see any differences in the cancer rates among those groups.

As I said earlier, I think it's very important to look at two factors. One is the difference between cancer rates among Gulf war veterans and Gulf-era veterans to see whether or not something peculiar to the Gulf war deployment is in play here. The second is to look at the difference in the cancer rates among military veterans versus the civilian population at large, because we don't know

whether there could be differences just being in the military, some environmental or other risk factors we're not aware of.

We will be able to look at both of those, because we can also look at the civilian population through the California Registries of non-Gulf—I mean of nonmilitary people.

Mr. SHAYS. So it's not that difficult for us right now to know the incidence in the nonmilitary?

Mr. MAZZUCHI. In certain States—I yield to the cancer epidemiology experts at the end of the table, but I mean it's different in various States.

I also had a talk with one of the researchers from Great Britain where they do have a national registry where they are also flagging and looking at cancer rates among their Gulf war veterans and their Gulf-era veterans and the population at large through their national cancer registry, and that will also, I think, be a very important contributing piece to us, because while it's not necessarily generalizable to our population, it still gives us another piece of that picture.

Mr. SHAYS. So this study will be completed when?

Mr. MAZZUCHI. The study is completed. The manuscript has been submitted for publication; it should be published this year.

Mr. SHAYS. And you all have previews of that manuscript?

Mr. MAZZUCHI. I have not seen the manuscript yet. When a manuscript is submitted—one of the things that we have tried to do is make sure that when the Department of Defense, or one of its researchers, publishes that we go to a peer review journal so that the manuscript goes through the rigors of the scientific review process of that journal when it is published.

There is an open invitation for criticism from other scientists. This is a good way, I think, to make sure that the science and the methodologies are sound.

Mr. SHAYS. And that California study will tell us what would be the response—well, I'll get to that later. It will tell us what?

Mr. MAZZUCHI. It will tell us the hospitalization rates for cancer for the cohort groups, the comparison groups and the cohort and what they are, whether they're different, if you're a Persian Gulf veteran versus a Persian Gulf-era veteran.

Mr. SHAYS. And it will give us the incidence?

Mr. MAZZUCHI. No, it won't give you incidence because incidence would be new cases. It would simply give you the prevalence of cancers among those groups at that time, treatments for cancers among those groups, hospitalizations.

Mr. SHAYS. Dr. Mather, when do you think that we will have data that will give us a clear picture?

Dr. MATHER. We'll begin to have clearer pictures as time goes on. I think that the study that Dr. Kang and Dr. Murphy are doing with the national survey will give us additional information on prevalence. I think the Boston Environmental Hazards Center's work with a New England Cancer Registry, will give us additional information.

The California study, I think, will be a very important one. British study——

Mr. SHAYS. Are you telling me what's important here? You said when time goes on. I don't want it when time goes on.

Dr. MATHER. I think we'll have a much better picture in the next 18 to 24 months.

Mr. SHAYS. Dr. Kang.

Mr. KANG. I can comment on the progress we made on a national survey. This is a random sample of deployed troops and nondeployed troops, so we have a scientific——

Mr. SHAYS. I'm sorry, I missed the word.

Mr. KANG. Deployed and nondeployed.

Mr. SHAYS. Right, deployed and nondeployed.

Mr. KANG. Right, so this is a scientifically valid sample, and we have enough statistical power in the study to assess overall cancer prevalence between two groups, whether one group has more cancer than other groups. We may not be able to give you an answer on a particular cancer, whether in fact that one group has more cancer or, say, soft tissue sarcoma or mesathelioma, but as a group we can tell whether one group is suffering from cancer more so than other groups, and that study should be completed in 6 months to 8 months.

Mr. SHAYS. OK.

Dr. Murphy.

Dr. MURPHY. I think many of the important studies have been discussed, but in addition, we have asked for help from the Institute of Medicine in two regards on Gulf war veterans' illnesses. First, we have asked them to advise us on the best methodology to study health outcomes, such as cancer; but also for another study that reviews all of the existing scientific literature to see whether there is any association between the exposures that have been reported by Gulf war veterans and adverse health outcomes. One of the important outcomes studied will be cancers.

The IOM is beginning to put together a committee this month and they expect their first report out in 18 months. So that's another piece of information.

I understand your impatience. It's going to be very difficult to get the complete picture. But if you look at the scientific process as putting together the picture by getting pieces of the puzzle, so that we actually do get a coherent look at Gulf war veterans' illnesses and at cancer prevalence in particular, then all of these studies have very important relevance to the questions that you're asking.

Mr. SHAYS. See, there are two parts to this, and I'm going to go out and come back. But there is one motivation and that is, I can see a more definitive study is needed to help us to treatment, as I'm looking at it; but it seems to me a less definitive a study to have me appreciate and have us appreciate whether we should make a presumption that when—like our two veterans who came before you, before this committee, whether we should say, "I'm sorry, there is no indication that your illness is caused by your experience in the Gulf war," and that we can at least get by that hurdle. I don't want to wait until the definitive study, which deals with treatment, before we have some indication of how we treat our veterans.

I have less than 4 minutes. I'm really sorry. I think this is my last vote, and I know you kind of went down to the cafeteria. You really do have 15 minutes to go to the cafeteria, and we'll recess.

[Recess.]

Mr. SHAYS. I call this hearing to order. I keep forgetting quite at what point we're at, so I end up just thinking what I'm thinking, and I'm going to share it with you. I think I have a sense of your challenge. Your challenge is first, I lack some knowledge as you perceive it; and second, I have a gigantic bias which is accurate.

I believe that every stage of the way I feel like we have to take the VA and the DOD to the altar, dragging and kicking. I feel like there's never an indication that we could do this, or we should do this; and Dr. Mather, I'll tell you why I feel that way.

In your response to this report you basically take the report to make statements as to others. For instance, there is no objective data to suggest the Gulf war veterans are more likely to develop cancers than their nondeployed peers. I read in testimony that this, indicates basically an affirmation of what you believe, that there is not any indication that—let me get some operative records here—maybe you can find some for me. But the bottom line is, you take the report and come to a conclusion that says it doesn't tell you anything different than what you believe now; and that is that there is nothing to establish the fact that there is a higher cancer rate or that our veterans have a higher cancer rate than the general population.

Then, when I ask you about the fact, Dr. Mather, that it is basically doubled from the statistics when we combined all these together, your response to me is to talk to me about benign and to say that almost everyone in this room has a benign tumor. And then that would suggest to me that every person who went into the VA would be recorded as having a benign tumor.

But somehow there were some veterans who had tumors that were noted as benign, and somehow they showed up on someone's radar screen. Then we talk about malignant. Then your suggestion is—not suggestion, conviction—that the data isn't significant because you really don't know if it's cancerous or not, and then when we go to say, "Well, why don't you just find out?" your first reaction is to say, "It's going to take months."

Dr. MATHER. Well, my reaction is that even reviewing these charts will not give you data about rates or incidence. We need a comparable population.

Mr. SHAYS. May I ask you a question? This is what triggered me, though.

Dr. Mazzuchi talked about the California study being based on rates. And so why is that important?

Mr. MAZZUCHI. I have not seen the manuscript. I would imagine that it would have numbers of Persian Gulf-era vets from California, but I have not seen the manuscript.

But I said—if it wasn't prevalence—I mean, wasn't new incidents——

Mr. SHAYS. But incidence is rates, isn't it?

Mr. MAZZUCHI. New cases.

Mr. SHAYS. OK, it's new cases. And wasn't your criticism that this doesn't show us new cases?

Dr. MATHER. Well, that's part. This shows prevalence, which is the number of cancers that exist at this time. And we could look at a comparable population, but we don't have a comparable popu-

lation, and see the prevalence in that population. This would be an important study, and I'm not willing——

Mr. SHAYS. What would be an important study?

Dr. MATHER. A study that looked at prevalence of cancers in Gulf war veterans and prevalence of cancers in a similar population, not necessarily the general population, but people who were matched and who were in the military at the same time.

Mr. SHAYS. So the GAO is prevalence, it's not incidence.

Mr. KANG. Right.

Mr. SHAYS. All I'm saying is that then I feel like you're playing a word game where you seem to know a little more than I do, and I'm having a hard time catching up. And I'm asking you to slow down and you'll win that game, but you won't win the game of convincing me that you're not trying to just win the game.

Dr. MATHER. I'm not trying to play games, Mr. Chairman, so I apologize if that's the impression I've given you.

Mr. SHAYS. Well, the one thing you can be assured of is I have no problem exposing my ignorance. For the Gulf war veterans, I will expose my ignorance and I will plug away and learn more about this. And then I will look back over the transcript, and I'll say, "yeah, chalk it up for the panel, they put one over on me; but damn it, if I knew the right question to ask, they would not have." I don't want to play that kind of game.

Dr. MATHER. No, and you have one of the country's experts on cancer epidemiology sitting right at this table, and I think we would all learn from her.

Mr. SHAYS. I wanted to get down there, but I just couldn't get beyond the attitude that I think I'm dealing with; and the attitude is my biggest problem with the VA. It is as if someone in the VA had said, "you know what, the GAO report tells us this, this and this, Congressman, but it doesn't tell us this; and frankly, you know, you're right, we could have done it. Maybe the reason we didn't do it is we didn't think that it would tell us as much," but for 3 weeks of work, it seems to me we could have learned something.

What I have a hard time understanding is, after 8 years, why we haven't tried to get the data within the VA. With all the people you have as your resources, why you haven't sought to just get the data and have it be comparable.

And, for instance, I'm going to come back to this question and I'll take anyone's response on this. Dr. Swanson or Dr. Miller, do you want to respond to this?

Are we totally off the track? Is the GAO, looking at getting these different data in one package, is that helpful? And if it's not helpful, what would we need to make it helpful?

Dr. Miller or Dr. Swanson.

Dr. MILLER. I'll let Dr. Swanson respond.

Dr. SWANSON. I guess it depends on what the rest of your question is with regard to, is it helpful.

Let's just take the GAO number. They said there's about 150 malignant cancers, not benign tumors, but malignancies, and that's where we have useful data for comparison for population bases. OK? Let's take that 150, that's per 100,000. If you extrapolate that out to the entire 700,000 Gulf war veterans, that's about 1,000 per

year, it's 1,050 per year. But now those are incidence—that 150 is based on incidence rates per year. They're annual rates. So every year you would have another 150 for 100,000, OK? So you multiply that times your 700,000. Then you add it, times the 7 years——

Mr. SHAYS. Slow down just a little bit, I'm almost with you.

Dr. SWANSON. OK. We have 7 years since the Gulf war for which we have data. That would mean that today in those 700,000 there would be 8,300 cancers, if in fact the incidence was the same in the Gulf war veterans. I would be willing to estimate, knowing all the vagaries with the GAO data and the VA data, that those are probably overestimates. So in fact we do see what we expect, lower rates of cancer in this population.

The VA has told us that it probably really only represents 550,000, not all 700,000. If you extrapolate that out, then we'd have about 5,000—700,000, so you still have a lower rate.

Now, of course, what we don't have in those data is, the VA doesn't see everybody, as you've heard from——

Mr. SHAYS. No, I can deal with that, but what you're saying is where I start——

Dr. SWANSON. The rate is lower, given the data that the GAO gave you. That suggests a lower incidence of cancer in the Persian Gulf population than in the general population if those were incidence. Even if they were prevalence data, because the prevalence data simply means of everybody in the population, today in 1998 who has cancer, no matter when this was diagnosed, versus everybody who is diagnosed this year.

Mr. SHAYS. So let's just take its prevalence.

Dr. SWANSON. Right, so the prevalence is the 8,000 or the 6,000, whichever number you want to use.

Mr. SHAYS. OK, let's take—and we're talking malignant.

Dr. SWANSON. Yes, cancers only.

Mr. SHAYS. So we're basically saying on the data that we had 3,126, acknowledging that it's in a pool of 550,000 and we don't know how representative that pool is.

So what you're saying to me, which is helpful, is my even making the assumption that you go to 700,000 and the 150 that was being shared by Dr. Chan was incidence, not prevalence.

Dr. SWANSON. That's what he said. He said that was the projected number based on the SEER incidence data for that age group, 15 to 44.

Mr. SHAYS. And you're saying that 150 per 100,000, you then would have to multiply times——

Dr. SWANSON. Times 7 for your 700,000 and then for each year. If you wanted it for 2 years, it would be 2,000; if you wanted it for 5 years, it would be a little over 5,000.

So it's about 1,000—it's 1,050 per year, roughly.

Mr. SHAYS. And so—and I'm going to say it in my own words since I said something earlier. If I made an assumption it was 700,000, we have a lower rate.

Dr. SWANSON. Right.

Mr. SHAYS. Then we would—based on the same age group, then we would make assumptions about health and so on.

Dr. SWANSON. Well, if you assume that, overall, cancer is going to be the question that you want to answer, is it helpful. If you

think something—if you had good exposure information that you think was related to a very specific type of cancer, or if you think without exposure data, there was—some very rare kind of cancer occurred, then you're going to have to have a surveillance system that finds every single cancer in this Persian Gulf group for every single year.

And I heard you say earlier you want an answer now. I understand that. I see cancer patients all the time, and believe me, you want answers now. The problem is, cancers occur over a long time period, and it's probably too soon for solid numbers to occur.

Mr. SHAYS. No, I want two types of answers. One kind is the definitive answer, and one is an indication.

Now, I have to make an assumption, in the medical community, that you get indications or trends that can lead you to make some assumptions, and I have two purposes. Obviously, one assumption is that if in fact there is a higher rate, if we still can't come to any conclusion based on—we don't know what representative body, and we don't know prevalence, incidence and so on.

Dr. SWANSON. Even if we had a very definite exposure, it's too soon. It takes solid tumors 20 to 40 years to develop after a known exposure. If we thought it was hematologic or leukemia types of tumors, blood-borne tumors, then it takes about 10 years. So it would be right to start looking for those. I mean, that's the frustrating part of this thing; the pathology and the biology of the disease takes longer to occur, and you can't come up with answers before that pathophysiological process takes place. So in about—if the Gulf war veterans had their exposures around 1990, it would be 2010 before you'd really see solid tumors occurring.

Mr. SHAYS. Explain to me, because in my most generous moments with the VA, I can't explain why the VA can't provide and get better data from the people that they're serving——

Dr. SWANSON. I'm not that familiar with. I don't use their data sets on a daily basis.

Mr. SHAYS. You use data. I mean, is it a complex process?

Dr. SWANSON. We collect data through the SEER program from every hospital in the community. It is a terribly complex process.

Mr. SHAYS. Well, it's complex for you because you get it from different hospitals.

Dr. SWANSON. Right, we do too. There's hundreds of hospitals—VA hospitals all over the country.

Mr. SHAYS. Right. With all due respect, though, they are the VA hospitals. There is some uniformity of process.

Dr. SWANSON. OK.

Mr. SHAYS. And if you were running the VA and you wanted to get data and have it be comparable, is it all that difficult to tell those who are your employees that you need this information and to provide it in a systematic way?

Dr. SWANSON. Because the data are not computerized, it probably is.

Mr. SHAYS. Well, why isn't it computerized?

Dr. SWANSON. I presume the funding isn't there and the priorities——

Mr. SHAYS. No, no. But, see, that's when I have a big disconnect. I mean, it is 1998.

Dr. SWANSON. I understand, but most hospitals aren't computerized. Let me say that the VA hospitals aren't different than any other one. I was just telling somebody——

Mr. SHAYS. What you don't know is, we've had hearings for years and we have veterans who come and say they're sick, and they are sick; and there is a history with the VA in which they didn't quite get it at first.

So the issue to me is, this is your field. You gather data. So you're saying, one, we would do what some schools do and other places do and most businesses do, we have a system that could gather this data through computer. And——

Dr. SWANSON. Which means you have to have a uniform data base, you have to agree on all the information you're going to collect on every single facility, and it has to use the same coding structure. And in fact there is a committee going on, which I serve as an adviser, on protecting the health of deployed forces, that's looking at this kind of consistency.

Mr. SHAYS. What is the largest private hospital system?

Dr. SWANSON. The largest? You know there are so many mergers these days, I'm not sure I can tell you. But—many of those will have computerized systems, but it is focused on billing. It doesn't give the kind of answers that you want or that I want. And you actually want less of them than I do. You just want to know, for crying out loud, tell me how many people in your hospital had cancer last year.

Mr. SHAYS. Well, no, I would like more. It just seems to me you can start with cancer.

Dr. SWANSON. But most hospitals can't even tell you that. It's fairly appalling when you see what actually the condition of medical records are, of paper records in hospitals.

Mr. SHAYS. So you're saying to me, if I brought in some of the larger private hospitals that have to coordinate billings and so on, and brought them forward, they would say that they can't coordinate data.

Dr. SWANSON. Some can and some can't. I mean, I would think if you ask them for management and financial data, they would have outstanding information systems. I would think if you ask them the kind of questions we're trying to get answered here about can they provide the data we need just to start research, not to do it, but to identify the cases and then start the research, some can do it, most cannot.

And cancer registries don't even exist in every single hospital in this country even in paper form, never mind in computerized form. It does—I mean, it does seem in a way a silly conundrum. How could it be that one of the most important pieces of information about health is not computerized? I mean, when I think about economic growth and the security of the country, whether it's deployed forces, military or the general population, I don't think there's much that's more important than health, because if you're not healthy you can't do much.

Mr. SHAYS. OK, tell me what's wrong with my logic.

Dr. SWANSON. Well, I think you have reasonable expectations of a system. The problem is the systems haven't been—they have been in place for decades. And priorities properly have been given

to medical care, not to record systems. I mean, let's face it, the first objective of a hospital is to take care of patients, or of a physician or a nurse is to take care of that patient.

It's a similar situation when you look at the military. Believe me, they're not going to have data systems in deployed situations that are there that will satisfy me as a epidemiologist. Their main job is not to do epidemiologic research. Their main job is to do something quite different.

Mr. SHAYS. Have you been focusing much on Gulf war illnesses? I mean, I don't know how much——

Dr. SWANSON. No. I mean, I do cancer epidemiology and chronic disease epidemiology.

Mr. SHAYS. What conclusion should I draw from cancers with other physical challenges besides?

Dr. SWANSON. Well, that's a question I can answer in one regard. I'm doing a very large study right now where we have interviewed 16,000 cancer patients in the metropolitan Detroit area, and I'm looking just at chronic disease comorbidity, which is a subset of all the other illnesses a person could have. Eighty percent of cancer patients have at least one other major chronic disease, and that's things like diabetes, hypertension, cardiovascular disease, cerebrovascular disease. So it's not a small problem, and it's something that increases with age.

If you go to 40-year-olds, that prevalence rate is about 30 percent. When you get up into the 60's and 70's, it gets up to 80 percent. So it's not unusual. I mean, aging isn't fun and it's not healthy actually. So as—until we learn more about preventing diseases, we're not going to really have a situation where people are healthy, whether we're talking about single diseases like cancer or heart disease, or whether we're talking about multiple.

Mr. SHAYS. OK.

Dr. Miller, do you have any comments you wanted to make?

Dr. MILLER. No. I think Dr. Swanson has just given you epidemiology lecture 101 and done a good job of it.

Mr. SHAYS. OK. Where can I get 102?

Dr. SWANSON. Send me an e-mail.

Mr. SHAYS. Before we end this hearing, I want to be clear on why I can't know and you can't know the number of—taking the data that's available right now. You heard the dialog earlier with Dr. Mather, and she was saying, it would take a long time to look at the individual charts and so on. Maybe, Dr. Swanson, you can help me out on that one.

Dr. SWANSON. As I said, I don't know—I don't know the details of their data system.

Mr. SHAYS. Help me out on my understanding, because she tried and it didn't get through. So you did well in 101. Tell me the significance of her point about outpatients and the 25 percent that may not in fact be malignant.

Dr. SWANSON. Well, as she was pointing out, people look at symptoms, and if they don't know exactly what's going on, they say, well, if it's a mass, obviously you want to make sure it isn't cancer.

And so if you look at something like—I'm trying to remember the data for breast cancer, because that's probably the best known—

something like only 17 percent of surgical biopsies for breast cancer turn out to be cancer, and that's at the—sort of at the narrow end of the continuum. That's not looking at physical exams and that sort of thing. If you look at mammograms and suspicious findings or supposedly positive findings, then it turns out that—I think it's about 4 or 5 percent of those actually turn out to be cancer.

So there is a difference between a series of diagnostic workups and the results of those tests and the end result which says, yes, you have, in that case, breast cancer.

Mr. SHAYS. Thank you. I'm going to keep you here about 10 more minutes and then we'll be done. I know, Dr. Murphy, you have to get on your way soon.

Dr. Mazzuchi, in your testimony on page 4 you said, nearly 8 years after the fighting ceased, there has been, quote, "no objective data to suggest that Gulf war veterans are more likely to develop cancer than nondeployed peers"; and then you go on to say, in fact, that "The objective data available thus far suggests no difference in risk, but we continue to monitor Gulf war veterans, and as I noted later, it is really too soon to detect definitively whether there is or is not an increased incidence of tumors among Gulf war veterans."

Would you just explain to me the second part?

Mr. MAZZUCHI. I think again this was—as was discussed, tumors take a long time to form and to be detected, so what we know now in terms of looking at DOD hospitalization data indicates to us there is no increased risk today. But we will have to follow the charts and the health care of those veterans over a long period of time, 10 to 12 years, before we're going to be able to see whether or not there's any—I mean, again, if the exposures that they would have experienced occurred in the early 1990's, it is going to be long past 2005–2010 before we're going to be able to see whether there are any increased tumors.

Mr. SHAYS. How many more years? What did you say, how many more years?

Mr. MAZZUCHI. It's going to be at least 10 years before you're going to see some cancers, and 20 to 40 years for other cancers.

Mr. SHAYS. Counsel, ask questions?

Mr. HALLORAN. Thank you.

On that point, and anybody else who might respond, the GAO report says that in certain situations cancer can develop more quickly than the lengthy periods you've discussed. For example, when the immune system is compromised, certain types of cancer may appear in much less time. So I guess the question is two parts then.

What cancers might meet that description, might be accelerated in an immune-suppressed patient, and so therefore what trends should we look for in a surveillance system as leading indicators of a larger trend that might appear sooner.

Dr. SWANSON. Probably the largest population of immune-suppressed patients we have are those with AIDS and HIV, and even those are—most of those take 5 to 10 years to occur. It's very rare that—and that's usually leukemia or Hodgkins or one of the lymphatic systems.

Mr. HALLORAN. Lymphoma?

Dr. SWANSON. Yes.

Mr. SHAYS. Dr. Murphy, you need to leave at 3. Do you have 5 minutes——

Dr. MILLER. Beg your pardon?

Mr. SHAYS. Dr. Murphy, I'm sorry.

Dr. Miller, you need to——

Dr. MILLER. No, no. I thought you were pointing at me.

Dr. MURPHY. I'm sorry. I have a child I need to get to the doctor.

Mr. SHAYS. OK, we're going to let you get on your way then. If you want to make a closing comment, I'm just going to keep the other panel—OK, thank you for being here.

Dr. MURPHY. No comments.

Mr. SHAYS. Is Dr. Cianflone here? Why don't you come up to this desk here and just sit at the corner?

Thank you, Dr. Murphy, for being here.

Dr. Cianflone, you've had to watch this tortured process of my questions here. How are you reacting to what's going on, and if you were asking the panel a question, what would you be asking them?

Dr. CIANFLONE. Well, I'm certainly not as trained as the individuals of this panel, I'm just a family practitioner and I just do clinical medicine; I'm not a academician. And certainly we all know that people can use statistics to come to almost any conclusion they want, and the feeling that I've gathered from this panel is really what is at issue, and I really feel sorry for the veterans, I feel sorry for the sick veterans.

I think there has to be a philosophical attitude from the top that we're here to take care of the veterans, and we're going to find a way to treat them, not just looking for causalgia and statistics. I'm kind of dismayed that with all the academics we have here that in our little hospital in north Denver, we can keep track of pathological diagnosis; those are computerized. We don't give people diagnosis of malignant cancers without definitive pathology or radiological confirmation, and that data is readily available to any practitioner in our small hospital.

Mr. SHAYS. On that point, if I could, and Dr. Mather, I mean that's addressing the issue I guess of whether it is—maybe, Dr. Swanson, you could just respond to that point.

I guess what I'm wrestling with is, if I was told I have a malignant cancer, I'd be pretty upset about it. So I guess you wouldn't tell someone that lightly. So if 1,900 people basically believe they have a malignant cancer and this is going over 7 years, wouldn't there be something a little bit more definitive?

Dr. MATHER. I would just like to say that what—we're talking about two different things.

Mr. SHAYS. OK, I need to know.

Dr. MATHER. Patient care and data bases.

I mean, the data base is developed, it is computerized, but it's a paper record on which the physician has written the operating diagnoses, the diagnoses that were responsible for that outpatient visit; and they've written down perhaps diabetes, arthritis, high blood pressure, a lump and then "rule out cancer." Then a clerk takes that record and assigns a code to each of these diagnoses, and that goes into the computerized data base.

Mr. SHAYS. But you wouldn't make an assumption that was malignant?

Dr. MATHER. No.

Mr. SHAYS. So it wouldn't be done here as——

Dr. MATHER. That just explains what was responsible for that outpatient visit, and that's what the outpatient treatment——

Mr. SHAYS. You mean, the person was concerned they had a malignant tumor, and even if they didn't, it would be recorded as——

Dr. MATHER. That they're doing a diagnostic work-up to rule out cancer.

Mr. SHAYS. So this would merely be a diagnosis?

Dr. MATHER. It's a——

Mr. SHAYS. You're saying, I could have come to the——

Dr. MATHER. A potential diagnosis for which we're going to do certain diagnostic studies to try to rule it in or rule it out. "Rule out" is a kind of doctor shorthand for "maybe it is and maybe it isn't."

Mr. SHAYS. I just want to be clear, because we want to go back and check, and your testimony before us is that it's your understanding that of these 1,900 that this could just be someone coming in with a suspicion that they had—they knew they had a tumor, and they just needed to know if it was malignant. So they were benign, but they wanted to know if it was——

Dr. MATHER. No, it's what the doctor has written down as part of the reason for that visit.

Mr. SHAYS. OK.

Dr. MATHER. And this is the first year that we have been dealing with diagnoses in the outpatient clinic records, so I believe that the data bases have some glitches in them that we are in the process of working out. It's my personal opinion that, of the data bases that I'm familiar with, the outpatient data base is the least dependable.

Now, I think we have to separate data bases from the doctor's desire to take care of the patient.

Mr. HALLORAN. Could I stop you there? While you're on that, though, the question then is how long a diagnosis of "malignant tumor" or "rule out related tumor" would remain tentative in the outpatient file.

Dr. MATHER. I don't know that. It would really be until the point that the—it might have been ruled out.

Mr. HALLORAN. Right. But the question is, if it's a long time, the GAO would have captured a lot of those temporary diagnoses in their data. If it was a short time, it would have captured only a few. So would you estimate that it's 25 percent that are in transit?

Dr. MATHER. I don't have any way of judging that, I'm sorry. I will look into that when I go back and see if I can make a better answer.

Mr. SHAYS. These are where the suspicions will arise, because we're going to look into it and if it turns out to be 1 percent, then I've got a continual sense of suspicion; if it turns out to be closer to that 25 percent that you seem to feel it might be——

Dr. MATHER. I don't know. It may be. I just don't have much faith in this particular data base. That's not to say I don't have faith in the caring approach that the physicians and the outpatient clinic have for their patients. That's a different thing.

The data involves what the physician wrote down and then a clerk codes it. There are a lot of different places errors could be

made. The physician could have written down a potential diagnosis that hasn't been confirmed. The clerk can make an error in what code he or she picks out. Then the person who actually puts it into the automated data base can make a mistake in the numbers.

Mr. SHAYS. I mean, if your argument is, it can be a mistake, that's another issue.

Dr. MATHER. There are some of those as well.

Mr. SHAYS. I mean, but you got onto a whole different tangent then. If we're dealing with mistakes, there can be mistakes anywhere; and maybe the VA makes more mistakes than others, but I'd like to think—well, I'd like to think that we're not dealing with a lot of mistakes.

Doctor, do you want to just finish? I interrupted your comment.

Dr. CIANFLONE. The other thing—because it pertains to me, but I'm sure it pertains to a lot of people.

Not all benign tumors are benign and not every one of us has a pimple or a dimple that's benign. My particular case is an aggressive osteoblastoma that's recorded as a benign tumor. The Mayo Clinic study, those in 1994 show that 16 percent of those have reoccurrences and of those that have reoccurrences have a high degree of mortality when they occur in the vertebral system. So not all benign tumors are just minor skin tags.

Mr. SHAYS. I think that it's good for you to make that point, but I think we have a sense of that.

Dr. Swanson, would you just enter this dialog to help me out again? What should I be thinking about the 11,550 benign tumors, is it realistic? If everybody potentially has a benign tumor and we had 550,000 that showed up on a doctor's radar screen as needing to catch their attention, should I dismiss these as what we all—I don't want to put words in Dr. Mather's mouth, and I don't think she did it that way. But the attitude I get when I hear that we all have benign tumors is that then this is an irrelevant number. What's the relevance of 11,550?

Dr. SWANSON. Without knowing what they are specifically, it's very difficult to say. Some of them, we know are precursors to malignancies. Certainly there certain melanomas have benign lesions that are precursors. In some cases, as with cervical dysplasia and cervical cancer, we think the benign lesions have something to do with the malignancies, but we're not sure.

Similarly, in some colon cancer cases, there are benign polyps that are related to the later malignancy, and in terms of the science of cancer those are things we're just beginning to find out. I mean, we would love it, in terms of early detection of cancer, before it became a malignant process, to know what it is that's an early stage in those pathophysiological changes. If they take so long, there has got to be some way to find out along the way, before they cause major health problems, to find out what these changes are and cure them. I mean, that's what the objective of a lot of research is.

So I don't know what the 11,000 mean. One would have to think that if they got into the medical record either somebody complained about them or a physician saw them and said, you know, we have to do something about this, so they're in a class of needing some kind of attention, so they're different than, you know——

Mr. SHAYS. I would think that if it did show on someone's radar screen, a veteran who happened to not feel very well—Dr. Kang, you have been real patient. You've been here a long time, and you really haven't been asked to make much of a contribution here. I'm happy to have you make any comment you want to make, and I thank you.

Mr. KANG. I guess you sense that looking at this number, nobody is willing to make any kind of conclusion—draw a conclusion based on the number because of the limitation of each data base. But I like to add one more thing to maybe give you some perspective.

Malignancy is 3,895, which include 1,902 cases from outpatients. Now this malignancy includes skin cancer. The GAO person used 150 per 100,000 incidence rates. That happened to be without skin cancer because serious data, I cannot—do not catch skin cancer. The skin cancer rate 400,000 is 300. So if you add that into the equation, we already have 300-plus cancer occurring each year. Multiply that by 7, so this number is—certainly show less than what you expected.

Mr. SHAYS. I find that interesting and helpful, but it triggers one kind of last comment.

Would you show me in your report, your response to GAO where you actually talked about what we're talking about now in this hearing? You basically took the GAO report and said, but show me where you raise questions about the credibility of the findings based on all the dialog we've just had in the last 2 hours.

Dr. MATHER. The questions have been raised. The GAO published the report before they received the VA's comments.

Mr. SHAYS. But your statements here today—I mean, you saw the report. Why are you saying this publicly in your statement?

But I may have missed it, and that's why I just need to——

Dr. MATHER. These tables only came yesterday—we saw these for the first time yesterday. They were not in the GAO report we saw.

Mr. CHRISTOPHERSON. That's why it wasn't addressed in the report. These didn't exist at that time.

Mr. SHAYS. So you basically responded to the report?

Mr. CHRISTOPHERSON. Right.

Mr. SHAYS. Without the statistics?

Mr. CHRISTOPHERSON. That's correct.

Dr. MATHER. I will certainly be willing to respond in writing to these.

Mr. SHAYS. I think that would be helpful, but I think you've made it pretty clear in your public record.

I'm a little embarrassed that we would not give you the time to go through the data, because that's frankly helpful to us. I mean, it would be helpful for me to know your analysis beforehand.

So what were you really responding to? You're responding to their findings, but not their numbers; is that correct?

Mr. CHRISTOPHERSON. Right, we were responding to the original report, which talks generally about the need to have better data and data systems, and that's really what we're coming back on, saying, we agree we need better data to try to look at this issue and especially looking at the long-term questions, but this is new—

until we saw the testimony come out, this is the first time we saw these numbers.

Mr. SHAYS. OK. Is there any other comment that any of you want to make? I'm sorry that you've had to give me some basic lessons here, but in the long run, it will be helpful for everyone.

Dr. Swanson, do you want to make any comment, or Dr. Miller? We'll just go down the list. OK.

Dr. Kang. Dr. Mather.

Dr. MATHER. Just that we have the March 23 response that we sent to the GAO with our preliminary written comments on the report, and I offer that for the record.

Mr. SHAYS. That will be part of the record, but you don't have an analysis of the numbers.

[The information referred to follows:]

INSERT FOR PAGE 159, Line #3782

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration

CODING OF "RULE OUT" DIAGNOSES IN VA COMPUTERIZED MEDICAL RECORDS DATABASES AND DATA VALIDATION ACTIVITIES

Background

The VA has three general automated medical records databases, the Inpatient File or Patient Treatment File (PTF), the Outpatient File (OPC), and the National Patient Care Data Base (NPCD) which has replaced the OPC. In the future, VA will also merge the PTF database with NPCD, creating one national patient care database. In addition, information from the VA Persian Gulf Registry examination program is maintained in a computerized database.

Coding "Rule Out" Diagnoses

In the PTF, "rule out" diagnoses (as well as other suspected diagnoses, e.g., "probably", "questionable" or "possible" diagnoses) are coded as if the conditions exist using the appropriate ICD-9 diagnostic codes. This is in conformance with coding standards set by the American Hospital Association (AHA) for inpatient coding.

In the OPC (which is not an active database) ICD-9 diagnostic codes are not included.

In the NPDC, developed in FY 1996, ICD-9 codes are available starting in 1997. However, ICD-9 diagnostic codes are not used for "rule out" diagnoses and other unconfirmed diagnoses. Rather codes are entered for the symptoms, signs, abnormal test results and other reasons for the encounters.

In the Persian Gulf registry system there are separate sections for ICD-9 coding of symptoms and definite medical diagnoses.

Data validation activities

By VA policy, validation of the PTF and NPCD, including qualitative reviews and evaluation of the clinical information reported, is performed at locally established intervals. The same was true for OPC when that database was active.

The Persian Gulf Registry code sheets that are rejected by the Austin Automation Center for quality control problems are scrutinized by VA Central Office staff for incorrect coding or other errors. Also, in the Persian Gulf registry system, there are separate sections for ICD-9 coding of symptoms and definite

medical diagnoses.

Use of existing VA Data Bases to establish Incidence rates

Data for date of onset is not coded. Instead, VA codes the date of the clinic visit or hospital discharge. Therefore for both PTF and NPC, the diagnosis is associated with the time that treatment was provided not the date that the condition began, so it would not be possible to calculate incidence rates from this data.

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Dr. MATHER. Of the numbers that we didn't receive until last night.

Mr. SHAYS. OK.

The reason why I wanted Dr. Cianflone to come back up here though is, and I appreciate it, you know, because it's not common practice to mix the two panels, but I just want us to kind of continue to have a reality that while we're all talking numbers, here there are real people. And I know you know it, but I think it's always good to remind all of us.

And, Dr. Cianflone, we're going to try to do a better job for you because I just believe that there has got to be a better way to communicate with our veterans who are sick, and I know we're not doing it. And I think they see us coming from the opposite direction.

Any other comment you want to make, Dr. Cianflone?

Dr. CIANFLONE. I trained in a university setting as a medical student and I was—you know, did some of my rotations at the VA, and I think it's too much of us in the profession sometimes look down on the veteran that shows up at the VA hospital as a resident and as a student. And now, having been one of their patients, really the majority of veterans are not your "alcoholic compensationitus" individuals. They are people that are, especially in the Desert Storm individuals, professionals, they came from other walks of civilian life; they're not your Skid Row people, and they deserve the respect and concerns that we're bringing forth today.

Mr. SHAYS. Thank you very much. Thank you all. This hearing is adjourned. Thank you for your transcription.

[Whereupon, at 3:10 p.m., the subcommittee was adjourned.]