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Author Custis, Donald L.

Corporate Author

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**STATEMENT OF
DONALD L. CUSTIS, M.D.,
CHIEF MEDICAL DIRECTOR,
DEPARTMENT OF MEDICINE AND SURGERY
VETERANS ADMINISTRATION
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES**

September 15, 1982

Mr. Chairman and Members of the Committee:

Good morning. On behalf of the Veterans Administration, we are pleased to have the opportunity to appear before you today to provide an update on the status of both VA's Agent Orange-related activities and the Readjustment Counseling Program. We are continuing efforts to resolve the complex medical and scientific questions concerning Agent Orange. In the interim, we are providing medical care and treatment, as well as information to Vietnam veterans. We believe that a great deal of progress has been made in both areas since we last appeared before this committee on May 6, 1981.

Mr. Chairman, we are aware that both the Agent Orange issue and readjustment to civilian life remain key concerns for many Vietnam veterans. A great deal still needs to be done to resolve both of these concerns. Let me reemphasize, however, that the Veterans Administration has never lost sight of the special needs of the Vietnam veteran.

Agent Orange Program

On June 30, 1982, Robert P. Nimmo, Administrator of Veterans' Affairs, officially approved a revised Department of Medicine and Surgery program of Agent Orange-related activities. The most significant activity which was approved is a pilot study as a preliminary to the full epidemiological study provided for by Congress. Other major efforts included are the Vietnam veterans identical twin study, a mortality study, and specially-related research projects.

Approval was also given for the establishment of the Agent Orange Projects Office within the Department of Medicine and Surgery. This office will coordinate and monitor a variety of epidemiological projects. Efforts are now underway to identify key epidemiologic staff who will be responsible for these efforts. The core staffing will consist of an Epidemiologist, Biostatistician, Statistical Programmer, Health Science Specialist for Quality Assurance, an Administrative Assistant and supporting clerical staff.

In addition, approval was given for continuation and improvement of the Agent Orange Registry, chloracne activities, a follow-up to the literature analysis, a monograph series, establishment of a Vietnam service indicator in the Patient Treatment File (PTF), and a retrospective study of dioxins and furans in human adipose tissue.

STATUS OF VA EPIDEMIOLOGY STUDY:

The epidemiology protocol submitted to the VA by the UCLA School of Public Health on April 29, 1982, has now been reviewed by the VA Advisory Committee on Health-Related

Effects of Herbicides, the Agent Orange Working Group (AOWG) and the Office of Technology Assessment. The protocol is currently being reviewed by a committee of the National Academy of Sciences (NAS). The VA has been advised that NAS is now in the final stages of this review process. It is expected that the report will be completed and forwarded to the Veterans Administration shortly. Following incorporation of the various reviewers' comments, we will solicit bids for a contract for the conduct of a pilot study. We anticipate having that solicitation in place before this December.

The purpose of the pilot study will be to permit us to "fine-tune" the protocol for the conduct of the full-scale epidemiology study which will study a population of approximately 18,000 veterans. The pilot study has become the focal point of recent activity by the VA, the Army Agent Orange Task Force (AAOTF) and the AOWG.

The AOWG has appointed a subcommittee of its Science Panel to establish procedures for cohort selection for the epidemiology pilot study. The VA has brought in biostatistical consultants to work with this subcommittee and with the AAOTF. The subcommittee is now in the process of preparing its final report to the Science Panel.

Health Care

The Veterans Administration is implementing the medical care and treatment provisions of Public Law 97-72, the "Veterans' Health Care, Training, and Small Business Loan Act of 1981." Shortly after the law was signed, interim guidelines for the implementation of these provisions were issued to all VA health care facilities. Those guidelines were also published in in the Federal Register on December 5, 1981, to provide Vietnam veterans and the general public with the opportunity to comment.

Under the provisions of the guidelines, each veteran who served in the Republic of Vietnam and who requests VA medical care is being provided a complete medical history, physical examination and appropriate diagnostic studies. When it is determined that a condition exists requiring treatment, the responsible staff physician makes a determination as to whether the condition resulted from a cause other than the specified exposure to Agent Orange. The guidelines include a description of those conditions which I determined cannot ordinarily be considered to be due to such exposure. Ultimately, it is left to the treating physician to exercise professional judgment in determining whether the veteran should be provided care under this authority.

Agent Orange Registry

Since the initiation of the Agent Orange Registry in 1978, approximately 91,000 veterans have received an Agent Orange examination at VA health care facilities. The VA has provided approximately 20,000 follow-up examinations for Agent Orange. The basic registry process involving a comprehensive physical examination, completion of a questionnaire and informing the veteran of the results of the examination verbally and in writing, are continuing to be followed by all health care facilities.

The monthly report, transmitted by VA health care facilities and compiled at VA Central Office, is still an effective tool in measuring the numbers of examinations (initial and follow-up) being performed at the facilities and the number of pending examinations. The Environmental Medicine Office is continuing to monitor the numbers of pending examinations to assure that the veteran is provided the Agent Orange examination and related treatment in a timely manner. Facilities reporting "out-of-line" situations, that is, facilities with examinations pending more than 30 days or having more than 50 examinations pending during any reporting period are contacted by program officials at

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VA Central Office and directed to take immediate action to reduce the number of pending examinations to comply with Central Office guidelines.

Improvements in our registry procedures will enable the VA to match Agent Orange Registry records with records of hospitalization in the Patient Treatment File (PTF) system so that correlations can be made regarding the types of diagnoses Vietnam veterans are presenting for treatment at VA health care facilities.

The VA is cooperating with the Department of Defense with regard to Agent Orange examinations for active duty personnel. Instructions will be mailed to all VA health care facilities for processing an active duty service member's request for an examination and for processing the forms. The results from this examination will be entered into the Agent Orange Registry.

Twins Study

The VA has recently given approval for the development of a comprehensive protocol that will involve studying identical twins. The proposed study would involve identical twin veterans where one twin served in Vietnam during the period of Herbicide Orange spraying and where the twin sibling did not serve in Southeast Asia. This study will be designed to investigate whether the current psychological and physical health of Vietnam veterans was adversely affected by their military experience in Vietnam. Veterans Administration researchers at our St. Louis VA Medical Center have proposed the study and are currently developing the protocol. We would anticipate that if the protocol survives the scrutiny of appropriate scientific reviews, we will launch into the physical examinations of some 450 pairs of identical twins in late 1983 and should have an initial report of findings by October 1984.

Vietnam Veteran Mortality Studies

A carefully-designed and well-executed mortality analysis of Vietnam veterans will provide background to many questions raised by the Agent Orange exposure issue in particular as well as the possible health effects of service in Vietnam in general. The Vietnam Mortality Study is designed to analyze and compare death rates and cause-of-death profiles of veterans with service in Vietnam and comparable veterans with no service in Vietnam.

The studies will use existing computer records to assemble a cohort of veterans and determine their mortality experience. It should be noted that the mortality studies will provide mortality information which may prove useful primarily in suggesting areas for further scientific study. These mortality studies will be conducted by researchers at the Veterans Administration Central Office in Washington, DC. The collection and coding of death certificates and the abstracting of military records will be done by VA contractors. We are currently evaluating submitted proposals and hope to sign contracts for these efforts shortly. It is anticipated that it will take approximately two years to complete the mortality studies.

Retrospective Study of Dioxins and Furans in Adipose Tissue of Vietnam-Era Veterans

The Environmental Protection Agency has been collecting adipose tissue from the U.S. general population.

This National Adipose Tissue Bank was initiated in 1968 and now contains specimens from approximately 6,000 individuals. Represented within this bank is adipose tissue from approximately 300 males born between 1938 and 1952. It is estimated that

approximately 200 of these males may have served in the U.S. military during the Vietnam era and that as many as 70 may have served in Vietnam.

We are currently developing an agreement by which the VA would support an interagency study to be conducted at the EPA Dioxin Laboratory in Bay St. Louis, Mississippi. This will be a retrospective study of chlorinated dioxins and furans in human adipose tissue.

The study is designed to establish background levels of 2, 3, 7, 8-TCDD in the U.S. male population. In addition, this study may serve as a means of determining whether service in the military and especially in Vietnam has had an effect on the levels of TCDD in the adipose tissue.

The proposed effort would involve a jointly-funded program between the VA and EPA to develop the research protocol and appropriate sampling and analytical methods. The actual analyses of the human tissues will be costly and time consuming. Data should be forthcoming within two-three years.

Chloracne Activities

The review of skin conditions to identify questionable cases which may be chloracne is continuing. Over 3,200 Rating Decision Sheets on skin condition claims have been reviewed by VA Central Office physicians. The medical records of questionable cases were reviewed by a dermatologist consultant at the Washington VA Medical Center who tentatively identified 12 cases requiring a further clinical review which will include a physical examination of those individuals.

We are now in the process of making arrangements for the physical examinations, including dermatology examinations, of these individuals at selected non-VA clinics. I anticipate that these examinations will be conducted during October.

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We intend to continue our review of Rating Decision Sheets provided by VA Central Office Compensation and Pension Service to determine possible chloracne cases and recommend selected claimants for special dermatological examination. Additionally, we will review and analyze Agent Orange Registry data relating to types of skin conditions being reported by participants.

I am confident that our current emphasis on chloracne-related activities will assist us in more effectively identifying and treating skin conditions which may be the result of exposure to Agent Orange.

Vietnam Service Indicator for Patient Treatment File

The Patient Treatment File (PTF) maintained by the Department of Medicine and Surgery has great potential for epidemiological research related to Vietnam veterans. A major problem with this automated file is that there has been no entry to identify those veterans who actually served in Vietnam.

The establishment of such an indicator, in most instances, will require a hand search of the individual veteran's service record. This would best be accomplished by a contract with an organization which has a proven record of expertise with this type of effort.

We intend to conduct a study to determine the feasibility and cost of obtaining a veteran's service history. Based upon the results obtained, we will then decide whether to obtain this information for all Vietnam-era veterans in the PTF.

Specially-Solicited Research Activities

Medical Research Services has recently approved 10 new Agent Orange research studies that will investigate the impact on basic biological processes of low levels of exposure to components of Agent Orange. Two other ongoing studies address these issues also. The studies include analysis of the impact of Agent Orange components on:

- o Liver cell function
- o Skin cell chemistry relating to chloracne
- o Neurobehavioral function

The basis of the design of each of these biological studies includes exposing a test biological system to one or more components of Agent Orange, and subsequently measuring abnormalities of biological function.

The chemicals used in these experiments which are the main component parts of Agent Orange are: 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic acid (2,4,5-T). In addition to these chemicals, Agent Orange (and some other herbicides used less frequently in Vietnam) contained varying amounts of a contaminant commonly referred to as TCDD (dioxin) which will also be a focus of studies to determine whether and how delayed toxicity is manifested after low-dose exposure. Such studies may provide clues for clinicians as to what medical tests would best identify delayed, toxic effects, if any, of exposure of veterans to herbicides in Vietnam.

The biological systems thought to be affected by exposure to TCDD are:

- o Liver function: When animals are exposed to TCDD and related compounds, these chemicals are stored in the liver and produce acute liver damage. It

would appear likely that any delayed harmful effects of exposure to low doses of such compounds would be manifested by subtle changes in the biochemistry of the liver. Seven of the funded research studies will investigate the delayed impact of exposure to Agent Orange components and the contaminant TCDD on various aspects of liver cell functions in a variety of species.

- o Skin: Chloracne is the one documented effect of low-dose exposure to Agent Orange in humans. One study will analyze the underlying biochemical events that lead to chloracne in a mouse model and in human tissue culture cells.
- o The nervous systems: Acute accidental poisoning with TCDD in man has led to a variety of usually-acute neuromuscular abnormalities. Four studies will systematically investigate the effect of the components of Agent Orange on neuromuscular function, sleep and behavior in a variety of animal models.

A new effort to solicit and support research on the special health problems facing Vietnam veterans has just begun. The Research and Development Office has sent forward to all VA medical facilities a solicitation for research studies dealing with disorders affecting Vietnam veterans and their families. It is anticipated that a significant number of new studies submitted in response to this solicitation will be supported in Fiscal Year 1983.

Monograph Series

Funding has been provided during FY 1982 for the preparation of a monograph series designed to provide useful scientific information on environmental factors that may have affected the health of military personnel serving in Vietnam.

Monographs are planned on the following subjects: chloracne, birth defects and genetic counseling, insecticides used in the military, and Agent Blue.

Literature Analysis

Mr. Chairman, as you may know, the comprehensive literature review of worldwide scientific literature on Agent Orange and other phenoxy herbicides used in Vietnam has been completed in accordance with the provisions of Public Law 96-151. We have distributed this two-volume report (which includes an annotated bibliography and analysis of 1,200 scientific papers) widely within the VA.

Copies have also been provided to members of the White-House established Agent Orange Working Group, the Advisory Committee on Health-Related Effects of Herbicides, the National Academy of Sciences, the Office of Technology Assessment, the Departments of Agriculture and Defense, Surgeon General of the U.S. Air Force, Library of Congress, the Centers for Disease Control and other individuals, organizations, and scientific research groups. The successful completion of this review represents a step forward on the long road to understanding the complex health issues related to the use of herbicides. It will undoubtedly serve as an invaluable scientific resource which will assist scientists and others in identifying areas suitable for additional research.

We intend to periodically update this report and to augment it with a detailed critical assessment of all publications addressing herbicide exposure with particular emphasis on health consequences in humans. It is estimated that about 400 publications have appeared since October 1981. A critical review of these recent reports is needed in order to keep this effort current. The Veterans Administration will take necessary steps to ensure that the literature review and analysis remains as current as possible.

Armed Forces Institute of Pathology (AFIP)

The Veterans Administration is continuing to cooperate with the Armed Forces Institute of Pathology in providing biopsy and autopsy materials for analysis to the Institute. This special registry was established in 1978 with the purpose of analyzing tissue samples to determine what diseases Vietnam veterans are suffering from, as reflected in biopsies or autopsies.

The VA has repeatedly emphasized the importance of the AFIP Registry and will continue to urge VA health care facilities to send pathological material obtained from any Vietnam veteran.

Education Activities

Mr. Chairman, our environmental physicians, as Agent Orange coordinators at our major VA health care facilities, remain the key link in examining and advising the veteran concerned about exposure to Agent Orange. In order to ensure that these health care staff remain completely abreast of the latest developments, nationwide conference calls are held on a regular basis. When required, special conference calls are scheduled on significant developments requiring their immediate attention.

In addition to the conference calls, relevant Agent Orange-related literature is periodically sent to the immediate attention of environmental physicians. Staff support within the Environmental Medicine Office is available to assist in the explanation of specific documents or to answer questions which may be raised by the information received from VA Central Office.

Environmental physicians are encouraged to participate in important scientific meetings on Agent Orange and other environmental substances in order to keep abreast of scientific and medical developments. Members of our own VA Central Office staff played a key role in the planning and organizing of an "International Symposium on Chlorinated Dioxins and Related Compounds" which was held in Arlington, Virginia, on October 25-29, 1981. On October 12-14, 1982, Dr. Barclay M. Shepard, my special assistant, and Dr. Alvin L. Young will actively participate in the "3rd International Symposium on Chlorinated Dioxins and Related Compounds" which will be held in Salzburg, Austria. I have been advised that several of our environmental physicians are also planning to attend. Through such participation I am confident that our health care staff will remain professionally current with the latest findings on the short and long-range effects of Agent Orange and other environmental substances.

VA Public Information Activities

As part of our effort to inform Vietnam veterans, their families, and other concerned individuals and organizations about Agent Orange and the assistance provided by the VA, we produced and distributed to all VA field stations a videotape entitled "Agent Orange: A Search for Answers."

While a recent internal survey indicated that many thousands of people have viewed the program on television or in numerous groups of individual showings, we are encouraging greater use of the film.

We are very pleased to report that this videotape has received considerable acclaim from critics. The Health Education Communication Association and the Network for Continuing Medical Education presented an award of merit to the VA for "outstanding

achievement in the use of television for education in the health sciences." The International Television Association (ITVA) awarded its Golden Reel of Excellence for the videotape's "highly-effective form of communication, which helped the user organization better achieve its stated goals." The program also was cited by ITVA for creativity, innovative techniques, and high-production value. In addition, the program also received an Emmy Award from the National Academy of Television Arts and Sciences.

We are delighted by this recognition and encourage all interested individuals to view this program.

The VA takes seriously its obligation to keep veterans informed about Agent Orange. We have also pursued other avenues to provide information and education to concerned Vietnam veterans and their families and VA employees on matters related to Agent Orange.

Early this year, an automated mailing list was developed from the Agent Orange Registry. In June, letters were sent to these veterans along with the first two of a new series of printed information material on Agent Orange. One of these pamphlets was devoted primarily to Public Law 97-72. A third pamphlet has been issued and a fourth is in production.

VA officials have participated in public seminars, news media interviews and other public forums dealing with the subject of Agent Orange.

VA Liaison with State Agent Orange Activities

At the present time, 18 states have initiated programs directly related to the Agent Orange issue. The VA is continuing its efforts to maintain an effective, ongoing

relationship with each of these state programs. One of the prime responsibilities of our Agent Orange Research and Education Office is to insure that current and accurate information regarding VA Agent Orange-related activities is disseminated on a timely basis to the various states, as well as to veteran service organizations, government agencies, and interested parties. We consider it to be an essential part of our program to insure that the veteran population as a whole, and those who serve them at all levels, are fully informed both with regard to the current body of knowledge regarding the possible adverse effects of dioxins, as well as the status of VA Agent Orange programs.

To this end, the VA has provided the states with copies of all pertinent Agent Orange materials and we have extended to officials from all of these states an open invitation to attend the VA Advisory Committee meetings. Several of the states sent delegations to the meeting held on August 31.

The efforts are of a continuous nature and are beneficial to all concerned parties. As new states become involved in the Agent Orange issue, VA will include them in its information exchange program.

White House Agent Orange Working Group (AOWG)

We are pleased to report that the Veterans Administration is continuing to play an active role in the White House Agent Orange Working Group and its Science Panel.

This committee was established in July 1981 when the Interagency Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants was expanded and elevated in status to the Cabinet Council level.

The AOWG brings together policy officials and scientists from throughout the federal establishment to identify ongoing research activities on Agent Orange and related matters and to develop and organize the means to carry out additional needed scientific research.

The Department of Health and Human Services (DHHS) is the lead agency in the working group. In addition to DHHS and VA, the AOWG includes representatives from the Departments of Defense, Agriculture, and Labor, Environmental Protection Agency, Office of Management and Budget, Council of Economic Advisors, Office of Science and Technology and Office of Policy Development.

The AOWG has been very helpful to the VA in the review of our planned epidemiological study, mortality study, and other important research efforts. Through the AOWG mechanism, the VA also has been able to contribute to the success of Agent Orange research efforts conducted or sponsored by other federal departments and agencies. The more important of these research efforts are the U.S. Air Force's "Operation Ranch Hand" study and the Centers for Disease Control's Birth Defects Study.

We view our participation as vital to the scientific process and as fully consistent with the President's goal of ensuring "... that the full resources of the federal government are available to support the working group's continuing efforts."

Advisory Committee on Health-Related Effects of Herbicides

This committee, established in 1979, continues to meet quarterly at VA Central Office for the purpose of assembling and analyzing information which the VA needs to formulate medical policy and procedures on the complex questions surrounding veterans' herbicide exposure.

During recent meetings the committee has discussed the VA epidemiological study and herbicide literature review, the VA-solicited in-house research program regarding Agent Orange and Agent Blue, the VA mortality study, international dioxin symposiums, the Air Force Health Study, the CDC Birth Defects Study, the proposed VA Twin Study, the AFIP Agent Orange Registry, the VA monograph series, and many other research activities and matters of concern to Vietnam Veterans and scientists searching for answers to the difficult questions raised about the possible human health effects of herbicides.

The committee has been particularly helpful in advising the VA on the literature review and the epidemiological study. The literature review, published October 1981, was the subject of several sessions and considerable time and attention have been devoted to a critique of the proposed epidemiological study design.

Verbatim transcripts are prepared and made available to appropriate government offices and interested organizations and individuals. A copy of each transcript also is sent to all environmental physicians.

Policy Coordinating Committee

In recognition of the importance of the Agent Orange issue, the Administrator has reorganized and elevated in status the Policy Coordinating Committee (PCC) which was the Agency's central coordinating point for Agent-Orange related activities. The PCC develops policy for review and approval by the Administrator. It now is composed of the top leadership of the major departments and staff offices within the VA. Mr. Everett Alvarez, Jr., Deputy Administrator, chairs the PCC.

I wish to conclude this part of my testimony on Agent Orange, Mr. Chairman, by again expressing the total commitment of the Veterans Administration to attempting to resolve the many issues relating to Agent Orange. Although there is no way that we, or anyone, can guarantee that ultimate and conclusive answers will be found to the extremely-complex medical and scientific issues stemming from the use of the defoliant Agent Orange in Vietnam, nevertheless, we will continue to vigorously pursue the search for those answers. These efforts will center not only on our own research initiatives, but will be closely interfaced with the intensive research now underway by other federal, public and private institutions.

Readjustment Counseling

The Vietnam-era Veterans Readjustment Counseling Program has seen a number of important developments in recent months.

In January, the Veterans Administration vested responsibility for this program in a new independent professional service--the Readjustment Counseling Service--and established that service on the same administrative level as Medical, Surgical, Nursing, Prosthetics, etc.

A new program director was appointed by the Administrator of Veterans Affairs on February 10, 1982, following an intensive and thoughtful search and selection process. The new Director of the Readjustment Counseling Service, psychiatrist, Arthur S. Blank, Jr., M.D., is a Vietnam veteran and has been psychiatric consultant to the program since its earliest planning stages in 1979.

A third leadership initiative was taken on June 1, 1982, when a new position was created, Chief of Counseling Services, and an expert clinician Dr. Raymond M. Scurfield from the Brentwood VA Medical Center was hired for this position.

Underscoring the significance the Administrator attaches to the Readjustment Counseling Program is the establishment in November 1981 of a high-level Agencywide steering committee to monitor the program.

Improving the management and organization of the Vet Center Program has been one of our top priorities. In addition to augmenting our Central Office program management group, we have taken steps to strengthen the offices of our six Regional Coordinators who oversee Vet Center operations in their respective regions. During the developmental phase of the program, each of these important offices was staffed by a Regional Coordinator and a single secretary. Each Regional Office now has an Assistant Coordinator for Administrative Services, and we are further strengthening the Regional Coordinators' staffs with the appointment of an Assistant Coordinator for Clinical Services and an additional secretary.

From an organizational standpoint, the most important development of recent months has been the publication of a new program circular, which clarifies lines of authority and responsibility. It contains several key elements:

- a. The responsibilities of the Director and the Readjustment Counseling Service staff in Central Office for overall supervision and management of the program are spelled out. The Director and his staff have direct operational control of the Vet Center system through the Regional Coordinators and, within Central Office, report to the Deputy ACMD for Professional Services and to the Chief Medical Director through the Associate Deputy Chief Medical Director.

b. The responsibilities of the Regional Coordinator's staff are also clarified. We have established clear lines of authority and responsibility from Vet Centers to the Regional Coordinator's staff to the Readjustment Counseling Service in Central Office. The Regional Coordinators are responsible for selection and all supervision of the Team Leaders, and the program director is responsible for selection and all supervision of the Regional Coordinators. We have also spelled out the relationship between Vet Centers and their local VA Medical Center parent facilities. The circular directs that the parent VA medical center is responsible for providing the Vet Center all required support services. On professional matters, the medical center's role with respect to the Vet Center operations is to be consultative and collaborative only.

As part of our reconstituting of the management and organization of the readjustment counseling program, we have instituted financial and accounting procedures which track all program funds and maintain their earmarked character at the local level.

As you know, Mr. Chairman, we have also established a mechanism to contract with private sector providers to furnish readjustment counseling services to Vietnam-era veterans who do not have access to one of our Vet Centers. We are using a decentralized model with a contracting committee at each of 122 medical centers. The contracting committee includes two members of a Vet Center staff in each instance. As of August 31, over 300 contracts had been awarded. We are currently evaluating the quality and effectiveness of this new mode of service delivery.

That concludes my statement, Mr. Chairman. I will be pleased to answer any questions you or members of the committee may have.