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Statement of the AAMC on The Department of Veterans' Affairs Research Program Presented by Joseph H. Bates, M.D. Chief, Medical Service McClellan VA Medical Center Little Rock, Arkansas

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STATEMENT

OF THE

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

on

The Department of Veterans' Affairs Research Program

Presented to the

U.S. House of Representatives
Committee on Veterans' Affairs
Subcommittee on Hospitals and Health Care

Presented by

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Mr. Chairman, Members of the Subcommittee:

My name is Joseph H. Bates. I serve as Chief of the Medical Service at the John L. McClellan VA Medical Center in Little Rock, Arkansas. Today I am appearing on behalf of the Association of American Medical Colleges (AAMC). The AAMC serves as the national voice for the nation's 127 accredited medical schools, over 85 professional academic societies, and 435 major teaching hospitals. Seventy-seven of those 435 teaching hospitals are VA facilities; in addition, over 100 of the medical schools, including the University of Arkansas, share an affiliation with one or more VA medical centers. The AAMC understands and strongly supports the VA's medical care and research endeavors. On behalf of the AAMC, I am pleased to have the opportunity this morning to present my views about the Department of Veterans Affairs (VA) research program.

I will begin by stating that I joined the staff of the VA hospital in Little Rock in 1963 after completing my training in internal medicine and subspecialty training in infectious disease. One of the primary reasons I chose to work at the VA was the research opportunities offered. After several years, I was appointed Chief of the Chest Disease Section and finally Chief of the Medical Service. I have continued my research over 26 years and have been fortunate to receive VA funding continually. At present I maintain an active research laboratory in the McClellan Medical Center that is supported by research grants from the VA, NIH, and private pharmaceutical firms. My story with slight variations is a very common one throughout the VA. That is, young physicians join the VA clinical staff because the VA provides outstanding

opportunities to practice medicine and do clinical research in an institutional setting.

As Chief of Medicine, I spend a major portion of my time in recruitment of new staff physicians and in the nurturing and development of an active staff. I can say without reservation that the single most important factor that makes VA staff positions attractive is the opportunity to be involved in clinical research and be associated with other like-minded clinicians. Absent the research program, the benefits of VA employment would be less competitive with those found in private practice or in university academic centers. The research program serves as the intellectual carrot that attracts some of our best and brightest physicians to treat veteran patients.

I would also like to highlight the extraordinary benefits that the research program offers to veterans. The conduct of research within a clinical practice is an excellent combination. It insures that veteran patients are cared for by physicians who are exceptionally knowledgeable, careful and dedicated. In addition, the research program provides many veterans the opportunity to participate in studies involving the latest techniques and therapies that medicine and surgery have to offer. You will hear more about the value of this opportunity from some of the patients testifying today.

The accomplishments of one part of the VA research program, the Cooperative Studies Program, deserves special emphasis for its uniqueness and impressive record. It may surprise you to learn that the first, prospective, randomized

clinical research trials in medicine were conducted by the VA in 1946. The VA provides an ideal setting for such studies.

A prospective, randomized clinical trial requires a set of patients with a specific disease or condition who meet very precise medical criteria. A research trial of this type is designed to resolve differing views about how to treat a specific condition; in other words, the research will evaluate the best form of treatment for that condition. A reliable study must involve a large number of patients with the same medical problem who are divided into two or more groups. The patients in each group are treated differently, for instance, one group with regimen A and the other group with regimen B, followed over a course of months or years so that their condition can be carefully monitored. After a sufficient number of patients have entered the study, the results of each treatment are analyzed and compared. A definite answer usually results in the determination of the best treatment method. This type of trial is the ideal way to answer many complex medical questions concerning medical, surgical, and psychiatric disorders. Prior to this approach, physicians used flawed methods, leading to unreliable conclusions. That is, trials done by different individuals, at different times, with different types of patients would be compared. Trials of this type lacked adequate controls and frequently led to erroneous answers. The prospective randomized trials developed by the VA have become the standard method for conducting research on human subjects.

In 1946, the first of such studies involved a drug called streptomycin, effective in fighting the tuberculosis germ. Streptomycin had many problems

with toxicity and the tuberculosis germ developed resistance to the drug after short periods of use. To study these problems, the VA enlisted the participation of seven VA hospitals, all working under the same research design. For the first time the VA's unique hospital network was utilized for simultaneous clinical research. The VA network provided multiple resources and research participants, enhancing the design and quickening the pace of the research and its outcomes. The results of this study and perhaps 50 or more related studies completed over the next 15 years revolutionized the treatment of tuberculosis. Patients who previously would have required hospitalization were cured and sent home early. From these cooperative studies in tuberculosis, a framework for all future VA cooperative studies was born.

The Cooperative Studies Program has become a major component of the VA's medical research agenda. In addition to tuberculosis, VA cooperative study trials have made major contributions to our understanding and treatment of high blood pressure, stroke, kidney diseases, coronary heart disease and many forms of cancer. The program now includes more than 50 ongoing clinical research trials involving 72 Veteran Administration Medical Centers. The research being conducted in these clinical trials provides answers to critical questions that cannot be obtained in any other way. Clinical trials will always be required to measure the benefit and effectiveness of various modalities proposed to prevent or treat medical problems. The VA system lends itself in a unique manner for the conduct of these trials because of its large patient population, the dispersed location of the health care facilities, and the formally established close working relationships with colleges of medicine, dentistry and allied health professions.

One of the major areas of on-going research concerns the treatment of high blood pressure. A recent study has demonstrated that control of blood pressure can be well maintained on much less medication than is presently recommended. In the VA alone there are 243,000 patients under treatment for high blood pressure. The VA spends over $3 million on medication for this one problem each year. With this modification of treatment, drug costs can be reduced by one-third, saving the VA over $1 million per year. This cost savings will be multiplied many-fold as it is adopted for patients treated in the private sector. For patients, less medication means reduced toxic side effects, improving the patient's quality of life. Another high blood pressure clinical trial involves 1400 patients at 15 different VA medical centers. The study evaluates the use of drugs administered individually or in various combinations. When the study is completed, it will enable researchers to recommend a new course of therapy that will benefit thousands of patients, veterans and non-veterans alike, making it easier to take this medication on a long-term basis.

Another ongoing study focuses on the treatment of advanced cancer of the larynx or voice box. Preliminary results suggest that nonsurgical treatment will be as effective as the surgical approach. If these preliminary results are confirmed, it will mean an annual savings of $1.7 million to the VA alone. It will also mean that the voice box can be preserved and patients' chances of maintaining the ability to speak will be markedly improved.

VA Cooperative Studies have made major contributions to the treatment and prevention of cardiovascular disease. Presently there are trials underway on the management of angina pectoris (the chest pain associated with severe heart disease), acute heart attack management, coronary artery bypass surgery, and the treatment of congestive heart failure. In the U.S. 200,000 persons die each year of congestive heart failure. For patients who do not die suddenly from heart attacks, congestive heart failure is usually the cause of chronic disability and death. This is true no matter what the cause of the heart disease. In other words, patients develop congestive heart failure from a wide variety of types of heart trouble such as coronary artery disease, valvular heart disease, heart disease secondary to high blood pressure or heart infection. It is important to understand that once congestive heart failure is diagnosed, half of those afflicted will die within in 2 1/2 years and 90 percent will die within in five years. This is about the same outlook for lung cancer victims.

The terrible outlook for congestive heart failure patients changed little over the past 30 years until a recent VA treatment approach called vasodilator therapy was proposed. The VA clinical trial evaluating vasodilators was the first study conducted that clearly showed a medical treatment that prolonged life for congestive heart disease patients. I am pleased to be accompanied today by Mr. William Insull, a retired Marine who participated in this VA cooperative study. Following my remarks, Mr. Insull will describe how participation in this trial has improved his health and prolonged his life.

Presently, the VA funds 54 clinical trials covering a wide range of medical problems including cancer, stroke, AIDS, cardiovascular disease, kidney disorders, prostate enlargement, cataracts, alcohol dependence, liver disease, ulcers, impaired hearing, influenza, and a variety of psychiatric disorders including depression and post traumatic stress disorder. Nine additional studies that have been carefully evaluated and approved have been put on hold until funds become available for implementation. Among this group are trials to study drug abuse and dependence, treatment of diabetes, prevention of dental caries, and treatment for alcohol liver disease.

The VA Merit Review component of the research program is as important as the cooperative studies. As a personal aside, it is the merit review program that brought me into the VA and has induced me to remain throughout my entire career. I am certain this statement would be true for many other senior clinicians throughout the VA system. The ability to combine clinical duties with research strengthens the quality of the hospital's health care operation. Research work provides intellectual vigor, drawing young trainees to the system who become actively interested and involved in veterans' health promotion. In many areas of medicine and surgery, our ability to recruit and maintain adequate levels of staff depends heavily on our ability to offer professionals an opportunity to spend part of their time conducting research.

The laboratory research in my hospital concerns fundamental questions such as what happens to tissue cells as they age. Investigators are looking at the molecular and genetic events taking place within individual cells that account for aging and cell death. Other investigators are studying exciting new

methods for the diagnosis of lung infection and for the treatment of cancer by raising the temperature of the involved organ and combining this effect with drugs that interfere with cell metabolism. Still others are studying nutrition of the elderly and the effects of malnutrition on various body functions. I could name many more examples of work that could lead to exciting medical advances. I hope that I make my point; that is, VA physicians are conducting high quality research with direct benefits to veterans.

VA research provides critical information that, over time, builds the knowledge base required to solve any type of medical problem. Almost every diagnostic and treatment modality at use in my hospital is the result of biomedical research. When we stop research, we halt medical progress. The quality of our basic research program is very high and it is directly linked to patient care.

I assure you that it is because of the VA Research Program that I and many other Chiefs of Medicine throughout the system are able to attract some of the best minds and most capable clinicians in the nation to VA medical centers. These individuals provide superb care for our patients. Without the opportunity for research, we would risk losing many of these physicians, threatening the VA's ability to provide an acceptable level of quality health care to America's veterans.

In summary I wish to state with all the emphasis and force that I can that the VA Research Program provides an absolutely essential ingredient of the VA

health system. All aspects of the VA Research Program make major contribution to the nation's health. The VA's contributions to research have an established record, including an impressive number of Nobel Prizes awarded to and numerous important papers published by VA investigators. Per research dollar, the VA compares most favorably with any other arm of government-sponsored research. More importantly, the record includes an immeasurable value; by that, I mean the benefits of the VA research program to veterans whose lives have been improved and prolonged. This factor is beyond assessment.

I thank you for the opportunity to present this statement. Following Mr. Insull's statement, I will be happy to answer questions or expand and clarify my remarks.