the National Health Council strongly supports the Clinical Research Enhancement Act. As you know, it has been more than three years since the Institute of Medicine (IOM) documented the major challenges confronting clinical research in our country. Your bill would implement a number of the IOM recommendations for addressing these problems. It is critically important that the NIH move forward as rapidly as possible with these initiatives.

The NIH is the major funding source in the United States for basic biomedical research. However, the major dividends from this investment are discoveries that improve our ability to prevent, effectively treat, and cure disease and disability. The NIH must foster not only the basic research that begins this process but also the translational research through which a basic science discovery is applied to a medical problem. There is generous industry support for clinical research and clinical trials aimed at the development of new products. However, private funding is extremely limited for initial translational research that may have little or no commercial product potential. Examples of such research include studies of nutritional therapies, new approaches to disease prevention, transplantation techniques, behavioral interventions, and studies of off-label uses of approved drugs. In the past, such research was often subsidized from patient care revenues to academic medical centers. However, competition in the health care marketplace has begun to erode this source of funding; therefore, NIH must play an expanded role in providing support for this research. The Clinical Research Enhancement Act would foster NIH funding opportunities for this type of research through the establishment of ''innovative medical science awards.'' Such studies will focus on translating basic research discoveries into tools that health care professionals can use to cure disease and relieve suffering.

In addition, we support provisions of the bill that would foster opportunities for physicians to pursue careers in clinical research. There is ample evidence that American physicians are opting out of careers in science for a variety of reasons. Steps must be taken to rebuild our nation's supply of well-trained physician scientists if the United States is to continue its leadership of the world in medical science.

Finally, the bill would direct the NIH to improve the peer review of patient-oriented research. Studies have documented the fact that clinical research proposals are at a disadvantage when reviewed by NIH study sections because of NIH's primary focus on basic biomedical research. This must be changed, as proposed in your bill, so that scientific opportunities to improve medical care are not lost.

The undersigned organizations are extremely grateful for your leadership in addressing the problems confronting clinical research. We support your initiative to assure that the NIH invests in the translational research that holds the key for patients around the country who are waiting for a cure. We are pleased to endorse the Clinical Research Enhancement Act.

Alzheimer's Association, American Autoimmune Related Diseases Association, American Diabetes Association, American Kidney Fund, American Paralysis Association, Digestive Diseases National Coalition, Epilepsy Foundation of America, Foundation Fighting Blindness, Juvenile Diabetes Foundation International.

Glaucoma Research Foundation, Myasthenia Gravis Foundation, National Alopecia Areata Foundation, National Multiple Sclerosis Society, National Osteoporosis Foundation, National Tuberous Sclerosis Association, Paget Foundation, Sjogren's Syndrome Foundation, Tourette Syndrome Association.

AMERICAN FEDERATION FOR MEDICAL RESEARCH,
Washington, DC, November 7, 1997.

Hon. NANCY JOHNSON,
Hon. NITA LOWEY,
U.S. House of Representatives, Washington, DC.

DEAR REPRESENTATIVES JOHNSON AND LOWEY: I write to express the strong support of the American Federation for Medical Research for the legislation you will introduce to enhance clinical research programs at the National Institutes of Health. The AFMR is a national organization of 6,000 physician scientists engaged in basic, clinical, and health services research. Most of our members receive NIH support for their basic research but are finding it increasingly difficult to obtain public or private funding for translational or clinical research—studies through which basic science discoveries are translated to the care of patients. In the past, academic medical centers provided institutional support for this research through revenues generated by patient care activities. However, as the health care marketplace has become increasingly competitive, academic centers have all but eliminated internal subsidies, clinical research or the training of clinical investigators. In fact, the Association of American Medical Colleges has estimated that these institutions have lost approximately $800 million in annual ''purchasing power'' for research and research training within their institutions. In this context, the $60 million in spending entailed in your legislation (representing less than one-half of one percent of the NIH budget) would seem an extremely modest investment in a much-needed program to reinvigorate our nation's clinical research capabilities.

The Clinical Research Enhancement Act is a conservative approach to a severe problem. The Institute of Medicine (IOM) expressed alarm about the challenges confronting clinical research in a 1994 report, and your bill is based on the initiatives recommended by the IOM:

The IOM recommended that the General Clinical Research Centers program be strengthened. Your bill would codify this program, which has existed since the late 1950's, so that the Congress will have greater discretion over GCRC funding.

The IOM recommended enhanced career development in clinical investigation, and your bill proposes such awards.

The IOM noted problems with the NIH peer review of clinical research. Your bill directs the NIH to improve the peer review process for such research and establishes ''innovative science awards'' that will be reviewed by scientists knowledgeable in clinical investigation.

The IOM recommended programs to relieve the tuition debt of physicians pursuing clinical research careers. Your bill would expand an existing NIH intramural program for this purpose to the extramural community.

The IOM recommended structured, didactic training in clinical investigation. Your bill authorizes funding for advanced degree (master's and Ph.D) training in clinical research as successfully initiated at several institutions around the country.

The list of almost 150 organizations that support the Clinical Research Enhancement Act indicates the consensus of scientific, medical, consumer, and patient organizations that steps must be taken as soon as possible to stop the deterioration of the U.S. clinical research capacity, to reinvigorate the clinical research programs of academic medical centers, and to assure that the American people and the American economy benefit from the translation of basic science breakthroughs to improved clinical care and new medical products. The American Federation for Medical Research is pleased to have the opportunity to express its strong support for your legislation.

Sincerely,

JEFFREY KERN, M.D.,
President.

THE ADVANCE PLANNING AND COMPASSIONATE CARE ACT OF 1997

HON. SANDER M. LEVIN

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Sunday, November 9, 1997

Mr. LEVIN. Mr. Speaker, the Advance Planning and Compassionate Care Act of 1997 seeks to improve the medical care of individuals nearing the end of their lives so that they and their families can have confidence that this care respects their own desire for autonomy and dignity.

The compassionate care bill builds on the Patient Self-Determination Act enacted in 1990. The Patient Self-Determination Act requires health care facilities to distribute information to patients regarding existing State laws on living wills, medical powers-of-attorney, and other advance directives, which enable individuals to document the type of care they would like to receive at the end of their lives. Since passage of that legislation, there has been an increase in the number of individuals who have an advance directive, but a recent Robert Wood Johnson study found that many people do not understand the importance of discussing their advance directives with family members and their health care provider. For example, while 20 percent of hospitalized patients had an advance directive, less than half of those patients had talked with any of their doctors about having a directive and only about one-third had their wishes documented in their medical record.

The compassionate care bill takes another important step in raising public awareness of important end-of-life medical issues and improving the quality of the care individuals receive during this period.

The bill improves the type and amount of information available to consumers by making sure that when a person enters a hospital, nursing home, or other health care facility, there is, when requested, a knowledgeable person available to discuss end of life care. This will facilitate good decisionmaking on medical care based on the patient's own needs and values. The bill requires that if a person has an advance directive it must be placed in a prominent part of the medical record where all the doctors and nurses can clearly see it. It also establishes a 24-hour hotline and information clearinghouse to provide consumers with information.

The bill also ensures that an advance directive which is valid in one State will be honored in another State, as long as the contents of the advance directive do not conflict with the laws of the other State. In addition, the bill requires the Secretary of Health and Human Services to gather information and consult with experts on the possibility of a uniform advance directive for all Medicare and Medicaid

beneficiaries, regardless of where they live. A uniform advance directive would enable people to document the kind of care they wish to get at the end of their lives in a way that is easily recognizable and understood by everyone.

The compassionate care bill also focuses on the need to improve end-of-life care for Medicare beneficiaries. This bill will encourage seniors and families to have more open communication with health care providers concerning their preferences for end-of-life care. The bill also addresses the need to develop models of compassionate care and quality measures for medical care during this period.

Currently, there are few standards available to assess the quality of care provided to Medicare beneficiaries at the end of their lives. The tremendous geographic variation in medical care that currently exists reinforces the notion that many people do not receive care driven by quality concerns, but rather by the availability of medical resources in the community and other factors not related to quality care.

The bill requires the Secretary of Health and Human Services, in conjunction with the Health Care Financing Administration, National Institutes of Health, and the Agency for Health Care Policy and Research, to develop outcome standards and other measures to evaluate the quality of care provided to patients at the end of their lives.

The only Medicare benefit aimed at improving end-of-life care for Medicare beneficiaries is hospice care, which only serves a small number of beneficiaries. In 1994, the Medicare hospice benefit was provided to 340,000 patients for the last few weeks of their lives. The hospice benefit is limited to beneficiaries who have a terminal illness with a life expectancy of 6 months or less. A review of studies done by an Institute of Medicine panel found that 40 to 80 percent of patients with a terminal illness were inadequately treated for pain ''despite the availability of effective pharmacological and other options for relieving pain.''

The compassionate care bill provides funding for demonstration projects to develop new and innovative approaches to improving end-of-life care provided to Medicare beneficiaries, in particular those individuals who do not qualify for, or select, hospice care. Also, it includes funding to evaluate existing pilot programs that are providing innovative approaches to end-of-life care.

With a few exceptions, Medicare does not generally pay the cost of self-administered drugs prescribed for outpatient use. The only outpatient pain medications currently covered by Medicare are those that are administered by a portable pump. The pump is covered by Medicare as durable medical equipment, and the drugs associated with that pump are also covered. It is widely recognized among physicians treating patients with cancer and other life-threatening diseases that self-administered pain medications, including oral drugs and transdermal patches, offer alternatives that are equally effective at controlling pain, more comfortable for the patient, and much less costly than the pump. The bill requires Medicare coverage for self-administered pain medications prescribed for outpatient use for patients with life-threatening disease and chronic pain.

Instead of allowing these important end-of-life issues to be eclipsed by the debate over physician-assisted suicide, this legislation seeks to ensure that the medical care of patients at the end of their lives reflects their desires, increases comfort to the extent possible and is of the highest quality.

INTERNAL REVENUE SERVICE RESTRUCTURING AND REFORM ACT OF 1997

SPEECH OF

HON. MAX SANDLIN

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, November 5, 1997

Mr. SANDLIN. Mr. Speaker, I rise today in strong support of H.R. 2676, the IRS Restructuring and Reform Act. I thank the gentleman from Maryland [Mr. CARDIN] and the gentleman from Ohio [Mr. PORTMAN] for their hard work on this issue. I am a cosponsor of their legislation, H.R. 2292, which is the foundation of the legislation we are passing today, and I have been a strong supporter of initiatives to improve customer service, increase management accountability, and give the taxpayer expanded rights.

The oversight board should bring private sector expertise to the IRS, streamlining procedures, easing citizen interaction, and improving efficiency. The provisions regarding the oversight board have been carefully drafted to avoid privacy violation and conflict of interest concerns while still injecting the experience and skills of business managers and tax experts to the IRS agency. Taxpayers should see immediate and long lasting improvements in the service and efficiency of the agency.

The provisions in this bill that shift some of the burden of proof in tax disputes from the taxpayer to the IRS encourage my belief that the Government can become more responsive and more accountable to the people. When law-abiding citizens live in fear of threats from Government bureaucrats, it is time to change the way the Government conducts its business. Most taxpayers accept IRS challenges to valid exemptions because they are intimidated or can't afford to fight the Federal Government in court. By shifting the burden of proof to align the IRS code with the values of our criminal justice system, the IRS is forced to back up its challenges so that law abiding taxpayers are not forced to forfeit money that is legally theirs.

These reforms are only the first step in our struggle to reduce the impact of Federal taxes on taxpayer's lives. The real problem is the several thousand page Tax Code, created by Congress, that the IRS attempts to administer. This year alone, Congress added 600 pages to the Code by passing $85 billion in tax cuts. When a tax cut makes the Tax Code more complex, you know it is time to scrap this Code and start over with one that is simple, fair, and understandable.

PERSONAL EXPLANATION

HON. ALLEN BOYD

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Sunday, November 9, 1997

Mr. BOYD. Mr. Speaker, today, November 9, I was unavoidably detained and missed the vote on H.R. 1129. Had I been present, I would like the RECORD to reflect that I would have voted ''yes.''

INTRODUCTION OF THE CLINICAL RESEARCH ENHANCEMENT ACT

HON. NANCY L. JOHNSON

OF CONNECTICUT

IN THE HOUSE OF REPRESENTATIVES

Sunday, November 9, 1997

Mrs. JOHNSON of Connecticut. Mr. Speaker, I rise today to announce with my good friend from New York, Congresswoman NITA LOWEY, the introduction of the Clinical Research Enhancement Act that will improve the quality of health care by enhancing our investment in clinical research. We introduced a similar bill in the 104th Congress, and I am once again glad to be working with Congresswoman LOWEY and the health research community, led by the American Federation for Medical Research, on this proposal.

Clinical research is the critical component we need to bring the discoveries of basic research to the patient in the form of medical treatments. Our Government makes significant investments each year in basic research through the National Institutes of Health. In fact, the Federal Government is the major source of investment in basic biomedical research. However, it is crucial that the Government focus not only on basic research but also on the translational research that utilizes the discoveries of basic research to improve our ability to prevent, treat, and cure disease and disability.

While there is industry support for clinical research and clinical trials, private funding is very difficult to secure for the initial steps of translational research, which may have little or no commercial potential. Examples of this initial research include nutritional therapies, new approaches to disease prevention, transplantation techniques, behavioral interventions, and studies of off-label uses of approved drugs. These initial steps of clinical research used to be subsidized in part from patient care revenues to academic medical centers. As we heard in our debate on Medicare reform and graduate medical education, however, these teaching hospitals are more and more stretched for teaching and patient care dollars. They are finding it much more difficult to maintain their teaching role, let alone their investment in clinical research. Therefore, it is more important than ever that NIH devote greater attention and resources to providing support for clinical research.

Without the important link of clinical research, the investment that our country makes in basic research does not have the impact on the quality of health care that it could have. We have heard concerns from the research community that clinical research based on our basic research discoveries is going on overseas because it does not have financial support in the United States. It would be ironic if our expanding commitment to medical research, as evidenced in by NIH's growing budget, should create jobs overseas because we fail to address the need to fund clinical research, the link between basic research and a vital biomedical industry on our soil.

This legislation also will encourage more of our young researchers and physicians to pursue careers in clinical research. The data