Statement of the AAMC on S. 2222 The National Research Institutes Reauthorization Act of 1988
Submitted to the Senate Committee on Labor and Human Resources

April 12, 1988

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STATEMENT OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES on S. 2222

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The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on S. 2222, the National Research Institutes Reauthorization Act of 1989. The AAMC represents all 127 accredited U.S. medical schools and their students, 435 teaching hospitals, and 87 scientific and professional societies, whose members participate in the biomedical research supported by the National Institutes of Health (NIH). In fact, over half of the extramural research funded by the NIH is conducted in the institutions represented by the AAMC.

We commend the Committee for its thoughtful revisions of Title IV of the Public Health Service Act, including the necessary renewal of the expiring authorities under the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the medical library assistance program of the National Library of Medicine (NLM), and the National Research Service Award (NRSA) program. In this era of important new research opportunities, it is essential that these programs be provided with adequate authorization levels to allow for the necessary growth to take full advantage of these opportunities.

Of particular importance to the Association is the NRSA program, which provides valuable research training support for the next generation of biomedical and behavioral scientists. Based on separate analyses by the NIH and the AAMC Division of Biomedical Research, we endorse the $350 million authorization level contained in S. 2222 for the NRSA program for FY 1989. We understand that this level of funding will provide support for approximately 13,465 trainees, as recommended by the National Academy of
Science Institute of Medicine Personnel Needs Study

In addition, funds would be available to provide payment of full tuition for predoctoral trainees and to increase the stipends to $8,500 a year for predoctoral and to an average of $21,500 a year for postdoctoral trainees, as recommended by NIH. It is important that sufficient funding be available to increase stipend levels without reducing the number of trainees.

Research Facilities Construction

The AAMC, having endorsed the recommendations made earlier to this committee by Chase X. Peterson, M.D., President of the University of Utah on behalf of the AAMC and NAS/NC supported biomedical and behavioral research facilities construction authority in Title I of S.222. The research infrastructure in our universities and medical schools is in critically poor condition. Aging and obsolete research buildings and over funded instrumentation are beginning to jeopardize our ability to conduct preeminent biomedical research and to maintain our international superiority in biomedical science. Title I of S. 222 recognizes the critical need for revitalization of our research facilities and reaffirms the appropriateness of the federal role in maintaining and expanding the academic research infrastructure.

The federal government, through the NIH, has been an unparalleled source of support for the biomedical research conducted in the nation's medical schools and teaching hospitals. Academic medicine's partnership with the Federal government in this area has led to dramatic advances in the improvement of health and the conquering of disease and premature
death. While the federal support for biomedical research grants continues, the government’s commitment to maintaining the facilities component of the research infrastructure has been virtually non-existent for the past 26 years. Given that so much of the research being conducted in our institutions is sponsored by NIH, it is reasonable to expect that NIH should also contribute to the cost of the space needed to house the research.

The AAMC has developed a model to estimate the financial need to keep current academic research facilities “in shape.” The details of this analysis were presented to a group of outside experts convened by NIH at Congress’ request to explore the research facilities deficit. It was also appended to Dr. Peterson’s testimony to this Committee. In our estimation, an annual investment of $301 million is needed simply to maintain the existing inventory of research facilities. Research space in most institutions is used so intensively, and is at such a premium, that it is not really adequate for existing programs. If we hope to expand biomedical research endeavors in order to make advancements against emerging health crises and intractable health problems, new and modernized facilities will be essential.

The facilities in our institutions have not been able to keep pace with the expansion in biomedical research primarily because funding mechanisms for construction costs are inadequate. Tax-exempt borrowing and charitable contributions, previous sources for private universities, were seriously constrained by the 1986 Tax Reform Act. Moreover, the mechanism
of indirect cost reimbursement does not necessarily result in a full recovery of costs.

The construction authority in S. 2222 will begin to address the critical need to remodel, replace, and enhance the current biomedical research infrastructure. It will enable NIH to reembrace, on a systematic, coordinated approach to meeting facilities' needs around the country. Several essential components of a facilities program are contained in S. 2222, including matching formula, a merit review requirement, and criteria for determining grant awards.

By acknowledging the appropriateness of the federal role in biomedical research facilities construction, S. 2222 will begin to correct a long-neglected area of federal responsibility. A renewed federal partnership in maintaining the total research infrastructure will help ensure the preeminence America's biomedical research enterprise in the years to come.

Research Centers

Given the existence of the new general construction authority in Title I, the AAMC questions the need for a separate authority in Title VI of the bill for the National Center for Nursing Research. We are concerned that a separate construction program will duplicate, and draw funds away from, the general construction authority. The facilities needs of nursing research programs should compete on an equal footing with the facilities needs identified in other areas of biomedical and behavioral research.
The AAMC supports Title III and IV of S 2222 to develop or expand centers for the study of deafness and other communicative disorders within the National Institute of Neurological and Communicative Disorders and Stroke and centers for geriatric research and training within the National Institute on Aging. Support of such centers recognizes the need for an increased research capacity in these areas, including the need to train additional scientists to develop and pursue promising research leads. With respect to the geriatric centers, the AAMC believes that the "educational and training activities for students of the health professions" specified in Title IV will not duplicate, but rather will enhance, the existing health professions education programs for geriatrics under section 788(e) of the Public Health Service Act.

Fetal Research

Regarding Title II, the AAMC supports the several steps the legislation takes to reactivate national discussion and consideration of ethical matters relating to fetal research. At the same time, we are opposed to the two-year extension of the statutory moratorium on the ability to exercise the waiver of the regulations governing Federally funded fetal research.

The federal regulations pertaining to the conduct of fetal research were established in 1975, and were based on recommendations made by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The regulations ensure that pregnant mothers and
babies will be able to benefit from biomedical science's ability to understand human development and combat the diseases which can deprive fetuses of the chance for life and health. With equal force, they ensure that fetal research conducted with federal funding adheres to a strict moral code and ethical standard of respect for human life. The regulations uphold the dignity and moral status of individual persons and fetuses while enabling society to fulfill its natural and profound urge to save and enhance life.

Two essential components of the federal regulations, the Ethical Advisory Board (EAB) and the HHS Secretary's authority to waive the regulations in extraordinary circumstances, have been suspended since 1986. Activated for the first time in 1975, the initial EAB existed for only two years. In that time, it approved one waiver of the regulations. Since the charter of the first EAB expired in 1986, the Board has never been reactivated. In 1985, Congress placed a three-year moratorium on the use of the waiver and mandated a study of the ethical implications of the waiver authority.

These de facto and de jure restrictions have caused the fetal research regulations to lose the careful moral balance they were designed to maintain between the pursuit of fetal and maternal life-saving advancements and the safeguarding of human research subjects. The result has been a diminution of federal support for fetal research and widespread confusion about federal laws and rules governing it.
It is incumbent upon the Congress to restore the federal commitment to
fetal research and the advancements in fetal and maternal health it makes
possible. Restoring the commitment requires the reactivation of the
Ethical Advisory Board coupled with the lifting of the moratorium on the
waiver authority. Because S 2222 establishes an EAB without lifting the
moratorium, it will fail to restore the commitment.

When Congress enacted the three-year long prohibition of the waiver
authority in 1985, it did so with the intention of appointing the
Biomedical Ethics Board and Advisory Committee to study the "nature
advisability, and biomedical and ethical implications of exercising any
waiver" of the federal regulation that holds non-therapeutic fetal research
to the minimal risk standard established for human research subjects. The
Biomedical Ethics Advisory Committee has not been appointed and, perforce,
the ethical issues and concerns that led to the moratorium have not been
explored.

In our view, the ethical issues and concerns that have cast such doubt
on the waiver authority are misplaced. The waiver is, in effect, a safety
valve which enables federal research to be responsive and adaptive to
extraordinary developments in medicine and human biology. A researcher's
ability to seek a waiver means that consideration can be given to a project
which may be of indeterminate risk but hold overwhelming promise of
improving health and the chances for life.

A project cannot receive a waiver without undergoing a painstakingly
careful ethical and scientific examination. The examination entails six levels of review and approval beginning with a local institutional Review Board. Federal level review is conducted by the relevant NIH Study Section and National Advisory Council and the appropriate Institute staff and Director. If the research proposal is cleared at these levels, it advances to the Ethical Advisory Board. The EAB uses strict review criteria in assessing the risks and benefits of the research proposal and ensuring that no other means exist by which the benefits could be obtained. The EAB deliberates in public and may solicit public comment and consideration of the proposal. If the EAB approves the research proposal, the final decision to approve or disapprove the project rests with the HHS Secretary.

In making a determination about waiving specific requirements of the regulations, the Secretary must be certain that the risks to the subject are far outweighed by the sum of the benefits to the subject, that the importance of the knowledge to be gained warrants the use of the waiver, and that the benefits can only be gained through the waiver. The approval of the waiver must be published as a public notice in the Federal Register. Clearly, the waiver authority is a complex mechanism which is employed only after rigorous review and public deliberation. It enables reasoned ethical consideration to be given to research proposals which may not be able to meet all the requirements of the regulations but which hold the promise of such significant benefit to fetal and maternal health that ignoring the potential would leave society morally bereft.

The AAMC believes the positive steps S. 2222 takes in helping to advance public understanding of the ethical issues involved in federally-
funded fetal research alone cannot restore the much-needed federal
commitment to research in fetal and maternal health. Mandating the
establishment of the Ethical Advisory Board and supporting a new effort to
examine issues in federal fetal research cannot make up for the fact that
the extension of the moratorium on the use of the waiver authority will
set back for another two years any possibility of significant federal
involvement in the effort to advance important new life-saving and life-
enhancing procedures and therapies for fetuses and pregnant women.

Rehabilitation Research Center

A second area of concern to the AAMC is the proposal for a National
Center for Medical Rehabilitation Research in Title V. While the AAMC
enthusiastically supports the coordination of federal efforts in the area
of medical rehabilitation research, we do not agree that the proposed
structure is the best method of accomplishing this goal. This proposal
appears to go far beyond a coordinative function. Indeed, the stated
purpose of this Center in Title V is "the conduct and support of
biomedical and related research and research training...." It is unclear
from the proposal what type of research would be supported, and how such
research would relate to existing rehabilitation research programs within
the other national research institutes or other federal agencies, including
the Veterans Administration and the Department of Education's National
Institute of Disability and Rehabilitation Research. In addition, the
current fiscal climate raises serious questions as to how this Center would
be funded if it undertakes to support such research.
If the goal is to coordinate existing federal research efforts in the area of medical rehabilitation, the AAMC recommends that the coordinating committee consisting of representatives from the appropriate research institutes and other federal agencies be established, as proposed in section 486F of the bill. This committee could be charged with responsibility for developing the national research plan to coordinate existing research and develop future priorities.

The AAMC appreciates this opportunity to comment on this legislation and would be pleased to work with the Committee staff to provide additional information on the positions contained in this statement.