

NOV 16 REC'D

THE WHITE HOUSE
WASHINGTON

November 15, 1993

file

MEMORANDUM FOR CAROL H. RASCO

FROM: Stanley S. Herr *SH*

SUBJECT: NICHD Funding

On Friday, November 12th, Peter Edelman and I met with representatives of the American Association of University Affiliated Programs for Disabilities (AAUAP) concerning their goal of boosting funding for the National Institute of Child Health and Human Development (NICHD).

For your information, I enclose a set of their materials since they may seek our involvement. Recalling your approach to the Arc representatives, I suggested that they might wish to contact the OMB Program Associate Director with jurisdiction over that area. Peter, who had identified a number of HHS officials for them to contact, seconded that idea and identified Nancy Min as the relevant actor.

Although the third page of their submission seems to suggest that NICHD's fortunes have soared, they are in a 14-way tie for third among NIH Institutes.

In essence, they argue that they are near breakthroughs on curing certain disabling conditions and make some strong appeals for additional resources. I am willing to remain a liaison on this issue.

Enclosures.



NICHD FUNDING OF RESEARCH FOR CHILDREN AND FAMILIES: A HISTORY OF INADEQUATE FUNDING AND MISSED OPPORTUNITIES

Carl F. Calkins, Ph.D.
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President-Elect

Gary W. Goldstein, M.D.
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William E. Jones, Ph.D.
Executive Director

The National Institute of Child Health and Human Development (NICHD) has primary responsibility for biomedical and behavioral research on maternal and child health, population issues, and rehabilitation. Since its establishment by the Kennedy Administration, the NICHD has directed its limited resources to the development of new knowledge that will assure that children are born healthy and wanted, and able to function throughout life, free from disease or disability, and with the ability to achieve their full potential.

Prominent among Health and Human Services priorities of the Clinton Administration, as described in its FY 1994 Budget, are expanded investments in research and services designed to improve the health and well-being of children and their families. Specifically, these include:

- * Pediatric and Maternal HIV/AIDS Research - A high priority is placed "...on addressing this infection which is increasing among women, children adolescents, (and) minorities...Specific areas of emphasis include... study of HIV-infected pregnant women to learn more about maternal-fetal transmission."
- * Maternal and Reproductive Health - The Administration has expressed its commitment to a broad range of research on women's health, including reproductive health, and the birth of healthy babies.
- * Prevention of Childhood Diseases and Disabilities - The Administration has expressed its commitment to a comprehensive strategy to prevent diseases and disabilities. In addition to programs aimed at significant improvement in the use of childhood vaccines, and the development of new vaccines; other strategies to prevent the incidence of severe disabilities, such as gene therapy, are also being developed.
- * Minority Health Research, particularly for Infants and Children - Emphasis has been placed on the Minority Health Initiative and related efforts which address issues related to infant mortality and the healthy behavior of young people.

Much of the research of the NICHD has been focused in these high priority areas. In pursuit of these priorities, the NICHD, in just the last five years, has launched a number of major initiatives, including the following:

- * The addition of two Mental Retardation Research Centers (MRRCs) to the 12 MRRCs that the Institute had supported for over 20 years. The MRRC program has led in the development of new knowledge to prevent the incidence of many forms of mental retardation, and to ameliorate the effects these conditions have on individuals and their families.
- * The launching of new Contraception and Infertility Research Centers. The three new Contraception Research Centers are focused on the development of new, safe, effective, and acceptable contraceptive drugs and devices, including contraceptive vaccines. The two Infertility Research Centers are seeking the means to overcome infertility and the many problems with which it is associated.
- * The establishment of Learning Disabilities Research Centers. These Centers increase our understanding of how to prevent or treat the social and educational effects of learning disabilities that affect such a large number of children in the United States.
- * The initiation of a large new program of research on pediatric, adolescent, and maternal HIV/AIDS. This effort has provided the majority of financial support for research and related clinical services focused on the prevention and treatment of HIV/AIDS among children, adolescents, and women.
- * The creation of new Child Health Research Centers. These Centers provide research training for pediatricians, and speed the transfer of research findings from "the bench to the bed." In the short history of this program, NICHD has established 19 of these Centers, which have begun to strengthen and expand the foundation of pediatric medicine.
- * The establishment of a Neonatal Intensive Care Units Network and a Maternal-Fetal Medicine Units Network, in order to speed the conduct of clinical trials designed to improve the well-being of pregnant women, their developing fetuses, and newborn infants. These Networks are a major thrust in the Institute's highest priority effort to reduce the incidence of infant mortality and morbidity.
- * The launching of the Minority Youth Health Behavior Research Initiative. The NICHD is the lead Institute for this NIH-wide effort, which is being developed in close cooperation with the NIH Office of Research on Minority Health. The Initiative supports the development of community-based health behavior intervention programs to lower the unacceptably high rate of morbidity and mortality among minority youth.

Almost all of the above initiatives have been endorsed or directed by congressional authorizing and appropriations committees. Yet, despite its strong statutory mandate to address important issues pertaining to the health and well-being of women, children and families, NICHD has been consistently undersupported for funding, relative to other NIH institutes, of research project grants.

- * Over the past decade, the Institute's success rate for funding grants has ranked among the lowest of the NIH institutes and centers:

<u>FY</u>	<u>NICHD Rank Among NIH Institutes and Centers</u>
1983	11th out of 14
1984	12th out of 14
1985	14th out of 14
1986	15th out of 16
1987	tied for 10th out of 16
1988	16th out of 17
1989	15th out of 18
1990	18th out of 19
1991	17th out of 19
1992	16th out of 19
1993	16th out of 19
1994	tied for 3rd out of 19

With resources less than adequate for the task, the Institute has made extraordinary efforts to launch many new initiatives while seeking to maintain its current broad research portfolio. Its success in meeting these competing objectives has been accomplished at the expense of appropriate support for both existing and new programs. The lack of adequate resources has required the Institute to steadily increase reductions from full-cost funding for research project grants, and virtually all programs funded by NICHD in order to spread scarce resources further. This has been particularly evident over the past three years.

- * As recently as 1985, there were only limited reductions of most research project grants and center grants approved for funding by NICHD.
- * Between 1986 and 1990, both competing and non-competing NICHD research project and center grants were subjected to reductions ranging from 8.3 percent to 17.1 percent.
- * By 1992, reductions for NICHD research project and center grants that were either new or competing renewals had grown to an average of 20 percent. That year, the Congress urged that continuing research and center grants no longer be subjected to reductions from full funding.

- * In 1993, NICHD reductions from full funding dramatically increased, averaging over 25 percent for competing research grants and a staggering 38.5 percent for competing center grants.
- * Although reductions from funding have been required throughout NIH, they have hit NICHD-funded programs disproportionately. For example, in FY 1991, the 25 percent average reduction for new and competing research grants funded by NICHD was the largest for any institute or center; the mean reduction across the rest of NIH was 11.7 percent.

Inadequate funding has led to reductions in the level of effort applied toward overcoming the wide range of biomedical and behavioral research challenges facing NICHD. As a result, several areas of research that hold dramatic promise for preventing childhood diseases have insufficient support. Such unfulfilled opportunities, and the potential fiscal impact to our society include:

- * Significant new research in the Nation's Mental Retardation Research Centers involving gene therapy has placed the Institute on the threshold of potential cures for diseases previously thought to be incurable. Research on gene therapy for Duchenne Muscular Dystrophy, for example, suggests that the muscle deterioration responsible for the disability and premature death (in their early 20's) of young males can be halted with genetic intervention. At the present time, in the United States, there are 13,200 children with Duchenne Muscular Dystrophy with 600 new cases each year. The effective intervention of Duchenne Muscular Dystrophy has the potential of saving health care systems in the United States more than \$60 million per annum. Adequate support for the research could lead to the successful intervention in the next decade.
- * Promising research on Cytomegalovirus (CMV). This common virus can cause mental retardation, cerebral palsy, hearing loss, and impaired motor development. It is the most common cause of acquired mental retardation in the United States, affecting over 5,000 infants each year. Tests to confirm current and previous CMV infection are now readily available. While neither a vaccine nor a cure for this infection currently exists, adequate research support would lead to these significant achievements in the next few years.
- * Each year, approximately 250 children are born with Prader-Willi Syndrome (PWS), a disease that causes mental retardation and a life-threatening eating disorder. People with PWS often require costly therapeutic residential treatment, with lifetime expenditures for people with this genetic disorder conservatively estimated at \$12.5 billion. Recent research has revealed the underlying genetic anomalies and resulting metabolic and brain chemical abnormalities responsible for

PWS. Research over the next five years may lead to an understanding of, and ability to treat or prevent, problems associated with this disorder. This information will be invaluable in providing clues to similar genetic mechanisms involved in other forms of mental retardation associated with behavior disorders, and may provide insights into one of the most common health problems in the general population: obesity secondary to appetite problems.

- * A promising new, joint initiative with the National Institute on Aging to investigate the possible correlations between the genetic basis for Down syndrome and the effects of the normal aging process is being delayed by a lack of resources.
- * The new Contraception and Infertility Research programs, mandated by the Congress, are required to operate with funding cuts averaging over 25 percent below approved funding levels. Cuts of this magnitude result in substantial delays in the development of badly needed new contraception and infertility options for the American people.

Research funded by NICHD has contributed substantially to the knowledge base regarding physical and behavioral aspects of maternal and child health, human reproduction, and the prevention and amelioration of mental and physical disabilities. This research base is required to fully inform public policy makers on issues ranging from health care priorities to best practices in the support of children. All too frequently, programs are implemented based on the well-intentioned beliefs that they will improve conditions, rather than on solid knowledge supported by research.

The failure to receive adequate resources for more than a decade has left the NICHD with a wealth of research opportunities that cannot be pursued. Often, the knowledge and skill to appropriately respond to critical issues facing women, children and families are found in approved, but unfunded research grants. This truly is an area in which expenditures now are cheaper than the price to be paid if the research investment remains insufficient. Significant increases in funding for the NICHD are necessary to improve the health and well-being of children and families, and thus to meet a central goal of the Clinton Administration.

For additional information, please contact the following:

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MENTAL RETARDATION RESEARCH CENTERS OF THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Carl F. Calkins, Ph.D.
President

Bruce Buehler, M.D.
President-Elect

Gary W. Goldstein, M.D.
Past President

Deborah Spitalnik, Ph.D.
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Member at Large

William E. Jones, Ph.D.
Executive Director

In 1962, it became clear that knowledge was required from many branches of science to understand the causes of mental retardation and other developmental disabilities and to begin the search for better means of diagnosis and treatment. A call for a concerted research effort came when a presidentially-appointed panel concluded that "we as a nation have for too long postponed an intensive search for solutions to the problems of the mentally retarded."

These recommendations were enacted into law with legislation that created Mental Retardation Research Centers (MRRC) at the National Institute of Child Health and Human Development (NICHD). Today, there are 14 centers that receive support grants from NICHD. Their mission is to pursue research that will lead to the full understanding of the causes of mental retardation and other developmental disabilities, the needs of people with mental retardation and other developmental disabilities, and ways to reduce the incidence of these disabilities.

Over the past 30 years this research effort, led by the MRRCs, has compiled an impressive record of scientific achievement that has helped improve the lives of many children and has become the foundation upon which we base so many of our country's successful prevention initiatives:

--Early intervention has been found to prevent intellectual decline in children at-risk for mild mental retardation because of disadvantaged circumstances. Over the past 20 years, researchers at the North Carolina MRRC have shown that children born to low-income families or those with a low birth weight have a much greater chance of growing up with average intelligence if they are enrolled in early intervention programs. The research has found that when low-income and low-birth weight children are enrolled in infant stimulation and special instructional programs until age 8, years later they score significantly higher on IQ and reading achievement tests than did children from similar backgrounds who did not have the benefit of such programs. Moreover, in the early 1960's, the Early Training Project at the John F. Kennedy Center at Vanderbilt University provided the intellectual stimulus for Head Start.

--Lead has been identified as a major cause of mental retardation even at levels previously considered safe. Beginning in the mid 1970's, researchers at the MRRC at Children's Hospital in Boston and at the Kennedy-Krieger Institute at Johns Hopkins University have been conducting a long-term study on the adverse effects of lead exposure on children. Their alarming finding: lead can harm children's brains at levels much lower than those previously considered safe, and the damage caused is essentially irreversible. These studies helped galvanize a national effort to reduce environmental exposure to lead, which has resulted in the lowering of children's blood lead levels across the nation.

--The dangers of maternal alcohol consumption, especially early in pregnancy, have been established. Clinicians have known since the 1970s that alcohol can cause birth defects and mental retardation. But researchers at the MRRC at the University of Washington have found that relatively low levels of consumption early in pregnancy can produce fetal brain damage, even if the mother abstains from alcohol later in pregnancy. These studies have alerted health care professionals to the importance of advising women to avoid alcohol consumption before they become pregnant.

--Successful treatments have been developed to reduce self-injurious behavior in some individuals with mental retardation. Many people with mental retardation are forced into restrictive living settings, not because of their mental retardation, but because of their tendency to harm themselves. Investigators at the University of Pennsylvania MRRC have successfully used applied behavioral analysis to demonstrate that this behavior can represent a form of communication. In addition, researchers at the John F. Kennedy Center at Vanderbilt University, at the University of Minnesota, and at the University of Kansas have found changes in brain chemistry that cause self-injurious behavior as well as medications that correct them. Combined with positive behavior management techniques, many of these individuals will experience a marked reduction in their self-injurious behavior.

While these examples are encouraging, it is sobering to realize that these advances might not have been possible without the cross-fertilization of ideas and collaboration among investigators prompted by a concerted national research effort. What's more, the talented young investigators who have been responsible for some of the most impressive research advances might never have devoted their energies to the problems of those with mental retardation had they not been actively recruited and supported by the MRRCs.

Even more sobering, however, is the realization that many new opportunities to help children with mental retardation and other developmental disabilities may remain unexplored or lost forever due to insufficient support of the NICHD and drastic cuts in MRRC core grants -- up to 25 percent per year over the last five years alone. And this comes at a time when the absolute number of individuals with mental retardation is increasing. Every year 125,000 children join the 7.5 million Americans with mental retardation. Moreover, new causes of mental retardation, such as neonatal HIV-infection are emerging as serious threats to public health.

While African American children constitute 15 percent of all American children, they account for 60 percent of cases of pediatric HIV. Similarly, Hispanic children represent ten percent of the population of children, and account for over 20 percent of pediatric HIV.

cases. Well over 90 percent of children with HIV infection will acquire mental retardation or other developmental disabilities. Researchers at the Rose F. Kennedy Center at the Albert Einstein College of Medicine report that in high incidence areas, such as the South Bronx, almost four percent of all newborns now test positive for HIV.

But while we as a society face ever-growing challenges in providing the necessary services and supports for individuals with mental retardation, we also stand to profit from recent technological advances that could prevent the incidence of many new cases of mental retardation. For example:

--More accurate methods of diagnosis and screening are being developed earlier for many inheritable developmental disorders, along with treatments that can minimize or prevent harm to essential organs. The most celebrated screening program is the one for PKU, a metabolic disorder that caused mental retardation. Over the past three decades, this screening program has identified thousands of newborns who, when treated with a special diet, have grown up with average intelligence. Now, researchers at the Baylor MRRRC are using recently developed molecular genetic techniques to expand the number of diseases that can be detected in newborns. One such screening test has been developed for MCAD deficiency which can cause profound intellectual and neurological disabilities or sudden infant death syndrome unless a simple, inexpensive and effective dietary treatment is begun early in life. At the University of Colorado MRRRC, researchers are working to improve vitamin and dietary treatments for glutaric acidemia type I, which has many of the same symptoms of cerebral palsy and causes death in the first or second decade of life.

--A potential cure for many inheritable disorders has been developed. In what was hailed by the Harvard Medical Letter as one of the world's top ten medical advances of 1992, researchers at the Waisman MRRRC at the University of Wisconsin-Madison found that they could correct a genetic defect by injecting "healthy" genes into muscle with an ordinary syringe and needle. This gene therapy technique has been likened to immunization in that it is relatively easy to perform and likely to be comparably cost-effective. This technique could potentially lead to cures for many inheritable disorders, including those that cause mental retardation and muscular dystrophy. Moreover, at the University of Pennsylvania MRRRC, investigators are starting trials of gene therapy in liver tissue for a number of genetic disorders that cause developmental disabilities.

--A surgical treatment has been developed for severe cases of pediatric epilepsy. Brain surgery pioneered by researchers at the MRRRC at UCLA has enabled more than 70 percent of treated children with severe epilepsy to become seizure free and enjoy marked cognitive improvement. Without the new operation, these children would have had frequent and severe seizures.

--New techniques for teaching children with mental retardation have been developed. Researchers at the Shriver Center in Massachusetts have developed new computer technology to teach certain reading fundamentals to children who do not learn well with other methods. These methods teach children to relate letters of the alphabet with pictures and words that have the same beginning sound.

In 1966, research on mental retardation received 7.7 percent of total federal dollars allocated to services and support of people with mental retardation. Last year, research received only 0.5 percent of federal allocations. Such a decline in support seems a false economy, given that research provides us with the best hope of preventing the incidence of mental retardation and other developmental disabilities and providing appropriate services and supports to individuals with mental retardation and their families.

Research can also be cost-effective. Approximately 125,000 children with mental retardation are born annually. It can cost more than \$75,000 annually to provide appropriate services and supports to a child with severe mental retardation. This cost is most often borne by Medicaid or state funding. Furthermore, some 635,000 children with disabilities were eligible for \$343 million in Supplemental Security Income benefits from the Social Security Administration last year. Many of these children have mental retardation or other developmental disabilities.

While NICHD has one of the broadest research mandate of any NIH institute, it has grown less than almost all other institutes at the NIH in recent years. For Fiscal Year 1994, the NICHD Professional Judgement Budget recommends \$684.99 million for the Institute. Congress appropriated \$555.19 million.

Despite major achievements by NICHD-supported scientists many areas of important research will continue to be hampered significantly by the declining ability of the Institute to fund promising research projects. Moreover, reductions have kept centers from acquiring necessary equipment and technology, from hiring the next generation of scientists, and from pursuing new science for fear that it will be too costly. The efforts of the Mental Retardation Research Centers have contributed to effective treatment and prevention of many forms of mental retardation. The centers have been instrumental in bringing about the modern beliefs that people with disabilities can be educated, productive, contributing members of mainstream society. They also have been cost-effective by finding cures and prevention strategies to eliminate certain causes of disabilities and thus saving the country tens of millions in related health and education costs. However, without additional resources, the battle to prevent the incidence of childhood disabilities and diseases through greater understanding of human development could be lost.



Carl F. Calkins, Ph.D.
President

MENTAL RETARDATION RETARDATION CENTERS
FUNDING FY 1989 TO 1994

Bruce Buehler, M.D.
President-Elect

Gary W. Goldstein, M.D. Past President	FY 1989	\$10.6 million	13 centers
	FY 1990	11.3 million	14 centers
	FY 1991	"	"
Deborah Spitalnik, Ph.D. Past President	FY 1992	"	"
	FY 1993	10.9 million	"
Fred Orelove, Ph.D. Secretary	FY 1994	n/a	14 centers

Valerie N. Williams, M.P.A.
Treasurer

RATES OF NEGOTIATED REDUCTIONS
FY 1989 TO 1994

Rita Hohlstein, M.S., O.T.R.
Member at Large

Clydie K. Mitchell, M.Ed. Member at Large	FY 1989	13.6 percent
	FY 1990	17.1 percent
	FY 1991	21.5 percent
Cordelia Robinson, Ph.D. Member at Large	FY 1992	21.5 percent
	FY 1993	25.4 percent
I. Leslie Rubin, M.D. Member at Large	FY 1994	n/a

Clifford J. Sells, M.D., M.P.H.
Member at Large

NICHD FUNDING FY 1989 TO 1994

Travis Thompson, Ph.D.
Member at Large

Sheryl White-Scott, M.D.
Member at Large

William E. Jones, Ph.D.
Executive Director

	FY 1989	\$425.64 million
	FY 1990	441.95 million
	FY 1991	478.96 million
	FY 1992	524.45 million
	FY 1993	527.77 million
	FY 1994	555.19 million

NICHD RANK AMONG NIH INSTITUTES AND CENTERS
FY 1989 TO 1994

	FY 1989	15th out of 18
	FY 1990	18th out of 19
	FY 1991	17th out of 19
	FY 1992	16th out of 19
	FY 1993	16th out of 19
	FY 1994	Tied for 3rd out of 19

Mental Retardation Research Centers

Mental Retardation Research Center
University of California
Los Angeles, CA
310/825-5542
Director: Nathaniel Buchwald, Ph.D.

B. F. Stolinsky Research Laboratories
University of Colorado Health Sciences Center
Denver, CO
303/270-7301
Director: Stephen I. Goodman, M.D.

Kansas Mental Retardation Research Center
University of Kansas
Lawrence, KS
913/864-4295
Director: Stephen R. Schroeder, Ph.D.

Ralph L. Smith Mental Retardation
Research Center
University of Kansas Medical Center
Kansas City, KS
913/588-5970
Director: Paul D. Cheney, Ph.D.

Parsons Research Center
Institute for Life Span Studies
Parsons, KS
316/421-6550
Director: Joseph E. Spradlin, Ph.D.

Center for Research on Mental Retardation and Related
Aspects of Human Development
Kennedy Krieger Institute
Baltimore, MD
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Director: Hugo W. Moser, M.D.

Mental Retardation and Developmental Disabilities
Research Center
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Shriver Mental Retardation Research Center
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Director: Mark L. Batshaw, M.D.

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615/322-8242
Director: Travis Thompson, Ph.D.

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Houston, TX
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Director: Edward R.B. McCabe, Ph.D.

Child Development and Mental Retardation Center
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Director: Michael J. Guralnick, Ph.D.

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Director: Terrence R. Dolan, Ph.D.