Minnesota Department of Health

Report on a Process for Distributing Research Funds

Report to the Minnesota Legislature

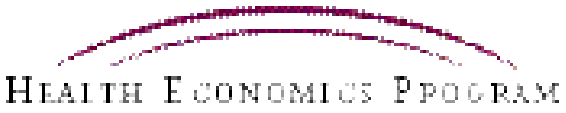
January, 2000

Health Policy and Systems Compliance Division
Health Economics Program
PO Box 64975
St. Paul, Minnesota 55164-0975
(651) 282-6367
www.health.state.mn.us

Report on a Process for Distributing Research Funds

Report to the Minnesota Legislature

January, 2000



Health Policy and Systems Compliance Division
Health Economics Program
PO Box 64975
St. Paul, Minnesota 55164-0975
(651) 282-6367
www.health.state.mn.us

Printed with a minimum of 10% post-consumer materials. Please recycle.

EXECUTIVE SUMMARY

> "make recommendations for a process for the submission, review, and approval of research grant applications. The process shall give priority for grants to applications that are intended to gather preliminary data for submission for a subsequent proposal for funding from a federal agency or foundation, which awards research money on a competitive, peer-reviewed basis." (62J.693, Sec. 11, Subd. 2)

Based upon this directive from the 1999 legislature, and amidst general discussions about the most appropriate use of Tobacco Settlement Endowment funding, the Minnesota Department of Health with the assistance of the Medical Education and Research Costs (MERC) Advisory Committee sought to identify the objectives of a medical research grant program, and define an appropriate, efficient and fair process for awarding grants to qualified medical researchers for a medical research grant program within the State of Minnesota.

The development and execution of medical research, and the infrastructure for funding that research is highly complex. Overall, the purpose of a medical research grant program is to connect bright, intelligent researchers, who possess insight, ideas, scientific and methodological skill, with the broader consensus of the state and nation regarding which areas of medical research have the most significant impact on individual well-being and the broader social good, and apply the resources of the researchers to solving the most challenging problems (diseases, chronic conditions, therapy applications) of medical research.

Given these broader goals, the challenge of medical research, and the desire to make the best use of the qualities of the many fine individual researchers in the state, and the research institutions which support them (for which the State of Minnesota is well renowned and regarded), the question should be raised: What is the best and most appropriate role of state government, and what is the best application of state resources to address the challenges of medical research at the state level? Some have suggested that the most valuable way of utilizing limited state resources toward the funding of research would be to use state funds as seed money to give researchers in Minnesota a competitive advantage relative to researchers in other states. This approach would appear particularly appropriate and fruitful given the increasing levels of federal research funds becoming available through the National Institutes of Health and other federal sources. This strategy would allow for smaller seed grants which could support preliminary data collection in the development of a grant proposal to leverage more substantial federal funding. Not only would the state bring in federal funds for research, but the state may reap economic benefits in the future as developments made possible by the funding of research are both translated into clinical practice and used in the development of medical device advances and other manufacturing areas.

The challenge of approaching research funding from this perspective is identifying the types of research that would most likely bring in federal funds and lead to future economic development. It is widely held that "Clinical Research"; involving the studies of human disease and how body systems are affected by the disease process, or "Applied Research"; studying diagnostic and therapeutic modalities involving human and animals in clinical and laboratory trials, may be more likely to leverage funding from federal research agencies, or other private and foundation sources. It is certainly true that some specific types of research have traditionally found favor as candidates for specific types of medical research funding. Applied and Clinical Research fall into this category relative to the traditional funding sources such as the National Institutes of Health, or private foundations. Nonetheless, there is no guarantee that one or two particular types of research, or a particular research

approach will continue to find favor amongst federal and foundation funding sources, particularly in a dynamic health care and medical research environment. Furthermore, the variety of sources of funding reflect as great a variety of types of research and preferred research approaches.

Because of the challenges of identifying the types of medical research and research approaches that are likely to find favor in competition for funding from federal and other foundation sources, the Department of Health makes three specific recommendations regarding establishing a medical research grant application and award process.

1) Broaden the definition of "health care research" that would be considered as acceptable for award through a state sponsored medical research grant program. While current statute indicates that "health care research" means "approved clinical, outcomes, and health services investigations," the Department feels that this definition does not provide enough flexibility to fit with the objective of using research grants as seed money, and therefore recommends that the definition of "health care research" be removed, or revised to include those types of research likely to leverage NIH funds, or funds from major outside funding sources.

2) Include as criteria for award of research grant proposals, additional weight for those proposals that support objectives of the State of Minnesota's ***Public Health Improvement Goals***, including: reducing behavioral risks that contribute to morbidity and mortality; improving birth outcomes and early childhood development; promoting and improving mental health; improving the outcomes of medical emergencies; reducing infectious disease; promoting the well-being of the elderly, and those with disability, disease or chronic illness; and promoting early detection and improved management of non-infectious disease and chronic conditions.

3) Proceed with further evaluation of and make recommendations to establish a legislatively chartered Strategic Medical Research Planning committee. This committee, appointed by the Commissioner of Health would develop a 3 to 5 year Medical Research Strategic Plan, which would include the objectives and priorities of a state medical research agenda based, in part, upon the Minnesota ***Public Health Improvement Goals***.

Additionally, the Strategic Plan would include a compendium or outline of research topics and approaches, thought to be most effective in leading to additional successful research, the leveraging of additional funding from Federal and foundation sources, and providing the greatest potential for future economic development within the state of Minnesota. Additional analysis and research needs to be performed to determine the most appropriate structure of the committee, its focus, and to identify the mechanisms by which a Medical Research Strategic Plan would be developed, approved and communicated.

4) In addition, this report includes, as appendices, the MERC Research Subcommittee recommendations to the Commissioner for a process for the submission, review, and approval of research grants, as well as, an illustration of the likely administrative process to implement the proposed submission, review and approval criteria.

During the development of this report, including the work of the Department of Health and the MERC Advisory Committee Research Subcommittee, certain issues became apparent as being of concern within the research community of the state of Minnesota. First, the experience of researchers and research program administrators

suggests that the financial commitment necessary to establish successful research seed grant programs is relatively great. Substantial financing and time per researcher are required for successful research programs and a minimum of three years is necessary to develop a "line of inquiry". Consequently, the MERC Research Subcommittee believes that any grant award process that was developed reflect the need for a commitment of funding for multiple years and a minimum of three years.

Additionally, the consensus of the Research Subcommittee in identifying criteria for a research grant program, suggests the following: 1) It is important that funded research have an impact on the health of Minnesotans, regardless of the type of research that was funded; and 2) the research grant application criteria should give weight to research proposals that focus on preliminary data collection that would make Minnesota researchers competitive for national funding; that demonstrate a potential for collaboration amongst various research organizations, and that demonstrate a potential for technology transfer or economic development.

Next Steps

The Department believes that certain areas deserve further consideration in identifying a process for the award and distribution of medical research grant funding. First and foremost among these is to develop the model through which a process will be managed and awards will be made. This requires that we evaluate and make a determination as to the structure and mechanism of a Strategic Medical Research Planning committee. While the Department has laid out a process for the submission, review and awarding of research grants in the appendix to this report, there are still additional details to be worked out, such as the composition and terms of board members, and the appropriate life-span for a strategic plan.

Additionally, the Department will work towards finding appropriate ways to provide weight in research application criteria, and to integrate into the Medical Research Strategic Plan the Minnesota ***Public Health Improvement Goals***. Every goal on the ***Public Health Improvement Goals*** list may not lend itself to an appropriate medical research agenda, but from the Departments perspective, every effort should be made to tie state funded medical research, or a portion of state medical research funds, to broader public health goals.

Finally, establishing a medical research grant application and award program, the Department feels that the experiences of Colorado, Michigan, Ohio, and Pennsylvania may be particularly instructive. Specifically, in setting up a medical research grant application and award processes, these states have attempted to make their researchers competitive for federal funding dollars, focus on collaboration, technology transfer, and economic development, and connect their research programs to population health goals.

BACKGROUND AND INTRODUCTION

The State of Minnesota, via its health reform activities, has long recognized the role that medical education and research play in ensuring the continued vitality of Minnesota's health care system. In 1993, the Minnesota Legislature directed the Commissioner of Health to undertake an examination of the financing of medical education and health care research in Minnesota and to analyze the role of these activities in a reforming health care system with a focus on cost containment. The Legislature affirmed the benefits of medical education and research through Minn. Stat. Sec. 62J.045 (1993) of the MinnesotaCare Act.

> Subdivision 1. Purpose. The legislature finds that all health care stakeholders, as well as society at large, benefit from medical education and health care research. The legislature further finds that the cost of medical education and research should not be borne by a few hospitals or medical centers but should be fairly allocated across the health care system.

In 1996, the Legislature established the Medical Education and Research Costs (MERC) Trust Fund, funding it for the first time in 1997. Over the past two years, the Department of Health has distributed nearly $40 million to medical education training sites throughout the State of Minnesota in support of the training of Advanced Practice Nurses, Dental Students, Dental Residents, Medical Students, Medical Residents, Doctor of Pharmacy Students, Doctor of Pharmacy Residents, Physician Assistants, and beginning in 2000, Chiropractors. While none of this financing has, to date, gone for the direct support of medical research in Minnesota, the Minnesota legislature has continued to affirm the value of medical and health care research through its continued inclusion of research as part of the Medical Education and Research statute.

The issue of medical research and the funding of medical research was raised during the 1999 legislative session amid debates surrounding the use of the tobacco settlement funds. While ultimately the 1999 Legislature did not allocate any funding for medical research in Minnesota, the Minnesota Legislature directed the Minnesota Department of Health to:

> "make recommendations for a process for the submission, review, and approval of research grant applications. The process shall give priority for grants to applications that are intended to gather preliminary data for submission for a subsequent proposal for funding from a federal agency or foundation, which awards research money on a competitive, peer-reviewed basis. Grant recipients must be able to demonstrate the ability to comply with federal regulations on human subjects research in accordance with Code of Federal Regulations, title 45, section 46, and shall conduct the proposed research. Grants may be awarded to the University of Minnesota, the Mayo clinic, or any other public or private organization in the state involved in medical research. The commissioner shall report to the legislature by January 15, 2000, with recommendations."

In accordance with the authority given the Commissioner in this statute, the Department of Health convened a Research Subcommittee of the Medical Education and Research Costs (MERC) Advisory Committee in order to provide advice and input on this study. Members of this Subcommittee are listed in Appendix C.

This report provides background information on definitions of medical research, discusses the present state of research funding in Minnesota, examines the activities undertaken in other states to fund research through

tobacco endowments, and presents a process for the submission, review, and approval of research grant applications.

Defining Medical Research

Defining "research" has always been a challenge in the context of the Medical Education and Research Costs (MERC) project. The range of health care research that is conducted in Minnesota is remarkable, and the contributions of many types of research continue to bring Minnesota acclaim around the country and world. As the Department of Health's report Future Funding for Medical Education and Research in Minnesota pointed out in 1994, "health care research stretches on a continuum extending from basic biomedical research through behavioral, clinical, and applied research to traditional health services research."

Much of the original MERC project in the early 1990s was focused on examining ways to ensure the continued vitality of education and research in a dynamic health care system that was focused on cost containment. As managed care and cost containment became more prominent in Minnesota, the ability of providers of medical education and research to finance these activities out of patient care dollars became more constrained. Therefore, the original vision of MERC was to examine ways to replace these lost patient care dollars to support medical education and research.

One of the distinctions that has always existed between the financing of medical education and medical research, however, was that the portion of medical research that was funded by patient care revenues has been relatively small in comparison to medical education, which has relied more heavily on this source. Historically, medical research has relied predominately upon federal, private industry, and foundation funding for support, while the cost of medical education was largely funded by patient care revenues. As a result, the education financing provided through the MERC trust fund has focused on replacing lost patient care revenue. Nonetheless, some have suggested that financing of medical research should also focus on the loss of patient care revenues.

Research as an Investment Opportunity

With ever-increasing levels of federal research funds becoming available through the National Institutes of Health and other federal sources, some have suggested that a more valuable way of spending state resources toward research would be to use state funds as seed money to give researchers in Minnesota a competitive advantage relative to researchers in other states. This approach would allow for smaller seed grants which could support preliminary data collection in the development of a grant proposal to leverage more substantial federal funding. Much of the impetus for directing the Department to produce this report grew out of this view of using state funds to leverage more federal funds into Minnesota. The advantage of this approach would be that, not only would the state bring in federal funds for research on the front end, but the state may reap economic benefits in the future as developments made possible by the funding of research are both translated into clinical practice and used in the development of medical device advances and other manufacturing areas that might benefit Minnesota. This approach is similar to that being used in Michigan, Ohio, and Pennsylvania with tobacco-settlement funds. Among the noted advantages of the "seed grant" type of approach are the following:

1. This approach could help Minnesota researchers leverage national funding by providing seeds funds for preliminary data collection.

2. The State could possibly share in the profits from any scientific breakthroughs that go to market and where the funding can be directly traced back to the State. The State may even want to consider reinvesting the State's share of generated profit back into the Tobacco endowment to further enhance this resource. In any case, the state would share, via increased tax revenues, from increased economic development.

3. Increased funding attracts eminent researchers to the State, and thereby enriches the level of scientific expertise in the State. This could create a so-called "critical mass" of scientific expertise leading to increased efficiency and effectiveness in the development of research, hypotheses, and research approaches (or modalities), resulting in more successful research endeavors.

4. Improved public health and lower public health spending, as savings are achieved through scientific innovations in disease management and elimination.

5. Economic development, in biotechnology and medical device industries, that is a direct outgrowth of scientific breakthroughs.

The challenge of approaching research funding from this perspective is identifying the types of research that would most likely bring in federal funds and lead to future economic development. The research subcommittee of the MERC Advisory Committee was unable to reach a consensus on which types of research are most likely to lead to increased funding from federal sources and ultimately to economic development breakthroughs. While this report does not recommend a specific type of research for funding, the Department notes that there are certain types of research that may be more directly related to NIH funding and subsequent translation to clinical practice and device manufacturing. These would include base science research, clinical research, and applied research.

In considering the types of research that may be undertaken under the general heading of medical or health related research, it is helpful to understand the definitions of the various types of research that are generally accepted for the purposes of classifying research programs or projects. For this discussion, the MERC Research Subcommittee referenced the Medical Alley report, Looking to the Future: Recommendations to Ensure Funding for Medical Research in the Climate of Cost Containment:

TYPES OF RESEARCH

Health-related research spans a continuum from the most fundamental research to the most traditional. The following definitions provide a framework for identifying the types of research along that continuum.

> ***Basic Research***: Encompasses development of the fundamental knowledge of behavioral and biologic systems. This type of research does not necessarily have specific diagnostic or therapeutic objectives.
>
> ***Clinical Research***: Involves studies of human diseases and how body systems are affect by the disease process.

Applied Research: Studies and evaluates diagnostic and therapeutic modalities involving humans and animals in clinical and laboratory trials. Patient-based research may involve normal or diseased populations.

Product Development Research: Evaluation and validation of pharmaceutical product or medical device.

Health Services Research: Defines and evaluates the methods and economics of healthcare delivery, patients' and providers' interactions and outcomes research.

While current statute indicates that "health care research" means "approved clinical, outcomes, and health services investigations," given the difficulty of identifying the types of research and research approaches that would most likely bring in federal funds and lead to future economic development, the Department feels that this statutory definition of "health care research" does not provide enough flexibility to fit with the objective of using research grants as seed money, and therefore recommends that the definition of "health care research" be removed, or revised to include those types of research likely to leverage NIH funds, or funds from other major outside funding sources.

Research Activities in Minnesota and other states

A Brief Snapshot of Research in Minnesota

To date, Minnesota has not undertaken a coordinated approach to state research activities. Research is primarily conducted by large public and private universities and hospitals, and to a lesser degree by private research institutions. Consequently, the State has never fully quantified research expenditures, and it is hard to estimate how much funding is currently being spent on research in the State. The 1994 MERC Report to the Legislature estimated fiscal year 1992 research expenditures for University of Minnesota Hospital and Clinic, St. Paul Ramsey Medical Center, Hennepin County Medical Center, Veterans Administration Medical Center, and Mayo Foundation as follows:

Total Research Expenditures	$ 216,968,535	100%
Funding Sources		
Federal	$ 101,196,140	46.6257%
State	$ 11,455	0.0053%
Other Public	$ 18,557	0.0086%
Pharmaceutical/Industry	$ 37,787,566	17.4155%
Donations/Grants/Subsidies	$ 9,949,274	4.5856%
Other	$ 7,754,000	3.5738%
Unfunded by Internal or External Source*	$ 60,154,791	27.7153%

* This unfunded portion exists mostly because total expenditures were first estimated, then the amount that comes from known sources backed out. Most institutions do not have accounting systems to track some of the minor sources of funds used to fund research, and these sources could range from parking fees, for example, to other less stable sources of funding.

NIH Research Financing

In Federal fiscal year 1999, Minnesota research institutions received $246,896,000 in National Institutes of Health (NIH) funding. By comparison, research institutions in Wisconsin received $222,479,000. Overall, Minnesota ranked 13th among states in terms of NIH funds distributed to research facilities within the state.

The vast majority of NIH funding in Minnesota goes to two institutions: The University of Minnesota and the Mayo Foundation. These two institutions receive approximately 93% of all NIH dollars in Minnesota, with the University of Minnesota receiving 62% of the total and the Mayo Foundation receiving approximately 31% of the total.

Selected Efforts in Other States to Fund Medical Research

This section of the report reviews selected efforts by other states to finance medical research. In general, these efforts grow out of financing provided by tobacco settlement funds. In general, the efforts undertaken by states show that they are aware of the medical and economic benefits of research, including improved population health, the economic benefits of increased patient revenue, and the development of secondary industries such as the medical device and pharmaceutical industries. These efforts are useful in providing possible models for research funding using tobacco funds for Minnesota. In particular, the models established in Michigan, Ohio and Pennsylvania are relevant, in that they attempt to use tobacco settlement funds to leverage outside funding and/or serve as an economic development tool.

Michigan

Michigan is planning to establish a "life sciences corridor" across the southern part of Michigan through an annual allocation of one-sixth, or $50 million, of Michigan's $300 million per year Tobacco Endowment. There will be a link between Michigan's three largest universities, and a new privately funded research center. The vision is to attract small growth companies to Michigan, and through cutting-edge innovations, place Michigan within the top echelon of research and technology states in the country. Of the annual $50 million research allocation, about 10%, or $5 million, will be spent in efforts to bring scientific discoveries to market, thus increasing the chances that any new breakthroughs also spur economic growth.

Called the Michigan Health and Aging Research and Development Initiative, Michigan's research fund will be apportioned into smaller funds. Forty percent (40%) will go to the Basic Research Fund, which will be competitively distributed, 50 percent will be dedicated to the Collaborative Research and Development Fund, with emphasis on testing and developing emerging discoveries, and 10 percent will go to a Commercialization Development Fund to help start-up companies develop and grow in Michigan.

Michigan has a steering committee that oversees the spending and the program is administered by the Michigan Economic Development Corporation.

Colorado

The State of Colorado's total settlement with tobacco companies was approximately $3.1 billion. The State expects to receive annual payments of between $32.9 and $117 million for the next 30 years.

The Task Force on the Tobacco Settlement's Contribution to a Healthier Future for Colorado Citizens recommended that Colorado spend 8.8% of these annual payments on tobacco-related and tobacco-focused research, including, but not limited to, disease, illness, education, evaluation, cessation, and prevention.

Evaluation research would focus on designing, implementing and evaluating effective cessation and prevention programs which reach community members who are at most risk for tobacco use. Clinical research would focus on developing effective pharmacological aids and other treatments to assist smokers in quitting smoking. Basic science research would focus on all aspects of the biological, physiological, chemicalogical, and psychological interactions between human body structures and all forms of tobacco. The Task Force also pointed out that although the national settlement provides grant funding and direct research through a foundation for some evaluative and clinical research, none of the foundation money was available for clinical research. The Task Force also recommended that federal, private, and other matching funds be sought, if possible.

Ohio

Ohio has developed a Tobacco Task Force charged with recommending uses for Ohio's $10.1 billion share of the tobacco settlement (funds through 2025). The Tobacco Task Force recommended that a Biomedical Research and Technology Transfer Trust Fund be created, and that this Trust Fund receive $1.8 billion, or approximately 18%, of State proceeds from the settlement.

The Board appointed to oversee the Trust Fund would make periodic strategic assessments to determine the types of investments in biomedical research and biotechnology the state should make. Ohio's strategy is to make investment which would create jobs, business opportunities, and improvements to public health and leverage private and public funding. The board intends to focus on tobacco-related illnesses and to coordinate its activities with Ohio's Tobacco Use Prevention and Control Foundation, while still funding other worthy research activities. The funding would go to individuals, public agencies, private organizations, and joint ventures.

Pennsylvania

Pennsylvania is slated to receive about $11.2 billion from the tobacco settlement, to be deposited into a Tobacco Settlement Investment Fund. Pennsylvania's Treasurer has commented that although Pennsylvania has some of the finest medical research facilities in the world, they deserve substantial additional public support, and the settlement provides a means to do so. She has recommended using the Tobacco settlement funds to fund research institutions with two requirements:

- That research institutions be required to earmark some of the money to fund research into addiction.
- That the Commonwealth insist on a share in the profits as the State's investment in an institution's research leads to a marketable medical breakthrough. The State would then use such profits to reimburse the Tobacco Settlement Fund.

Pennsylvania's Cancer Alliance also has a number of proposals that take advantage of the fact that a number of the nation's pre-eminent cancer researchers reside in Pennsylvania. According to the Alliance, funding from the tobacco settlement would augment and enhance these efforts and would have a leveraging effect in bringing more dollars to the state in terms of business development and from public and private funding sources. Their proposal would use the tobacco settlement dollars to focus on tobacco-related cancers.

SECTION 3

This section of the report provides a brief description of the criteria and a process that could be used to gather application for, review, award and distribute research grants, as well as, a recommendation on an advisory committee for the research component of grant distribution and review. In order to develop this process, the Department convened a subcommittee of the Medical Education and Research Costs (MERC) Advisory Committee to provide input and advice to the Commissioner on the development of a process for submitting, reviewing, and funding research grant proposals. The Research Subcommittee met six times during the summer and fall of 1999 to develop a process that is streamlined and efficient, but conforms to generally-accepted and accountable processes for the administration and evaluation of grant proposals. The process that was identified is appropriate for evaluating a wide range of medical research modalities and approaches, and can be used regardless of the research focus that the Legislature should choose to adopt.

ADVISORY COMMITTEE DISCUSSIONS

The Research Subcommittee membership included persons with backgrounds and knowledge of health care research, but who had worked in a variety of different areas of medical research and held differing perspectives on the value of the various types of research. As a result, the Subcommittee had difficulty reaching a consensus on what kind of research would best maximize any State funding, or would best leverage State funding in order to make Minnesota researchers more competitive nationally (see Appendix C, Research Subcommittee Letter to the Commissioner of Health). However, the charge given the subcommittee was to develop a process that could be used regardless of the type of health care research funded. It was stressed to the committee that, as per statute, whatever process developed should give preference to those grants which "give priority for grants to applications . . . intended to gather preliminary data for submission for a subsequent proposal for funding from a federal agency or foundation . . . "

One of the few elements of the discussions of the MERC Research Subcommittee, where a consensus was apparent, was on the subject of research funding strategies. In the context of these discussions, the subcommittee made the following points:

1) Funding for Medical Research should come from new sources of funds, not from funds currently allocated to medical education, and

2) The financial commitment necessary to establish successful research seed grant programs is relatively great; substantial financing and time per researcher are required for successful research programs; a minimum of three years is necessary to develop a "line of inquiry"; and the process of seed grant research requires substantial administrative support; Consequently, the committee recommends that the grant process reflect a commitment of funding for multiple years and a minimum of three years.

The advisory subcommittee chose to break the recommended process into three areas:

1. Describing and setting out the characteristics of a successful applicant,

2. Providing guidelines on the types of research projects to be funded, and

3. Developing a process for the appointment and function of a review panel.

Based upon the recommendations of the Advisory Committee, and in keeping with the statutory charge given the Department, the Minnesota Department of Health has further detailed the recommended administrative process for distributing grants. The Department worked closely with the Advisory Committee to structure a process which was as administratively simple as possible, while also establishing a process that had integrity.

An Illustration of the Administrative Process under the Proposed Process for the Submission, Review, and Funding of Research Grants

Given the difficulty of being able to predict, in advance, those types of research likely to leverage federal or other outside grant funds, as well as those types of research that best meet and fulfill the State's ***Public Health Improvement Goals***, the Department recommends the establishment of a Strategic Medical Research Planning committee, which would be charged with developing a three to five year Medical Research Plan to guide the grant-making process. More detail on the remainder of the administrative process can be found in Appendix B.

In summary, a legislatively chartered Strategic Medical Research Planning committee would develop a 3 to5 year Medical Research Strategic Plan. Each 3 to 5 year plan would include the objectives and priorities of a state medical research agenda based, in part, upon the Minnesota ***Public Health Improvement Goals***. Additionally, the Strategic Plan would include a compendium or outline of research topics and approaches, thought to be most effective in leading to additional successful research, the leveraging of additional funding from Federal and foundation sources, and providing the greatest potential for future economic development within the state of Minnesota.

It is suggested that this committee be composed of appointees of the Commissioner of Health with a minimum of two appointees from academic research facilities with a maximum membership of 6 to 8 appointees. It is also suggested that one member of the committee be a consumer representative.

The Medical Research Strategic Plan established by the committee would be communicated through the Request for Proposal (RFP) process. Researchers would be encouraged to submit proposals that support the objectives of the Medical Research Strategic Plan and on topics identified in the Strategic Plan. Additionally, proposals that focused on preliminary data collection that would make Minnesota researchers competitive for national funding, proposals, that demonstrated a potential for collaboration amongst various research organizations, and proposals that demonstrated a potential for technology transfer or leading to economic development would be given additional weight. However, all qualifying research proposals would be reviewed by the grant application review panel, regardless of research type or topic.

APPENDIX A

RESEARCH GRANT CRITERIA AND GRANT AWARD PROCESS RECOMMENDATIONS FROM THE MERC RESEARCH SUBCOMMITTEE

The Research Subcommittee felt strongly that the State should award funds only to nonprofit organizations with IRS 501(c) status. It was agreed by all members that the work of the grant award recipients should benefit all Minnesotans, and therefore results should be in the public domain. Additionally, data collected or derived from state-funded research could be kept private for proprietary reasons only. In addition, the committee felt strongly that guidelines around human subject use and other ethical concerns could piggyback on federal compliance, with researchers and institutions showing proof of compliance with federal standards. This would minimize requirements for administrative oversight by the Department of Health. The Committee also felt that it was important that grant applicants have an existing successful record with their previous research activities and evidence of appropriate institutional support from their sponsor organizations as this would provide some assurance of the quality of the institutions or researchers applying. In order to provide a variety of organizations and individuals an opportunity to be funded, the committee believed that individual researchers as principal investigators should be restricted to one proposal per grant application cycle.

What is a successful applicant (organization or individual)

> Statutory guidelines: Minn. Stat. Section 62J.693, subd. 2, states "grant recipients must be able to demonstrate the ability to comply with federal regulations on human subjects research in accordance with Code of Federal Regulations, title 45, section 46, and shall conduct the proposed research . . . Grants may be awarded to the University of Minnesota, the Mayo clinic, or any other public or private organization in the state involved in medical research."

Researchers applying for funds must:

1 Provide certification of 501(c) status per IRS Code (Entity is not-for-profit or nonprofit).

2. Be researchers in Minnesota and employed by a Minnesota-based entity.

3. Conduct the proposed research in Minnesota.

4. Submit certification of compliance to applicable Federal standards for medical research (a grant application template will contain a check list of possible Federal certifications).

5. Have evidence of appropriate institutional support and oversight through institutional sign- off, or letter of support signed by the appropriate institutional official.

6. Be affiliated with an organization that has demonstrated a history of successful research activities.

7. Submit only one proposal as principal investigator . . . (per grant application cycle).

Project Criteria Discussions:

The discussions of the Research Subcommittee to develop recommendations for criteria for a research grant program, reflect the consensus of the subcommittee members that it was important that funded research have an impact on the health of Minnesotans, regardless of the type of research that was funded. The criteria focused on rewarding ideas that enhance knowledge in specific areas and would most likely be translated into improved clinical practice. However, it was felt that grant funds should not displace existing research funding, but should be pooled with existing funding to gather preliminary data in order to make Minnesota researchers more competitive when applying for national funding. In addition, some members felt that instead of competing with each other, there was value in Minnesota institutions collaborating more on research projects and sharing information. It was pointed out that some states have implemented strategic plans for research and have encouraged their research community to pool resources and information, while providing opportunities for technology transfer. Finally, the committee put a focus in the criteria, as per statute, on those research proposals intended to gather preliminary data for subsequent submissions to federal or outside funding agencies.

Project Criteria

> Statutory guidelines:Minn. Stat. Section 62J.693, subd. 2, states "the process shall give priority for grants to applications that are intended to gather preliminary data for submission for a subsequent proposal for funding from a federal agency or foundation, which awards research money on a competitive, peer- reviewed basis."

The Department recommends that applications for research grants include:

1. Documentation of how the subject of the proposed research may ultimately benefit human health, or translate into clinical practice.

2. Documentation of the current state of knowledge and a description of how the proposed research will move beyond the current state of knowledge in the identified subject area.

3. Documentation of a research plan to include: identification of measurable objectives and goals and the methodology to be used to measure the outcomes of the objectives and goals.

4. A description of how the proposed research will contribute to creating a competitive advantage for further, more substantial funding from outside funding organizations.

5. Evidence that the Grant will not be used to offset existing research funding.

6. A description of the investigator's training, education, and past work experience as it relates to his or her ability to implement and complete the proposed project, and to obtain further, more substantial funding from outside funding organizations.

7. Description of potential collaboration and technology transfer opportunities that could result from the proposed research, and how these potential collaborations could lead to more substantial funding from outside funding organizations.

8. Results of the applicant's research should be in the "public domain"; Data may be kept private for proprietary reasons only. However, in all cases, results of the research initiative must be available for potential publication (Refer to recently enacted Federal Government statute, Revised Circular A110).

Research Grant Review and Award Process and Grant Review Panel Discussions:

The recommended grant review process would be overseen by both staff from the Minnesota Department of Health (MDH), and by an outside review panel of medical researchers. MDH staff would check for completeness, and provide initial screening to eliminate any research grants that did not include all required items. The section of this report on administration outlines how this process might work.

The Grant Review Panel could be made up primarily of researchers with a focus on a given type of research, depending upon the specific type of research proposed in grant applications. However, the MERC research subcommittee also felt it was important to include some generalist researchers, and potentially a consumer representative on the panel as well, to provide balanced perspective on the review of applications. Members of the review panel would be expected to disclose potential conflicts of interest. In some cases this would require panel members to recuse themselves from adjudicating specific grant applications, and in rare instances require panelist nominees to decline membership on the review panel entirely for a given application cycle to insure integrity within the review process. The subcommittee also felt it was important that reviewers have committee meetings where they can exchange information on those elements of the process that work, and recommend ways to fine-tune the process. The Subcommittee worked hard to ensure that the review process was fair, rewarded experience, and yet was open to new and innovative ideas.

Although the recommended process is streamlined, there was a general recognition that the work would be time consuming, since the Review Panel would have to review many proposals for purpose, scope, rationale, added value, and evaluation of results. Since this would be the first time that the State would be appropriating research funds without a designated field of scientific inquiry, it is difficult to estimate how many proposals will be submitted annually.

Finally, the Department recommends that, should the Legislature choose to provide funding for medical research initiatives, a specific research committee be empaneled to manage the research application and funding process. The committee could be made up of members of the review panel, or could be more broadly constituted to include non-researchers as well.

Research Grant Review and Award Process, and Grant Review Panel Characteristics

The following is an illustration of the general process to be followed for the evaluation of grant applications:

1. Sponsoring institution signs off on grant application (As required by project criterion.).

2. MDH staff review grant applications to assure application meets minimum qualifications ("Check Box" review).

3. Review panel examines applications and determines awards based upon given applicant and project criteria.

   Panel is composed of members with expertise broadly representative of applications (Size of panel to be determined by the number of anticipated applications.).

   A consumer representative is desirable as a member of the review panel.

   Members should have previous grant application review experience.

   Members must disclose potential Conflict of Interest. For example, members cannot be relatives of applicant(s), applicant mentors, collaborators, nor beneficiaries of an applicant's research project.

   Members cannot be a research applicant.

   Members are appointed by the Commissioner of Health.

   Applications will be distributed to primary reviewers.

   Scores will be allocated by primary reviewers, presented at the annual review committee meetings, discussed and revised if necessary.

   Proposals will be ordered by score and decisions made regarding distribution of funds based on scores and discussion by the review panel.

5. The commissioner will award grants in order of priority given by the review panel until all available dollars are expended.

6. At the end of the grant review process the review panel members will evaluate each other on:

   Fairness

   Thoughtfulness

   Open Mindedness

Results of this evaluation will be used in future review panel selections.

Other Opinions

In addition to the letter from the Research Subcommittee, other opinions were also submitted (see Appendix D, Letter to the Assistant Director of the Health Economics Program from Ms. Kirsten Libby; and Appendix E, Letter from Medical Alley's President to the Research Subcommittee, and Medical Alley's report on research, entitled

"Looking to the Future: Recommendations to Ensure Funding for Medical Research in the Climate of Cost Containment").

APPENDIX B

An Illustration of the Administrative Process under the Proposed Process for the Submission, Review, and Funding of Research Grants

A. Strategic Medical Research Planning committee

A legislatively chartered Strategic Medical Research Planning committee would develop a 3 to5 year Medical Research Strategic Plan. Each 3 to 5 year plan would include the objectives and priorities of a state medical research agenda based, in part, upon the Minnesota Public Health Improvement Goals. Additionally, the Strategic Plan would include a compendium or outline of research topics and approaches, thought to be most effective in leading to additional successful research, the leveraging of additional funding from Federal and foundation sources, and providing the greatest potential for future economic development within the state of Minnesota.

It is suggested that this committee be composed of appointees of the Commissioner of Health with a minimum of two appointees from academic research facilities with a maximum membership of 6 to 8 appointees. It is also suggested that one member of the committee be a consumer representative.

The Medical Research Strategic Plan established by the committee would be communicated through the Request for Proposal (RFP) process. Researchers would be encouraged to submit proposals that support the objectives of the Medical Research Strategic Plan and on topics identified in the Strategic Plan. Additionally, proposals that focused on preliminary data collection that would make Minnesota researchers competitive for national funding, proposals, that demonstrated a potential for collaboration amongst various research organizations, and proposals that demonstrated a potential for technology transfer or leading to economic development would be given additional weight. However, all qualifying research proposals would be reviewed by the grant application review panel, regardless of research type or topic.

B. SECTION I Request for Proposal

The RFP process would be administered by MDH staff and would be undertaken during the first quarter of the state fiscal year and would include:

I. Issuance of RFP (within 2 weeks of the beginning of the first quarter.).

II. Questions regarding the RFP from potential Principal Investigators (within 6 weeks of the beginning of the first quarter.).

III. "Questions and Answers" regarding the RFP mailed to potential Principal Investigators (within 9 weeks of the beginning of the first quarter.)

IV. Grant Application Proposals due (within 13 weeks of the beginning of the first quarter).

C. Section II Proposal Screening

The Department of Health would screen any submitted proposals to ensure that they contain the following required information:

I. Statement and evidence that the research institution is a Minnesota-based entity.

II. Statement and evidence that the proposed research will be conducted in Minnesota or primarily based in Minnesota.

III. Certification of compliance to applicable Federal standards for medical research (a grant application template will contain a check list of possible Federal certifications.).

IV. Evidence of appropriate institutional support and oversight through institutional sign-off, or letter of support signed by the appropriate institutional official.

V. Evidence that the sponsoring organization has adequate financing to support the researcher outside the scope of the research grant proposal, including annual or quarterly financial reports.

VI. Statement and evidence that the organization has demonstrated a history of successful research activities.

VII. Individuals must stipulate that they have submitted only one proposal as principal investigator during the current application cycle.

Department screening of submitted proposals should be completed within 18 weeks of the beginning of the first quarter of the fiscal year. Applications failing to meet the basic requirements of the MDH screening process would be notified at this time.

D. Composition of Review Panel

Once grant applications have been screened, qualifying grant applications would be considered to be the pool of applicants. Applications would be classified according to the type of research being proposed, and the subject matter of the research proposal. Based upon the expertise needed for review of the proposed applications, the review panel would be selected keeping in mind the need for balance, general knowledge of research as well as specific expertise, appropriate representation from state research organizations, and other criteria including:

I. Panel is composed of members with expertise broadly representative of applications (Size of the panel to be determined by the number of anticipated applications.).

II. Members will have previous grant application review experience.

III. Members must disclose potential Conflict of Interest. For example, the panel members cannot be relatives of applicant(s), applicant mentors, collaborators, nor beneficiaries of an applicant research project.

IV. Members cannot be a research applicant.

V. Members are appointed by the Commissioner of Health.

E. Criteria for Evaluation of Research Proposals

Project proposals should be properly formatted and include the following:

I. Cover Sheet

II. Table of Contents

III. Project Abstract

In addition, project proposals will be considered based upon the following project criteria:

I. Documentation of how the subject of the proposed research may ultimately benefit human health, or translate into clinical practice.

II. Documentation of the current state of knowledge and a description of how the proposed research will move beyond the current state of knowledge in the identified subject area.

III. Documentation of a research plan to include; identification of measurable objectives and goals and the methodology to be used to measure the outcomes of the objectives and goals. This documentation should include detailed descriptions of the:

   i. Research Design

   ii. Hypothesis

   iii. Sampling Methodology or other proposed Methodology

   iv. Data or Sample Collection Design

   v. Analysis Model

   vi. Limitations to Research and Analytic Approach

   vii. Criteria for determining the success or failure of the Research Project

IV. Applicant will describe how the proposed research will contribute to their competitive advantage for further, more substantial funding from Federal, foundation and other sources including discussion and evidence of Federal and foundation research agendas and objectives.

V. Description of how the proposed research project will benefit the state of Minnesota and its citizens.

VI. Description of how the proposed research will address one or more of the objectives of the State of Minnesota's Public Health Improvement Goals, which are:

i. Reducing behavioral risks that contribute to morbidity and mortality.

ii. Improving birth outcomes and early childhood development

iii. Reducing unintended pregnancies

iv. Promoting health for children, adolescents and families

v. Promoting and improving mental health

vi. Promoting a violence-free society

vii. Reducing behavioral and environmental risks that are primary contributors to unintentional injury

viii. Improving the outcomes of medical emergencies

ix. Reducing infection disease

x. Promoting the well-being of the elderly, and those with disability, disease or chronic illness

xi. Reducing exposure to environmental hazards

xii. Promoting early detection and improved management of non- infectious disease and chronic conditions

xiii. Promoting optimal oral health for Minnesotans

xiv. Reducing work-related injury and illness

xv. Assuring access to and improving the quality of health services

xvi. Ensuring an effective state and local government public health system

xvii. Eliminating the disparities in health outcomes and the health of populations of color

xviii. Fostering the understanding and promotion of social conditions that support health

VII. Description of the investigator's training, education, and past work experience as it relates to his or her ability to implement and complete the proposed project.

VIII. Description of potential for collaboration with other research entities within the scope of, or resulting from, the proposed research project. Description should include who collaborators might be, research expertise, skill sets and theoretical perspectives they would bring to the project, and financial, scientific and institutional resources.

IX. Description and evidence for potential technology transfer or economic development opportunities that could result from the proposed research.

X. Proof of compliance with the Federal requirements for human subjects and animal testing.

XI. Project line item budget including:

i. Personnel Salaries

ii. Supplies

iii. Equipment

iv. Administrative Costs

v. Indirect & Overhead Costs

XII. Evidence that the Grant will not be used to offset existing research funding.

XIII. Plan for release of research results into the "public domain"; Plans for release of data, and/or a statement of which portions of data may be withheld for proprietary reasons. (Data may be kept private for proprietary reasons only. However, in all cases, results of the research initiative must be available for potential publication. (Refer to recently enacted Federal Government statute, Revised Circular A110.).

F. Grant Application Review and Scoring

The grant application review panel will review and score the grant applications based upon the above criteria and according to the following process:

I. Applications will be distributed to primary reviewers.

II. Scores will be allocated by primary reviewers, the following items will be scored:

i. Project rationale

ii. Project description

iii. Evaluation Plan

iv. Project Budget

v. Benefit to Minnesota

vi. Evidence that the proposed research will contribute to competitive advantage in application for substantial Federal or foundation research funding.

vii. Evidence and description of how the proposed research may lead to further collaboration with other research entities.

viii. Evidence and description of how the proposed research may lead to opportunities for technology transfer or economic development.

III. Reviewers will present application evaluations at review committee meetings, discuss and revise if necessary. A series of meetings may be held, or a grant review retreat may be held to complete the review process.

IV Proposals will be ordered by score and decisions made regarding distribution of funds based on scores and discussion by the review panel.

V. At the end of the grant review process the review panel members will evaluate each other on:

i. Fairness

ii. Thoughtfulness

iii. Open Mindedness

Results of this evaluation will be used in future review panel selections.

The grant review panel process should be completed within 23 weeks of the beginning of the first quarter of the fiscal year.

G. Section III Award and Post Award Process

I. The Commissioner of Health will award grants in order of priority given by the review panel until all available dollars are expended (within 24 weeks of the beginning of the fiscal year.).

II. The Department of Health will mail award notices (within 25 weeks of the beginning of the fiscal year.).

III. The Department of Health will notify applicants who were not awarded grants (within 25 weeks of the beginning of the fiscal year.).

IV. Research Projects begin (Anytime beginning after notification of the grant award, but within the fiscal year that the grant is awarded.).

V. Grant Awardees will be required to file annual financial and progress reports with the Minnesota Department of Health through the completion of the project or until all funds are expended. These reports should be filed within the first quarter of the fiscal year following the initial award, and each successive first quarter until the project is completed. A final report is required after the completion of the research project.

VI. The Department of Health ensures that there is complete documentation of the Review Process in accordance with the Scored Items listed above, and written descriptions of applicants' addressing of criteria in case of any challenge or inquiry.

VII. A library of all published material resulting from the research projects, associated data, progress and financial reports will be established and maintained.

APPENDIX C

Letter from Research Subcommittee and member list

MERC RESEARCH SUBCOMMITTEE

January 21, 2000

Dear Commissioner of Health:

In reviewing the charge given us by the legislature and staff, the MERC Research Subcommittee submits the following points to be considered in making decisions regarding research funding for the State of Minnesota:

- The current allocation to Medical Education funding is insufficient.
- Medical research funding should be supported from new allocations and not from dollars already allocated to medical education.

★ There are a variety of valuable research activities being conducted throughout the state, therefore, it is difficult to establish which types of research activities (basic science, clinical, health services or outcomes) should be the primary focus of state funding.

★ Given the variety of federal funding streams, it is difficult to predict how state support of particular types of research would most successfully leverage national research funding. Consequently, a broad research agenda would be in the best interest of the state.

★ Research grant funding should also include those areas where there are gaps in funding, including institutional infrastructure, new researchers performing meritorious research and innovative research.

★ The commitment necessary to establish a successful research seed grant program is relatively great, and substantial dollars and time per researcher are required for successful research programs. Experience shows that a period of 3 - 5 years is necessary to develop a line of inquiry.

★ The process itself requires substantial administrative support, even at the minimal review process level recommended. Therefore, the committee recommends that the grant process reflect a commitment of funding for multiple years and a minimum of three years.

January 21, 2000
Page Two

These points are independent and not all members agree on all points listed. Subcommittee members did agree that this process continue with adequate dollars appropriated for distribution. Thank you for the opportunity for input into this process.

Sincerely,

Dr. Catherine Wisner, Ph.D.
Chair, MERC Research Subcommittee

Andrew Nelson, Executive Director
Group Health Foundation

Charles Moldow, M.D. Assoc. Dean
Research/U of M Medical School

David Edwards
MHP

Mary Bergaas
Mpls. Medical Research Foundation

Katherine Johnston
Academic Health Center/U of M

Mary Fahey, Director
Office of Research/Fairview Health Services

William Fehrenbach
HealthPartners

Anna Geary
Allina Health System

Beth Murphy
Allina Health System

Louis Ling
Hennepin County Medical Center

Mark Paller, M.D., M.S.
U of M Academic Health Center

George Isham, M.D. Medical Director
HealthPartners

Jed Gerlin, M.D. Medical Director
Memorial Blood Center of MN

Kathleen Kuha
Allina Health System

Jim Kehrt
Consumer

Timothy Gaspar
Winona State University

William Wasienberg, DVM

Kirsten J. Libby, Vice President
Hughes Institute

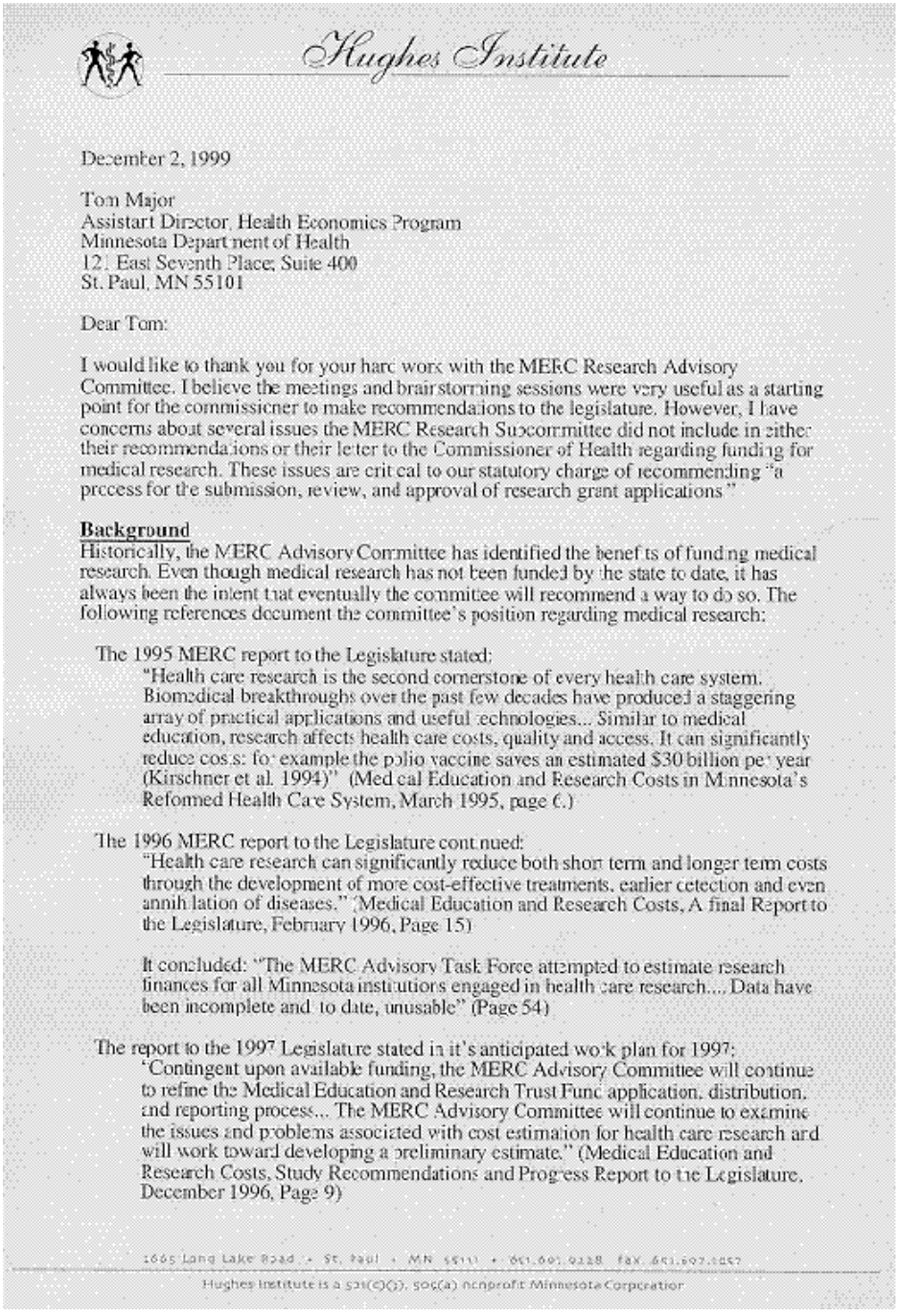
Sandra R. Edwardson, Dean
U of M School of Nursing

Kathleen A. Meyerle, Legal Council
Mayo Foundation

Larry Kunisisto, VP Educational Resources
Northwestern Health Sciences University

APPENDIX D

Letter from Kirsten Libby, Director of Government relations, Hughes Institute



Hughes Institute

December 2, 1999

Tom Major
Assistant Director, Health Economics Program
Minnesota Department of Health
121 East Seventh Place, Suite 400
St. Paul, MN 55101

Dear Tom:

I would like to thank you for your hard work with the MERC Research Advisory Committee. I believe the meetings and brainstorming sessions were very useful as a starting point for the commissioner to make recommendations to the legislature. However, I have concerns about several issues the MERC Research Subcommittee did not include in either their recommendations or their letter to the Commissioner of Health regarding funding for medical research. These issues are critical to our statutory charge of recommending "a process for the submission, review, and approval of research grant applications."

Background
Historically, the MERC Advisory Committee has identified the benefits of funding medical research. Even though medical research has not been funded by the state to date, it has always been the intent that eventually the committee will recommend a way to do so. The following references document the committee's position regarding medical research:

The 1995 MERC report to the Legislature stated:
"Health care research is the second cornerstone of every health care system. Biomedical breakthroughs over the past few decades have produced a staggering array of practical applications and useful technologies... Similar to medical education, research affects health care costs, quality and access. It can significantly reduce costs: for example the polio vaccine saves an estimated $30 billion per year (Kirschner et al. 1994)" (Medical Education and Research Costs in Minnesota's Reformed Health Care System, March 1995, page 6.)

The 1996 MERC report to the Legislature continued:
"Health care research can significantly reduce both short term and longer term costs through the development of more cost-effective treatments, earlier detection and even annihilation of diseases." (Medical Education and Research Costs, A final Report to the Legislature, February 1996, Page 15)

It concluded: "The MERC Advisory Task Force attempted to estimate research finances for all Minnesota institutions engaged in health care research.... Data have been incomplete and to date, unusable" (Page 54)

The report to the 1997 Legislature stated in it's anticipated work plan for 1997:
"Contingent upon available funding, the MERC Advisory Committee will continue to refine the Medical Education and Research Trust Fund application, distribution, and reporting process... The MERC Advisory Committee will continue to examine the issues and problems associated with cost estimation for health care research and will work toward developing a preliminary estimate." (Medical Education and Research Costs, Study Recommendations and Progress Report to the Legislature, December 1996, Page 9)

1665 Long Lake Road • St. Paul • MN 55113 • 651.697.9228 fax 651.697.9267
Hughes Institute is a 501(c)(3), 509(a) nonprofit Minnesota Corporation

In 1998, the MERC report maintained its support for medical research and suggested using some of the proceeds of the tobacco settlement for this purpose:

> "The MERC Advisory Committee has expressed a commitment to pursue the inclusion of MERC as a recipient of a portion of any proceeds from Minnesota's litigation with the tobacco companies. The Governor has already stated his interest in having MERC share in any settlement or judgment proceeds, both for medical education activities as well as for medical research." (Medical Education and Research Costs, Annual Report on Program Implementation and Recommendations, April 1998, Page 23)

Finally, the 1999 MERC report concluded:

> "The MERC Advisory Committee and the Department of Health should determine how medical research can most effectively and efficiently be funded in today's changing healthcare market, and what the State's role in funding medical research should be. It is important that the Department of Health examine these issues and begin to draw consensus on the role of the state in funding research and identifying funding mechanisms." (Medical Education and Research Costs, Annual Report on Program Implementation, March 1999, Page 7.)

In light of this background of the MERC Advisory Committee's position regarding medical research from 1995-1999, I believe it is appropriate to address the following three issues in our research recommendations and cover letter to the Commissioner of Health:

1. Committee Support for Medical Research

If the MERC Advisory Committee and the Research Subcommittee continue to advocate for funding of medical research at the state level, we should clearly identify the benefits of this state funding in the recommendations and cover letter to the Commissioner.

Among other benefits of medical research listed in the 1999 MERC report to the Legislature, the report concluded: "Good research attracts patients to Minnesota, bringing patient care revenue to the state. The state also benefits from a manufacturing industry, which has grown as a result of medical research, thereby increasing employment and tax revenue." This remains true, and should be included as a rational for advocating for state funding of medical research.

Additionally, it was not the charge of the MERC Research Subcommittee to compare the needs of medical research to the needs of medical education. The established Trust Fund for Medical Education is addressing the issue of budget shortfalls in medical education. The statement that "the current allocation to medical education funding is insufficient" is irrelevant, and should be deleted from the cover letter to the commissioner.

2. Research Budget Request Recommendation

The MERC Research Subcommittee did not make any recommendations to the Commissioner about the amount of funding needed to establish a medical research trust fund. Given the political climate at the capitol, this is a mistake. The Minnesota Legislature requested that the Commissioner of Health make recommendations for a process for the submission, review and approval of research grant applications in a year when the state has an enormous budget surplus as well as a unique influx of money due to the tobacco settlement. It would be a missed opportunity not to quantify the amount of money that would adequately fund this issue. I believe the

Legislature would prefer that the research community come to a consensus about how much state funding would be needed to establish a viable investment in medical research. The amount of the budget request should have been debated and resolved in the MERC Research Committee.

Finally, attached are other specific changes I believe should be made to the MERC Research Committee's recommendations, as well as my rationale for all substantial changes. These changes are meant to make the document more relevant to our statutory charge, or to make the criteria and evaluation process more fair to all applicants.

Thank you very much for considering these matters.

Sincerely,

Kirsten

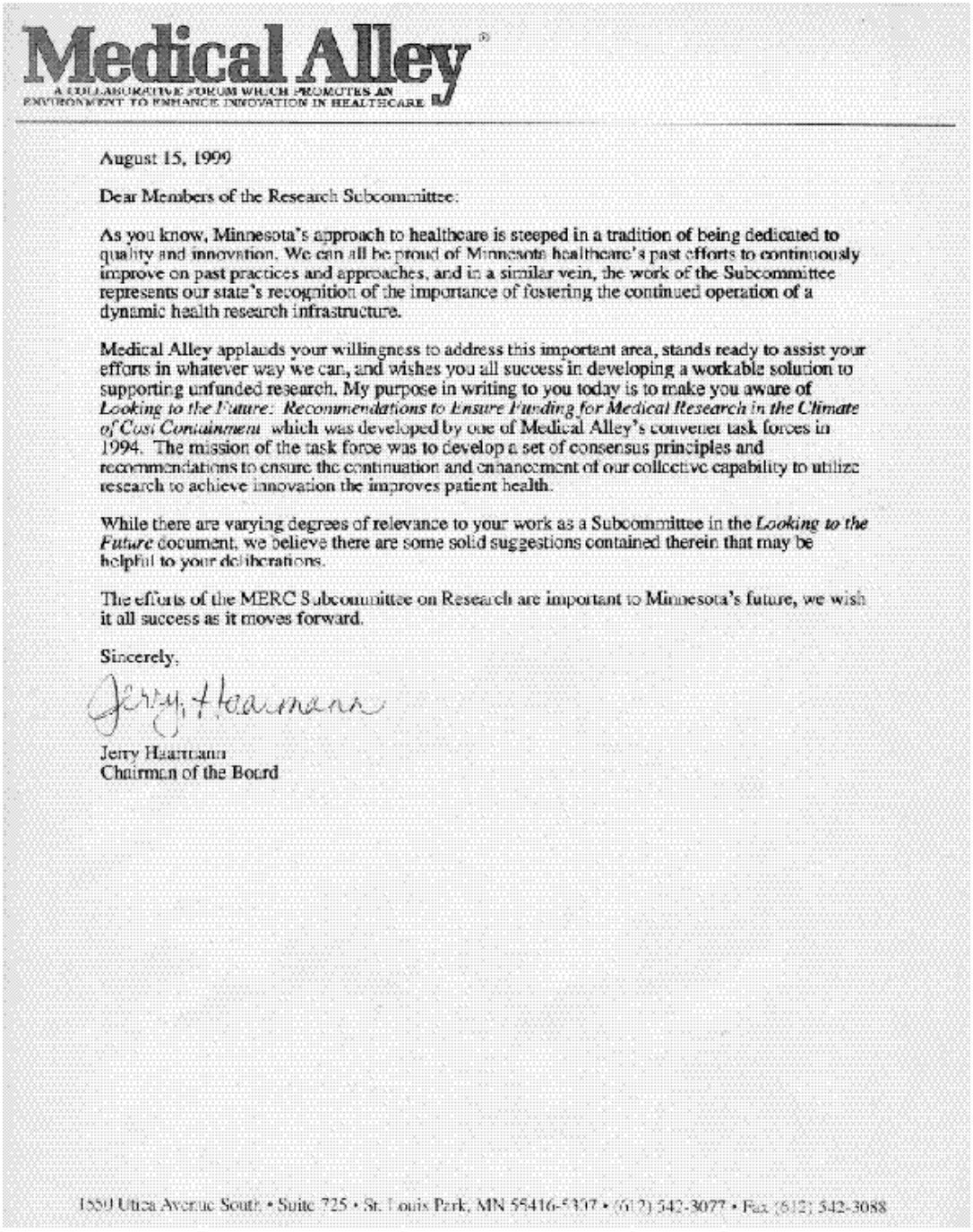
Kirsten J. Libby
V.P. Government Relations

CC: Dr. Fatih Uckun, MD., Ph.D.
President and Director of the Hughes Institute

enclosure: suggested changes to research recommendations

APPENDIX E

Letter from Jerry Harman and Medical Alley's Recommendations on Research



Medical Alley®

A COLLABORATIVE FORUM WHICH PROMOTES AN ENVIRONMENT TO ENHANCE INNOVATION IN HEALTHCARE

August 15, 1999

Dear Members of the Research Subcommittee:

As you know, Minnesota's approach to healthcare is steeped in a tradition of being dedicated to quality and innovation. We can all be proud of Minnesota healthcare's past efforts to continuously improve on past practices and approaches, and in a similar vein, the work of the Subcommittee represents our state's recognition of the importance of fostering the continued operation of a dynamic health research infrastructure.

Medical Alley applauds your willingness to address this important area, stands ready to assist your efforts in whatever way we can, and wishes you all success in developing a workable solution to supporting unfunded research. My purpose in writing to you today is to make you aware of *Looking to the Future: Recommendations to Ensure Funding for Medical Research in the Climate of Cost Containment* which was developed by one of Medical Alley's convener task forces in 1994. The mission of the task force was to develop a set of consensus principles and recommendations to ensure the continuation and enhancement of our collective capability to utilize research to achieve innovation the improves patient health.

While there are varying degrees of relevance to your work as a Subcommittee in the *Looking to the Future* document, we believe there are some solid suggestions contained therein that may be helpful to your deliberations.

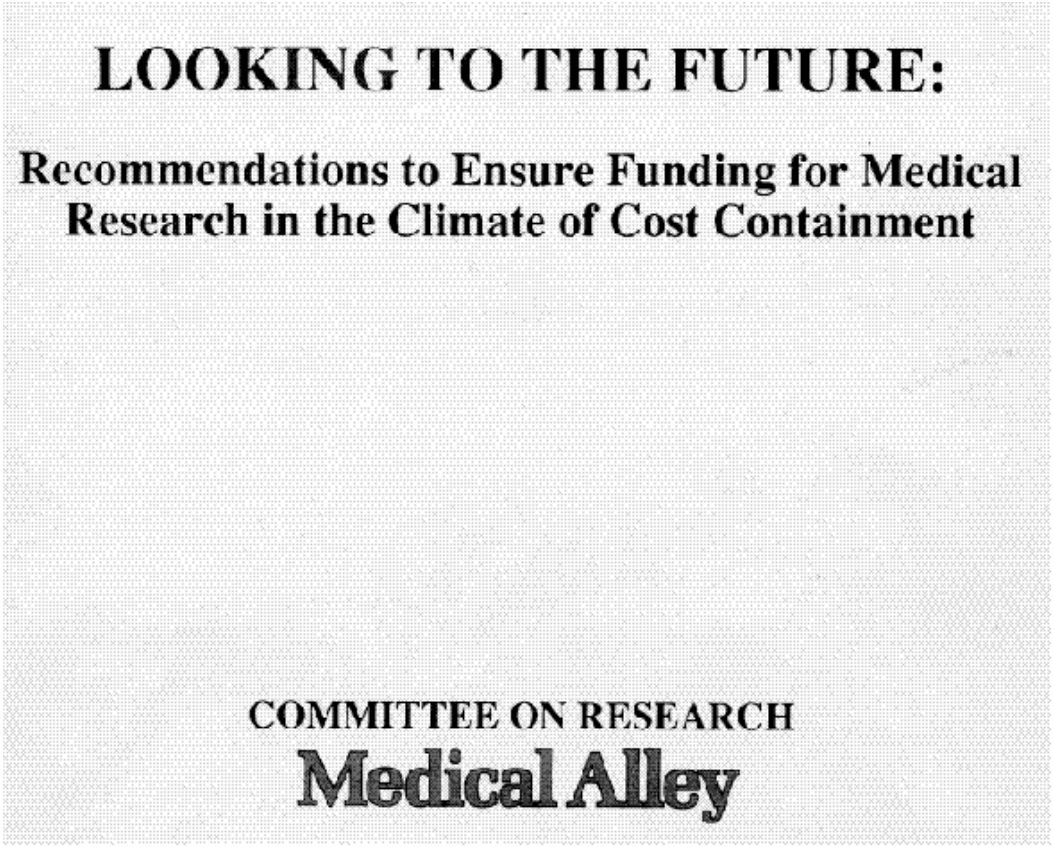
The efforts of the MERC Subcommittee on Research are important to Minnesota's future, we wish it all success as it moves forward.

Sincerely,

Jerry Haarmann

Jerry Haarmann
Chairman of the Board

1550 Utica Avenue South • Suite 725 • St. Louis Park, MN 55416-5307 • (612) 542-3077 • Fax (612) 542-3088


LOOKING TO THE FUTURE:
Recommendations to Ensure Funding for Medical Research in the Climate of Cost Containment
COMMITTEE ON RESEARCH
Medical Alley

Medical Alley
Travelers Express Tower, Suite 725
1550 Utica Avenue South
St. Louis Park, MN 55416-5307
(612)542-3077

TABLE OF CONTENTS

PREFACE

Minnesota's healthcare delivery system is a world leader in providing high quality care to its patients. As Minnesotans consider how they want their system of care to evolve, it is clear that we all have an interest in and desire for a system which is constantly improving. Advancement in our healthcare system is often achieved because of the community's collective interest in and support of research.

With this in mind, Medical Alley -- an organization that includes hospitals and clinics, health maintenance organizations, medical device and pharmaceutical companies, and the education and research community -- established its **Committee on Research.**

The Committee's primary goal was to develop a set of consensus principles and recommendations to ensure the continuation and enhancement of our collective capability to utilize research to achieve innovation that improves patient health.

The most significant focus of this document is recommending public policies to ensure funding for research which has in the past been funded by third-party insurance through reimbursement for clinical care.

COMMITTEE ON RESEARCH

Chairman:
Donald Maurer
CEO & Chairman
EMPI, Incorporated

David Brown, M.D.
Professor of Peciatrics, Laboratory Medicine & Pathology
Director, Pediatric Endocrinology
University of Minnesota

Thomas Elliott, M.D.
Director of Education and Research
Duluth Clinic

Wesley Johnson
Vice President, Scientific Affairs
Orthomet, Inc.

Caliana Lum, M.D., Ph.D.
Director, Organ Transplantation Services, Hennepin County Medical Center
Associate Professor of Surgery, University of Minnesota

Steve Norsted, Ph.D.
Vice President
Regulatory Strategies

Claude Tihon, Ph.D.
Vice President, Research & Technology Assessment
American Medical Systems, Inc.

Lynn Blewett, Ph.D. ex officio
Director, Health Economics Program
Minnesota Health Care Commission

Sue Donaldson, Ph.D.
Cora Midel Sieh Chair in Nursing Research
Professor, School of Nursing;
Professor Dept. of Physiology, School of Medicine

Marvin Heuer, M.D.
President/CEO
Heuer Associates

David Knutson
Director of Systems Studies
Park Nicollet Medical Foundation

Kathleen Meyerle
Legal Counsel
Mayo Clinic

Herbert Pulesky, M.D.
Director
Memorial Blood Center of Minnesota

Staff:
Thomas Meskan
President and Executive Director
Medical Alley

INTRODUCTION

Research is fundamental to the health status of the citizens of our state and nation. Progress in medical research will allow us with increasing sophistication to identify, cure, and prevent disease.

Public Support

The American public, in poll after poll, show overwhelming support for medical research. For example, in a poll by Louis Harris and Associates conducted last year, 64% of the respondents said that this country should spend "a lot more" on medical research to better diagnose, prevent and treat diseases.[1] Not only do Americans want more spent on medical research than energy, space and defense research combined, but they are willing to pay for it. In another recent poll, nearly 75% of the respondents would spend $1 more per week in either taxes, prescription drug prices or insurance premiums toward more research.[2]

Benefits of Research

It is clear that our investment in research has brought us many positive returns. Basic and clinical research expenditures have resulted in major changes in health status such as improved health and survival of women with breast cancer, preventive approaches to oral health, prevention of blindness and kidney failure due to diabetes, new curative treatments of duodenal ulcers, effective screening and early treatment of hypertension, the preferential medical rather than surgical treatment of tonsillitis and effective treatment of psoriasis. Advances in health can be put in monetary terms as well. According to the Battelle Medical Technology Research Center, over the next 25 years, drugs for Alzheimer's will avert $68 billion in health and related costs.[3]

Whereas many of the above advances resulted from funding by public and private agencies as well as contributions from industry, a great deal of vital research on diagnostic and therapeutic approaches is performed in the context of and in conjunction with patient care-derived funding. This research is performed in institutional settings that require peer-review and approval for content and procedure. Examples of patient care derived funding ("non-sponsored research") which have had major and cost-effective impacts upon health include the use of surfactant inhalation in newborn infants to prevent life-threatening and costly consequences of respiratory distress syndrome, the proper uses of preoperative antibiotics to avoid prolonged hospitalization and complications of surgery, the evaluation of the alternative uses of costly but very effective radiological imaging procedures such as ultrasound, computerized tomography or magnetic resonance imaging, and chemotherapy trials for the treatment of cancer, lymphoma and leukemia. Other innovations include devices for control of heart arrhythmias, heart valves, and assistive devices for the disabled which have dramatically improved the length and quality of life of a large number of people, as well as developed a large industrial base of employment. Minnesota examples of advances from non-sponsored research include open heart surgery, bone marrow and pancreas transplantation and treatment of childhood ear infections. Even in cases where the research is funded in part by federal agencies, unfunded clinical care and administration costs are incurred. Usually cost shifting results in patients who receive healthcare services at an institution subsidizing that research.

The Research-Education Link

Many of the advances from non-sponsored research have dramatically changed the practice of medicine. Many outdated practices would have been accepted without question if their precepts had not been challenged by those who conduct research. These challenges and their solutions are often best sought in environments where those mutually engaged in patient care -- practitioners, educators, students and researchers -- interact, the ultimate objective of the integrated research and education programs.

In fact, it is generally recognized that research and education related to health must be coupled. Although quality research is and can be carried out in other than an educational institution, there is a strong coupling between health science schools and clinical teaching institutions to pursue research because it is in this environment that existing medical and healthcare practices are frequently questioned. This questioning fosters reasoning and abilities which evolve into the processes of lifelong learning.

While strong sentiment exists for the continuation and funding of research, it is clear that many are calling for greater cost containment in healthcare spending. This has potentially dramatic implications for health research funded by patient care revenues.

Cost Containment and Research

Patient care revenues have been a major source of funding for healthcare research. Cost containment pressures are resulting in greater attention by providers and managed care plans to accurately account for health services costs and then to eliminate costs not directly required to provide a necessary level of care to the patient. Only specifically cost accounted components of healthcare will be reimbursed; therefore, there will be no allowances for costs beyond the minimum required to deliver services. This trend will create unintended negative consequences in situations for the service or activity that has been implicitly funded because of the recognition of its social value. Healthcare research is a health activity of great social value that will require preservation as cost containment forces drive out all costs but those explicitly required in the payor contracts and by medical standards.

While the MinnesotaCare legislation explicitly exempts certain patient funded research from the growth limit, this unfortunately does little to ensure the continuation of the flow of these dollars. Therefore, other sources for funding research must be designated.

Looking to the Future

Minnesota is leading the nation in healthcare reform in terms of delivery systems and health economics. However, the continuation of Minnesota's enviable record of health outcomes for its population could be jeopardized by eliminating the innovations in healthcare through research, a tradition of excellence which has stood the state well for over a century. The citizens of Minnesota expect and deserve healthcare based upon the most current and appropriate utilization of knowledge and advances. It is toward that end that the Committee offers its recommendations.

EXECUTIVE SUMMARY

COMMITTEE ON RESEARCH

Medical Alley created its Committee on Research because it sought to ensure that there is an opportunity for interested and qualified organizations to conduct research that was previously funded by patient care dollars. We refer to this type of research as "unfunded research."

We believe this research is important to the enhancement of Minnesotas' ability to enjoy a health system that grows through innovations created by health-related research and delivers care that is both effective and serves to mitigate cost increases.

MISSION OF THE COMMITTEE:

- To define research activities related to health and healthcare
- To provide a set of research-related principles for those involved in healthcare policy
- To provide specific recommendations that work to ensure our collective capability to utilize research to improve our system of care

RECOMMENDATIONS:

RECOMMENDATION 1:

THE STATE SHOULD ESTABLISH A RESEARCH FUND TO REPLACE RESOURCES THAT ARE CURRENTLY AVAILABLE THROUGH PATIENT-CARE BASED FUNDING.

RECOMMENDATION 2:

DISTRIBUTIONS FROM THE RESEARCH FUND SHOULD BE ESTABLISHED BY STATUTE AND ADMINISTERED BY THE COMMISSIONER OF HEALTH CONSISTENT WITH OUR SUGGESTED ALLOCATION CRITERIA.

RECOMMENDATION 3:

THERE ARE PRINCIPLES WHICH MUST BE CONSIDERED WHEN FORMULATING THE SPECIFIC PLAN FOR GENERATING THE RESOURCES FOR THIS FUND.

TYPES OF RESEARCH

Health-related research spans a continuum from the most fundamental research to the most traditional. The following definitions provide a framework for identifying the types of research along that continuum.

Basic Research:

Encompasses development of the fundamental knowledge of behavioral and biologic systems. This type of research does not necessarily have specific diagnostic or therapeutic objectives.

Clinical Research:

Involves studies of human diseases and how body systems are affected by the disease process.

Applied Research:

Studies and evaluates diagnostic and therapeutic modalities involving humans and animals in clinical and laboratory trials. Patient-based research may involve normal or diseased populations.

Product Development Research:

Evaluation and validation of a pharmaceutical product or medical device.

Health Services Research:

Defines and evaluates the methods and economics of healthcare delivery, patients' and providers' interactions and outcomes research.

RESEARCH FUNDING DEFINITIONS

Funded research - Research funded by external sources ranging from the federal government to private companies and foundations to charitable organizations, state government, and other organizations.

Unfunded research - The costs of research not covered by the above, and instead covered by patient care dollars. Often these are "the costs of clinical care for the underlying medical conditions (that) have generally been covered by third party insurance."[4]

- 5 -

PRINCIPLES

Overriding Principles

- Research is a tool to reduce the cost and improve the quality of care.
- Innovation grows from broadly-based research programs.
- Given the strong incentives to reduce the cost and improve the quality of care, institutions which pursue research should be allowed to prioritize their research activities.
- Research should always be of the highest quality.
- Private-sector research should be free from state scrutiny.
- Research and education are linked.
- Research is a long term investment and should be considered in this context.

Principles Surrounding Clinical Research and the State's Implementation of Healthcare Reform

- Funding for research and patient care should be separately accounted for.
- Access to research by patients and physicians must be fostered.
- Funding for research should be available for any qualified institution.
- Since funding for research comes from many different sources, both inside and outside of the state, actions taken by the state should enhance the capability to access these funding sources.
- Administration of a research funding program should be feasible, simple, and inexpensive.
- A state-level "National Institute of Health" process should not be utilized.
- The costs clinical institutions incur in managing research should be considered a necessary component of the overall costs of the research activity.
- It is valuable to enhance linkages between the delivery and the achievement of innovation.
- Care that is clinically beneficial to patients should be paid for by third party payers at the rate for the usual care of a given condition.

Principles Relating to Conducting and Disseminating Research

- The results of research receiving the benefits of state research funds should be widely disseminated with a minimum of proprietary restriction.
- Appropriate mechanisms/internal policies should be in place at research organizations to avoid investigator conflict of interest.
- The current mechanisms in the research community for quality control must be recognized.

RECOMMENDATIONS ON RESEARCH

SUMMARY

Healthcare research is of great social value. However, we believe the strategies of cost containment will emphasize efforts to eliminate costs not required to provide care to the patient. This emphasis could have a dramatically negative impact on research currently funded by patient-care dollars. Therefore, we offer three major recommendations to protect this research:

RECOMMENDATION 1:

THE STATE SHOULD ESTABLISH A RESEARCH FUND TO REPLACE RESOURCES THAT ARE CURRENTLY AVAILABLE THROUGH PATIENT-CARE BASED FUNDING.

The use of resources generated by the fund should be consistent with the following guidelines:

1) Emphasize innovative investigations which explore early hypotheses and questions.
2) Leverage external funding (both in-kind and matching).
3) Avoid funding institutionally specific investigations.
4) Avoid supplanting existing external funding.
5) The research pursued with fund resources should be responsive to healthcare needs and be sheltered from direct political and popular influence.
6) All organizations receiving organizational funding from the Research Fund must at a minimum have a qualified Institutional Review Board (IRB) to assure safe, ethical treatment of human subjects.
7) Research results should be publicly reported but the nature and extent of the dissemination should be appropriate to the project.
8) The state should not become involved in prioritizing health research activities.

RECOMMENDATION 2:

DISTRIBUTIONS FROM THE RESEARCH FUND SHOULD BE ESTABLISHED BY STATUTE AND ADMINISTERED BY THE COMMISSIONER OF HEALTH CONSISTENT WITH OUR SUGGESTED ALLOCATION CRITERIA.

1) Distribution would be made in two categories: "organizational funds" which recognize significant research organizations; and "project funds" which would support specific research projects.
2) The share of organizational funds received by an institution shall be determined on a percentage basis formula and would be adjusted bi-annually.
3) Project funds should be awarded by the Commissioner of Health.
4) Appropriate auditing safeguards should be put in place by the Department of Health to ensure that the research which is pursued from the state fund is consistent with the statutory guidelines of the fund (as outlined above).

RECOMMENDATION 3:

THERE ARE PRINCIPLES WHICH MUST BE CONSIDERED WHEN FORMULATING THE SPECIFIC PLAN FOR GENERATING THE RESOURCES FOR THIS FUND.

1) The financing mechanism should be designed as rationally as possible to both improve initial acceptance and better assure continuity.
2) There should be predictability, stability and sufficiency of funding to achieve desired policy objectives.

RECOMMENDATIONS ON RESEARCH

RECOMMENDATION 1:

THE STATE SHOULD ESTABLISH A RESEARCH FUND TO REPLACE RESOURCES THAT ARE CURRENTLY AVAILABLE THROUGH PATIENT-CARE BASED FUNDING.

We define "unfunded" research as the costs of research not covered by external funding sources and instead covered by patient care dollars. Often these are the costs of clinical care for the underlying medical conditions that have generally been covered by third-party insurance[5].

We believe this fund is likely to be necessary because cost containment pressures will require greater attention by those involved in healthcare delivery and managed care to more precisely account for health services costs than has been the case in the past. Further, these pressures, and subsequent accounting will lead to the elimination of costs not necessary to provide care to the patient. Therefore, there will be no allowances for costs beyond the minimum required to deliver services -- such as for healthcare research. We believe health-related research has great social value that will require preservation through alternative means of funding.

THE UTILIZATION OF THE RESOURCES GENERATED BY THE FUND SHOULD BE CONSISTENT WITH THE FOLLOWING GUIDELINES:

1) **Emphasize innovative investigations which explore early hypotheses and questions**

"Impromptu investigations" as described by Robert Heyssel, the past president of The Johns Hopkins Hospital, are investigations that are "not supported by funded grants or even explicitly acknowledged"; rather, they are "simply funded through the introduction of inefficiency into the patient care process by lengthened operating room times, extra time spent in the radiology suite, or by use of other added resources in investigation, paid for by purchasers of medical care." This kind of research, which according to Heyssel, "*often leads to real innovation in clinical practice*" (emphasis added) is often first publicized through publication in peer-reviewed journals and subsequent translation into practice.[6]

2) **Leverage external funding (both in-kind and matching)**

If research costs are not covered by external funding, but the opportunity for achieving that type of funding exists, institutions should be encouraged to find and utilize such dollars with the knowledge that clinical care costs would be covered by the fund.

3) **Avoid funding institutionally specific investigations**

The proposed fund should avoid funding investigations that are primarily directed at quality improvement for a specific institution even though these investigations may currently be funded with patient care revenue. These investigations include continuous quality improvement for clinical processes improvement and outcomes studies designed primarily for institutional quality management. These investigations often have formal research protocols and they often generate new and generalizable knowledge for clinical science. Although this fertile area of delivery-system-sponsored investigation can be a rich source of new hypotheses for further investigation, it is primarily designed for internal use and, although of some value to clinical science, does not require or warrant State funding. The benefit of such investigations are first and foremost to the competitive advantage of the specific provider organization.

4) **Avoid supplanting existing external funding**

The proposed funding should complement, not supplant, existing external funding sources for healthcare research. The complementary role that the patient care funded portion of healthcare research often plays is in providing the in-kind and dollar match local contribution often favored or required by external sponsors.

5) **The research pursued with fund resources should be responsive to healthcare needs and sheltered from direct political and popular influence.**

The fund should work to ensure that the healthcare institutions maintain a broad and balanced perspective in determining the importance of their proposed projects. It should also be recognized that research and researchers are accountable. Trivial research must be avoided. Therefore, the funded organizations should demonstrate a capacity to conduct meaningful, and high quality research and to disseminate those results to the healthcare community.

6) **All organizations receiving funding from the Research Fund must have a qualified IRB to assure safe, ethical treatment of human subjects. In those cases where an institution does not have an IRB and an appropriate peer review process, it should have access to both.**

A qualified IRB assures the safe and ethical treatment of human subjects participating in research. An appropriate scientific peer review process ensures that the scientific merit of research projects will be high. For those institutions that are without these capabilities, we recommend that a system be established to provide access to a qualified IRB and scientific peer review process.

7) **Research results should be publicly reported but the nature and extent of the dissemination should be appropriate to the project.**

Since this fund is generated from community dollars and the research pursued will have implications to a broad area of healthcare, it is appropriate that the community have the opportunity to access the major findings that have grown out of its investment.

8) **The State should not become involved in prioritizing health research activities.**

The incentives created for those who deliver care to contain costs and improve quality will require healthcare institutions to explore a wide variety of research initiatives to achieve these goals. Given these incentives, and the difficulty for any entity to correctly predict the future, the State should not be in the business of imposing research initiatives. Further, the expertise and creativity that generate innovation requires that those who conduct research must be given significant latitude in the process of determining what questions are important and relevant. Hence, research institutions that receive "organizational funds" shall be solely responsible for prioritizing their research efforts and should remain financially accountable for their use of the research funds.

- 9 -

RECOMMENDATION 2:

DISTRIBUTIONS FROM THE RESEARCH FUND SHOULD BE ESTABLISHED BY STATUTE AND ADMINISTERED BY THE COMMISSIONER OF HEALTH CONSISTENT WITH OUR SUGGESTED ALLOCATION CRITERIA.

1) Distribution would be made in two categories: "organizational funds" which recognize significant research organizations; and "project funds" which would support specific research projects.

Substantially all of the moneys in the fund should be allocated to organizations approved to receive organizational funds, while the remainder may be allocated to fund projects from qualified organizations as detailed on page (9) item (6).

Organizational Funds

A. Organizations will be approved to receive organizational funds distributed by the Commissioner of Health if they meet the following criteria:

1. Operate as a hospital or healthcare provider which is exempt under section 501(c)(3) of the Internal Revenue Code of 1986 or is owned and operated under authority of a governmental unit;
2. Have a mechanism to avoid conflicts of interest as demonstrated by establishment of appropriate policies and review procedures;
3. Have an institutional review board operated in conformity with the standards of the Office of Protection for Research Risks of the National Institutes of Health, or other federal agencies, or have an established relationship with an organization meeting this criteria; and
4. Receive research funds awarded on the basis of a competitive, peer review process. The following funding sources for patient/clinical care research only may be used to meet this criteria:

   a) To the extent that historic and current levels of unfunded research conducted by the organization is measurable by agreed-to criteria, it shall be the determiner for the distribution of funds;

   b) However, in the absence of that determination the Commissioner shall use a distribution formula which considers a balance of the following:

   i: Historic and current levels of unfunded research conducted by the organization
   ii: Grant awards from federal agencies (National Institutes of Health, Department of the Army, etc.)
   iii: Grant awards from national voluntary health research organizations, and other national health policy foundations, with 501(c)(3) or 501(c)(6) non-profit status under the Internal Revenue Code of 1986

B. Once the total amount of unfunded research by approved organizations has been determined, a particular organization will get the percentage of the organizational funds that is consistent with their share of the total unfunded research.

C. Given that an organization's "unfunded" interest in and pursuit of research could shift over time, the share of the organizational funds received by an institution shall be adjusted bi-annually.

- 10 -

2) **Project funds should be awarded by the Commissioner of Health.**

These funds should be used to promote the goals of Minnesota's healthcare reform efforts.

3) **Appropriate auditing safeguards should be put in place by the Department of Health to ensure that the research which is pursued through state sponsorship is consistent with the statutory goals of the fund.**

Application of proven safeguards for appropriate use of government funds will be the responsibility of the Commissioner of Health and will draw upon systems and procedures already in place.

- 11 -

RECOMMENDATION 3:

THERE ARE PRINCIPLES WHICH MUST BE CONSIDERED WHEN FORMULATING THE SPECIFIC PLAN FOR GENERATING THE RESOURCES FOR THIS FUND.

1) **The financing mechanism should be designed as rationally as possible to both improve initial acceptance and better assure continuity. The financing plan should be based on the following conditions:**

   Because the benefit of this research often cannot be feasibly quantified or allocated to a particular stakeholder or when the benefit is long term, the benefit should be perceived as a societal good. Given this perspective, the costs should be allocated to the public. If the allocation of these costs to the public through direct approaches is not feasible (i.e. taxes) a funding mechanism should be utilized so that the broadest possible base of stakeholders can be identified to bear the costs.

2) **There should be predictability, stability and sufficiency of funding to achieve desired policy objectives**

   Since the research function, especially as it related to healthcare, is often a proposition which necessarily has long-term horizons, institutions will need to have a great degree of certainty of the fund's operation and commitment. Also, to have insufficient fund levels is to limit the potential for the achievement of most appropriate evolution of our healthcare system.

- 12 -

FUTURE ACTION

Significantly better data on the costs of research funded by patients must be generated for more informed decision making.

The criteria for determining the costs of unfunded research require careful exploration and explicit definition.

It is only through a more complete and accurate understanding of the costs of unfunded research to a particular institution and/or the state's healthcare system that the final question of the resources needed for this fund can be answered. It is imperative that this data be gathered with as much certainty as is possible.

In examining these costs, consideration needs to be given to a variety of elements such as historic dedication and productivity in research, time allocation, patient costs and charges, fixed institutional costs, and other factors.

ENDNOTES

[1]Louis Harris & Associates. Medical Research and Health Care Concerns: A Survey of the American Public. published in *Insight* (a newsletter of the Health Care Technology Institute, November, 1993).

[2]Louis Harris & Associates. Medical Research and Health Care Concerns: A Survey of the American Public. published in *Research America* (November, 1993).

[3]Reported by Robert M. Goldberg, in Letters to the Editor, *Wall Street Journal*. (November 8, 1993).

[4]Peters, W.P, Rogers, M.C. Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer. *New England Journal of Medicine* 1993; 330 (7):473 - 477.

[5]IBID.

[6]Heyssel , R. Constrained Resources in Medical Education and Research. *Health Affairs* 1984;3(4):110-116; as discussed in "Future Funding for Medical Education and Research in Minnsota: A Report to the Legislature and Recommendations for Continued Study," published by the Minnesota Department of Health, March 1994; p 21.

APPENDIX F

1999 MERC Statute, Minnesota Laws 62J.691, 62J.692, and 62J.693

Sec. 9. [62J.691] [PURPOSE.]

The legislature finds that medical education and research are important to the health and economic well being of Minnesotans. The legislature further finds that, as a result of competition in the health care marketplace, these teaching and research institutions are facing increased difficulty funding medical education and research. The purpose of sections 62J.692 and 62J.693 is to help offset lost patient care revenue for those teaching institutions affected by increased competition in the health care marketplace and to help ensure the continued excellence of health care research in Minnesota.

Sec. 10. [62J.692] [MEDICAL EDUCATION.]

Subdivision 1. [DEFINITIONS.]

For purposes of this section, the following definitions apply:
(a) "Accredited clinical training" means the clinical training provided by a medical education program that is accredited through an organization recognized by the department of education or the health care financing administration as the official accrediting body for that program.
(b) "Commissioner" means the commissioner of health.
(c) "Clinical medical education program" means the accredited clinical training of physicians (medical students and residents), doctor of pharmacy practitioners, doctors of chiropractic, dentists, advanced practice nurses (clinical nurse specialists, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives), and physician assistants.
(d) "Sponsoring institution" means a hospital, school, or consortium located in Minnesota that sponsors and maintains primary organizational and financial responsibility for a clinical medical education program in Minnesota and which is

accountable to the accrediting body.
(e) "Teaching institution" means a hospital, medical center, clinic, or other organization that conducts a clinical medical education program in Minnesota.
(f) "Trainee" means a student or resident involved in a clinical medical education program.
(g) "Eligible trainee FTEs" means the number of trainees, as measured by full-time equivalent counts, that are at training sites located in Minnesota with a medical assistance provider number where training occurs in either an inpatient or ambulatory patient care setting and where the training is funded, in part, by patient care revenues.

Subd. 2. [MEDICAL EDUCATION AND RESEARCH ADVISORY COMMITTEE.]

The commissioner shall appoint an advisory committee to provide advice and oversight on the distribution of funds appropriated for distribution under this section. In appointing the members, the commissioner shall:
(1) consider the interest of all stakeholders;
(2) appoint members that represent both urban and rural interests; and
(3) appoint members that represent ambulatory care as well as inpatient perspectives.
The commissioner shall appoint to the advisory committee representatives of the following groups to ensure appropriate representation of all eligible provider groups and other stakeholders: public and private medical researchers; public and private academic medical centers, including representatives from academic centers offering accredited training programs for physicians, pharmacists, chiropractors, dentists, nurses, and physician assistants; managed care organizations; employers; consumers and other relevant stakeholders. The advisory committee is governed by section 15.059 for membership terms and removal of members and expires on June 30, 2001.

Subd. 3. [APPLICATION PROCESS.]

(a) A clinical medical education program conducted in Minnesota by a teaching institution is eligible for funds under subdivision 4 if the program:
(1) is funded, in part, by patient care revenues;
(2) occurs in patient care settings that face increased financial pressure as a result of competition with non-teaching

patient care entities; and
(3) emphasizes primary care or specialties that are in under supply in Minnesota.
(b) Applications must be submitted to the commissioner by a sponsoring institution on behalf of an eligible clinical medical education program and must be received by September 30 of each year for distribution in the following year. An application for funds must contain the following information:
(1) the official name and address of the sponsoring institution and the official name and site address of the clinical medical education programs on whose behalf the sponsoring institution is applying;
(2) the name, title, and business address of those persons responsible for administering the funds;
(3) for each clinical medical education program for which funds are being sought; the type and specialty orientation of trainees in the program; the name, site address, and medical assistance provider number of each training site used in the program; the total number of trainees at each training site; and the total number of eligible trainee FTEs at each site;
(4) audited clinical training costs per trainee for each clinical medical education program where available or estimates of clinical training costs based on audited financial data;
(5) a description of current sources of funding for clinical medical education costs, including a description and dollar amount of all state and federal financial support, including Medicare direct and indirect payments;
(6) other revenue received for the purposes of clinical training; and
(7) other supporting information the commissioner deems necessary to determine program eligibility based on the criteria in paragraph (a) and to ensure the equitable distribution of funds.
(c) An applicant that does not provide information requested by the commissioner shall not be eligible for funds for the current funding cycle.

Subd. 4. [DISTRIBUTION OF FUNDS.]

(a) The commissioner shall annually distribute medical education funds to all qualifying applicants based on the following criteria:
(1) total medical education funds available for distribution;
(2) total number of eligible trainee FTEs in each clinical

medical education program; and
(3) the statewide average cost per trainee, by type of trainee, in each clinical medical education program.
(b) Funds distributed shall not be used to displace current funding appropriations from federal or state sources.
(c) Funds shall be distributed to the sponsoring institutions indicating the amount to be distributed to each of the sponsor's clinical medical education programs based on the criteria in this subdivision and in accordance with the ommissioner's approval letter. Each clinical medical education program must distribute funds to the training sites as specified in the commissioner's approval letter. Sponsoring institutions, which are accredited through an organization recognized by the department of education or the health care financing administration, may contract directly with training sites to provide clinical training. To ensure the quality of clinical training, those accredited sponsoring institutions must:
(1) develop contracts specifying the terms, expectations, and outcomes of the clinical training conducted at sites; and
(2) take necessary action if the contract requirements are not met. Action may include the withholding of payments under this section or the removal of students from the site.
(d) Any funds not distributed in accordance with the commissioner's approval letter must be returned to the medical education and research fund within 30 days of receiving notice from the commissioner. The commissioner shall distribute returned funds to the appropriate training sites in accordance with the commissioner's approval letter.

Subd. 5. [REPORT.]

(a) Sponsoring institutions receiving funds under this section must sign and submit a medical education grant verification report (GVR) to verify that the correct grant amount was forwarded to each eligible training site. If the sponsoring institution fails to submit the GVR by the stated deadline, or to request and meet the deadline for an extension, the sponsoring institution is required to return the full amount of funds received to the commissioner within 30 days of receiving notice from the commissioner. The commissioner shall distribute returned funds to the appropriate training sites in accordance with the commissioner's approval letter.
(b) The reports must provide verification of the distribution of the funds and must include:

(1) the total number of eligible trainee FTEs in each clinical medical education program;
(2) the name of each funded program and, for each program, the dollar amount distributed to each training site;
(3) documentation of any discrepancies between the initial grant distribution notice included in the commissioner's approval letter and the actual distribution;
(4) a statement by the sponsoring institution stating that the completed grant verification report is valid and accurate; and
(5) other information the commissioner, with advice from the advisory committee, deems appropriate to evaluate the effectiveness of the use of funds for medical education.
(c) By February 15 of each year, the commissioner, with advice from the advisory committee, shall provide an annual summary report to the legislature on the implementation of this section.

Subd. 6. [OTHER AVAILABLE FUNDS.]

The commissioner is authorized to distribute, in accordance with subdivision 4, funds made available through:
(1) voluntary contributions by employers or other entities;
(2) allocations for the commissioner of human services to support medical education and research; and
(3) other sources as identified and deemed appropriate by the legislature for inclusion in the fund.

Subd. 7. [TRANSFERS FROM THE COMMISSIONER OF HUMAN SERVICES.]

(a) The amount transferred according to section 256B.69, subdivision 5c, shall be distributed by the commissioner to clinical medical education programs that meet the qualifications of subdivision 3 based on a distribution formula that reflects a summation of two factors:
(1) an education factor, which is determined by the total number of eligible trainee FTEs and the total statewide average costs per trainee, by type of trainee, in each clinical medical education program; and
(2) a public program volume factor, which is determined by the total volume of public program revenue received by each training site as a percentage of all public program revenue received by all training sites in the fund pool created under this subdivision.
In this formula, the education factor shall be weighted at

50 percent and the public program volume factor shall be weighted at 50 percent.
(b) Public program revenue for the formula in paragraph (a) shall include revenue from medical assistance, prepaid medical assistance, general assistance medical care, and prepaid general assistance medical care.
(c) Training sites that receive no public program revenue shall be ineligible for funds available under this subdivision.

Subd. 8. [FEDERAL FINANCIAL PARTICIPATION.]

The commissioner of human services shall seek to maximize federal financial participation in payments for medical education and research costs. If the commissioner of human services determines that federal financial participation is available for the medical education and research, the commissioner of health shall transfer to the commissioner of human services the amount of state funds necessary to maximize the federal funds available. The amount transferred to the commissioner of human services, plus the amount of federal financial participation, shall be distributed to medical assistance providers in accordance with the distribution methodology described in subdivision 4.

Subd. 9. [REVIEW OF ELIGIBLE PROVIDERS.]

The commissioner and the medical education and research costs advisory committee may review provider groups included in the definition of a clinical medical education program to assure that the distribution of the funds continue to be consistent with the purpose of this section. The results of any such reviews must be reported to the legislative commission on health care access.

Sec. 11. [62J.693] [MEDICAL RESEARCH.]

Subdivision 1. [DEFINITIONS.]

For purposes of this section, health care research means approved clinical, outcomes, and health services investigations.

Subd. 2. [GRANT APPLICATION PROCESS.]

(a) The commissioner of health shall make recommendations for a process for the submission, review, and approval of research grant applications. The process shall give priority for grants to

applications that are intended to gather preliminary data for submission for a subsequent proposal for funding from a federal agency or foundation, which awards research money on a competitive, peer-reviewed basis. Grant recipients must be able to demonstrate the ability to comply with federal regulations on human subjects research in accordance with Code of Federal Regulations, title 45, section 46, and shall conduct the proposed research. Grants may be awarded to the University of Minnesota, the Mayo clinic, or any other public or private organization in the state involved in medical research. The commissioner shall report to the legislature by January 15, 2000, with recommendations.

(b) The commissioner may consult with the medical education and research advisory committee established in section 62J.692 in developing these recommendations or may appoint a research advisory committee to provide advice and oversight on the grant application process. If the commissioner appoints a research advisory committee, the committee shall be governed by section 15.059 for membership terms and removal of members. Minn. Stat. Sec. 62J.045 (1993)

To obtain additional copies of this report, please contact:

Minnesota Department of Health
Minnesota Health Information Clearinghouse
P.O. Box 64975
St. Paul, Minnesota 55164-0975
(651) 282-6314; (800) 657-3793
TDD (651) 215-8980

As required by Minnesota Statute 3.197: This report cost approximately $6,770.00 to prepare including staff time, printing and mailing expenses

If you require this document in another format, such as large print, Braille or cassette tape, call (651) 282-6314