DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

C.T. 1
Tech Transfer

Dr. Donald S. Fredrickson
Director, NIH

December 3, 1975

Norman J. Latker
Patent Counsel, OS/GCB/DHEW

Definition of "Technology Transfer"

I have noted with some discomfort that the term "technology transfer" is being defined in differing and sometimes conflicting ways at NIH. I think this is unfortunate since it adds to the problems of enhancing technology transfer.

Attached is a recent article which I believe defines technology transfer as it is generally understood in the University sector and my office. This article discusses the problems of "transferee" and "transferer" in a particularily sensitive manner and I would recommend that interested staff review it.

I have underlined the sections of the article which I believe are still a problem at NIH.

Enclosure

cc: Mr. Storm Whaley, w/attachment
Dr. Leon Jacobs " "
Mr. Leon Schwartz " "
Dr. Lamont-Havers " "

DHEW/OS/GCB NJLatker:cam 12/9/75

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

I.

INTRODUCTION

This report contains the results of a study of current and future systems by which knowledge, developed by the bioscientific community in general and the National Institutes of Health in particular, is made available or could more effectively be made available, to the public, to practicing physicians and other health professionals, and to research scientists.

As part of this report, an analysis is presented of the processes by which new and useful bioscientific knowledge is currently assembled, presented and conveyed to those who can make advantageous use of it. Finally recommendations are offered of how those informational systems can be improved, enhanced and expanded, and other innovations developed, with the ultimate goal of making the highest quality of health care available to all.

It is clear that the National Institutes of Health is called upon to provide leadership in communicating the results of

biomedical research.

The public has an increasing awareness of the importance of research and its relationship to better health. As the principal focus of Federal biomedical research the NIH is expected to be a source of reliable and timely information about health, the concern of every citizen. The Congress has recognized this public expectation by making special provision in the National Cancer Act of _____ and the National Heart, Blood Vessel, Lung and Blood Act _____ for public and professionally oriented information programs. Other more recent Acts (Arthritis, Diabetes) have similarly stressed dissemination of information.

The role of NIH in communication of research results to the health professional community must be re-examined in the light of recent and prospective developments concerning patient care in which the Federal government has an important role, as for example PSRO's, Area Health Education Centers, and National

Health Insurance. Another consideration is the termination of Federal support for Regional Medical Programs. Continuing education of health professionals and the transmission of research results from the laboratory to the bedside were the principal missions of the Regional Medical Program Service.

The NIH has always been a leader in promoting and facilitating communication within the scientific community. Through the National Library of Medicine it continues to pioneer in new uses of technology to store, retrieve and transmit scientific information for the use of health professional schools, practitioners, and biomedical scientists.

Because of its close collaboration with academic medical centers, the NIH has also been an important channel of communication for health science educators and through them to practitioners. Mechanisms for direct communication to the practicing health professional are now being established in specific categorical

areas (cancer, heart disease). This report and its recommendations deal with communication of information comprehending all areas of progress in biomedical research, not only to the professional but, as appropriate, to the public as well.

In Section II of this report the uses of biomedical research information are analyzed and the means now being used to communicate its substance are described. The analysis points out the kinds of information which are needed and utilized by three general groups - members of the public, the practitioners, and the scientists.

Section III contains _____recommendations for improving the dissemination of research findings, and proposes the establishment of a permanent organizational unit to continuously study and lead in carrying out additional activities.

In Section IV the current efforts of the NIH in disseminating research-derived information to the public, to the health professional and the scientific community are enumerated.

II. COMMUNICATING THE RESULTS OF BIOMEDICAL RESEARCH

All of the research conducted by or supported through the National Institutes of Health is undertaken in the expectation that it will ultimately contribute to the development of better preventive, diagnostic or therapeutic measures. Good communication is essential to the realization of these expected benefits.

At every step in the progression from laboratory investigation of a research question to an innovation in health care, communication links are required. The needs are different at the different stages, and the useful means of communication differ accordingly.

This report addresses three critical communications linkages:

scientist to scientist

scientist to practicing health professional

scientist to the public

In analyzing currently used and proposed means for communication it is necessary to distinguish between the kinds of information needed by and useful to the intended recipient.

Scientist to Scientist Communication

In any given year thousands of research findings are reported by the individual investigators responsible for them.

Such reported findings are, in the main, new increments of knowledge which lead to better understanding of larger questions. These findings are the raw materials out of which, in time through refinement and combination with other findings new means of treatment, diagnosis or prevention will be developed.

New measures for health care almost invariably are the culmination of a long series of incremental steps. The "family trees" of such innovations usually have many branches. It is virtually impossible for an individual investigator to successfully pursue a research question from its conception to the development of an applicable means for therapy without reference to the work of other scientists. Communication among scientists is essential to the process of research.

Scientist to scientist communication is accomplished in

many different ways. There is constant informal interchange within larger research institutions. A prime example of such informal communication takes place within the NIH advisory systems. The study sections of the National Institutes of Health not only serve to review applications, but also provide a significant amount of scientific communication among leaders in biomedical research from all parts of the country. Some 1500 members of the study sections meet three times per year at NIH. The effectiveness of this informal exchange is enhanced through the fact that membership on the study sections changes from year to year with 350-400 new members being appointed annually as replacements for those whose terms end.

Many professional meetings are held each year among scientists in the various disciplines. In addition to the formal presentations at the meetings, the informal communications among peers are extensive and important.

Formal communication, scientist to scientist is carried on principally through the so-called "scientific literature," the scholarly and scientific journals in which detailed reports of research are published. In many instances important findings are reported by the researcher to his colleagues at scientific meetings and subsequently published. It is unusual for a research finding to be reported initially to other than the scientific community. This tradition provides an important safeguard against the further dissemination of unfounded or premature announcements and helps to avoid wasteful or possibly dangerous use of erroneous findings. The safeguard results from the fact that respected journals require that research papers be subjected to critical review as a condition of publication. Similarly, presentation of a paper to a scientific meeting subjects the author to the questioning and critical judgment of his peers.

Scientific literature has two uses:

1. as a mechanism for communicating new results; and

2. as a repository of data which at a later date may be picked up again and used in new ways which had not been thought of at the time of the original publication. The recombination of existing data to provide new insights is an important resource for the scientist.

It is our view that even though the traditional formal methods for scientist to scientist communication entail some delay, the advantages of critical review built into the system outweigh the disadvantages which may result from the time required for it.

We do not propose any alternative short cuts in the basic methods for communication within the research process, i.e. scientist to scientist communication. We emphasize, however, the need to continue the refinement and expansion of existing systems for storage and retrieval of research data, and for the development of new methods which will improve the scientists' access to such material. The experience and capability of the National Library

of Medicine offer great service and potential in this essential activity. The overall mission of the National Library of Medicine is the efficient and effective assembly, analysis, and distribution of biomedical information. It has been a pioneer in the systematic application of computer technology to the general problems of the storage, retrieval and distribution of general biomedical information. The Library has applied these advanced retrieval and distribution systems to the transfer of specialized data to selected populations of users.[1]

Communication of Research Findings for use by Health Professionals

The output of biomedical research, in terms of individual findings, covers a very broad spectrum ranging from discoveries at the frontiers of biology to readily applicable means of disease prevention, diagnosis or treatment.

Each element in the array of findings is useful, either

---

[1] For description of systems see Appendix ____

to the research scientist or the clinician or to both. However, the busy practitioner not only would be inundated by the sheer volume if the full output of published results were channeled to him, but would not have time to identify that part of it which might be applicable to his practice. For this reason it is essential that there be a sorting-out process, and that communication efforts be concentrated on the relatively small portion of research output which is ready for use by the health professional in patient care. Such selection and dissemination is taking place in a great variety of ways. There are many channels of communication to the practicing professional, some highly structured, others are patterns of custom.

Academic medical centers are key communicators. They take seriously their responsibility for the continuing education of their graduates and in many instances for health professionals practicing in their geographical area. Specialty and professional

organizations support many individual programs of continuing education as well.

While we have no evidence that research findings of clinical significance are languishing in the laboratory, we recognize that there are gaps in communicating research results from the laboratory to the bedside. The improvement of continuing education of health professionals deserves additional attention and stimulation. We do not believe that the NIH is the instrumentality through which a comprehensive program of this nature should be carried out, or that it should attempt to develop and maintain a complete communications system for conveying the benefits of research from the laboratory to the health professional. To do this would so divert manpower and funds from biomedical research as to seriously weaken that effort.

We should make sure, however, that NIH is doing the things it is best qualified to do to facilitate the communication of

applicable research findings. Such activities include special efforts to assure that there be no delay or omission in reporting broadly the findings that are ready for use, and the stimulation of research on the process of biomedical communication itself.

The National Library of Medicine has recognized that health professionals who are primarily concerned with research, education or health care delivery do not have easy access to competent, unbiased advice about possible technological solutions to many of their communication problems. Within the National Library of Medicine there are two organizational components whose purposes are to provide the health professional with the most recent advances in communication and technology and in the use of non-print media of information transfer and learning systems. These special organizational components are the Lister Hill National Center for Biomedical Communications and the National Medical Audiovisual Center.

Communication of "Developable" Research Findings

New biologicals, pharmaceuticals or devices discovered through research must pass through development, testing, and production stages to be available in usable form and in sufficient quantity for patient care.

In such instances the pharmaceutical and other health related industrial organizations have an obvious interest in knowing of promising research results. The channels of communication for disseminating developable research results to producers are generally effective. However we believe improvements are possible.

It should be noted that in addition to information, the potential producer must have incentive and be able to forecast a reasonable return for investment in development, testing, and production. The patent policy of the government with respect to products which emerge from federally supported research can be a critical issue in a company's decision to proceed with production. At this time a key case is before the courts on this question.

Whatever the outcome we believe that the NIH should take steps to assure the alerting of industry to research findings which have potential for development and beneficial use.

There are many formal as well as informal interrelationships among research scientists employed by industry and those who work in academic health centers in the government. Industry engaged in fundamental research as well as developmental.

Communication of Research Results to the Public

The general public has at least three levels of interest in reports of research findings from the National Institutes of Health, and the scientific community.

They are entitled to know, as taxpayers, of the activities of NIH, its policies, perception of mission and accomplishments.

The general progress of biomedical research and its significant findings, basic and applied, are matters of widespread and increasing interest.

Certain findings and their informational background are of direct benefit to the public and may be acted upon without initial assistance from a health professional. To acquaint the public with such information local and state governments as well as various agencies of the Federal government engage in a large number of programs of health education for the general public.

The voluntary health agencies (e.g. American Cancer Society, American Heart Association) play an extremely important role in health education. Hundreds of thousands of volunteers acquire knowledge about specific diseases and through them as well as the advertising campaigns sponsored by the agencies a major fraction of the nation's population is provided basic information about certain of the principal threats to health.

A large volume of substantive information on health is provided directly to the general public by the National Institutes of Health in the form of responses to mail and telephone inquiries, through regular newspaper columns, radio and

television broadcasts, and exhibits.*

The newly established Bureau of Health Education, a part of the Public Health Service Center for Disease Control, has the mission of coordinating Federal efforts in health education, and is a focal point for government cooperation with private organizations engaging in such activities.

Improving the Dissemination of Research Results

In Part III of this report specific recommendations are made for a plan of action to improve the communication of research information. The recommendations are based on the Committee's analysis summarized above. The Committee has been provided extensive information and advice from the constituent Bureaus, Institutes and Divisions of NIH and the other agencies of the Public Health Service. We have conferred with principal officials of the American Medical Association, the Association of American

---

* See Part IV for a summary of current NIH health education.

Medical Colleges, the Federation of American Societies of Experimental Biology, the research heads of three large pharmaceutical manufacturers and various officials of institutions engaged in innovative biomedical communication activities.

An article regarding the activities of the Committee was published in the FASEB Newsletter in December and numerous suggestions were received from its scientist members.

It is apparent that there is no single formula for improvements in biomedical communication, nor is it possible for an ad hoc committee to generate a long range comprehensive plan of action. We have recommended several specific actions as beginning steps but our most important recommendations call for the establishment of a permanent office within NIH concerned directly with research communications, and for increasing the resources of the communications arms of the National Library of Medicine. The new unit and the NLM together will continue to study needs for improvement, seek and evaluate new methods and channels for

communication, and promote cooperative efforts with other Federal and non-federal agencies in carrying out the dissemination of research information.

III. RECOMMENDATIONS FOR ACTION PLAN

1. Organizational

The Committee recommends the establishment of a permanent organizational office to assist the Director, NIH in improving the dissemination of research information and in promoting efforts to that end in collaboration with other public and private agencies.

It further recommends that the National Library of Medicine be provided additional resources to develop new and expanded programs for communication with the scientific and professional communities.

2. Specific Action Plans

As initial steps in improving the dissemination of research information the committee recommends that:

A. NIH prepare and arrange to publish in media widely used by physicians and other health professionals, a brief monthly review of the latest research advances selected on the basis of their current clinical significance.

B. NIH initiate pilot studies to test the feasibility of establishing comprehensive regional information centers to provide telephonic consultative service for practicing health professionals.

C. NIH take all steps necessary to assure its maximum participation in development and use of new communications technology, particularly in connection with the Communications Technology Satellite.

D. NIH increase its present output of audiovisual materials for general public health education through radio and television.

E. NIH conduct a series of national workshops on information needs of scientists, health practitioners and the general public for the purpose of reviewing existing means for disseminating research information, identifying needed improvements and suggesting steps for their implementation.

In the discussion section below suggestions are advanced for further study by the proposed permanent organizational office.

Discussion of Recommendations

1. The permanent organizational office

While each component of the NIH provides research information to its users through multiple channels the proposed central office will have communication as its principal concern. As a Director's staff office it will

a) be responsible for organizing functional groups to maintain continuous surveillance of biomedical research results for the purpose of identifying findings ripe for development or application; prepare reports on such findings; and disseminate them to developmental laboratories and practicing health professionals. The National Library of Medicine will be the principal action agency for communication of prepared materials;

b) recommend to the Director the nature and composition of exterior advisory groups to assist in developing and maintaining means for effective communication of research information;

c) collaborate with the National Library of Medicine in evaluating NIH's research information dissemination activities;

d) seek and conduct trials of additional methods for improving communications with the various target audiences.

The Ad Hoc Committee on Dissemination of Research Results suggests that the permanent office investigate:

1) The feasibility of launching another public effort similar to the apparently successful National High Blood Pressure Program. (Are there other widespread problems which can be attacked by a combined public-professional campaign?)

2) The possibility of giving a "sur-grant" to NIH supported institutions for the purpose of information dissemination. (On what basis should such funds be made available? What amounts?)

3) The feasibility of setting up a quasi-governmental non-profit organization to hold Federally acquired patents on biologicals, pharmaceuticals, and medical devices, to provide funds or arrange for their development and thus to expedite the production of

3) The possibility of making more use of existing NIH contract authority for the development of new products (biologicals, pharmaceuticals and medical devices) under Federally held patents. This mechanism might be used when the innovating organization does not wish to, or is not capable of proceeding with the development of needed products resulting from Federally supported research and in instances where costs discourage their development. The permanent office may also wish to investigate the feasibility of establishing a quasi governmental non-profit organization to hold Federal patents and arrange for their development.

innovations in instances where patent questions or development costs discourage commercial development.

The National Library of Medicine

The mission of the National Library of Medicine encompasses many of the activities related to the dissemination of research information.

One unit of the NLM, the Lister Hill National Center for Biomedical Research was established to provide assistance to health care professionals with problems in biomedical communication, especially those problems amenable to possible solution by the application of computer and communications technologies. The Center has many contacts with the medical community. It has operational experience with the development of communication networks. The purpose of the biomedical communications network is to connect sources of medical knowledge with those who need that knowledge. There in an inevitable tendency for sources of medical knowledge to become more concentrated. There is an equal and opposite tendency for the need for such knowledge to become more widespread. Whenever and wherever possible, within

the limits of the available technologies and the real needs of the various communities, the Center hopes to substitute the swift and certain transmission of electrical messages for the slow and expensive movement of people.

Another component of the National Library of Medicine is the National Medical Audiovisual Center (NMAC) which provides a national focus for the best use of nonprint informational materials by the entire community of health professionals. NMAC is skilled in technical development, evaluation, production and distribution of audiovisual materials needed by those whose primary concern is with the training of health professionals.

There exists, therefore, within the National Library of Medicine a wide array of information systems and communication linkages. The Library has a significant number of technological experts who are in daily working contact with other experts in biomedical research and the delivery of health care services.

The foundation exists on which with additional resources it would be possible to build on a long term basis a series of communication linkages and networks which can be both efficient and effective in distributing the fruits of research efforts of the NIH to appropriate audiences for application.

2. Discussion of specific recommendations

a) Monthly research reviews

The target audience for the monthly research reviews will be the practicing physician. For this reason the subject matter will be confined to topics immediately relevant to medical practice. The reviews should be brief, readable and candid and will include a concise summary of the state of knowledge in the subject field. Footnote references will identify source materials and extended reports for readers wishing to pursue the subject in depth.

After careful consideration the Committee concluded that at this time our efforts should be concentrated on better use of

existing information channels. The publication of a new journal was proposed and rejected because we believe the busy practitioner can be reached more efficiently and effectively through media on which he normally relies. For the same reason it was decided not to recommend an NIH Newsletter to physicians.

The ad hoc committee has made preliminary arrangements for monthly publication of the reviews in the Journal of the American Medical Association.

The permanent office on dissemination of research results should carefully evaluate the effectiveness of the monthly reviews and seek a wide range of outlets for such material, in the printed media as well as through established audiovisual services now being used widely. Contacts have been made with producers of libraries of audio cassettes for physicians. We are confident that such libraries would welcome NIH input.

The National Library of Medicine's Regional Medical Library Network can serve as additional distribution centers both for the

research reviews and the source materials on which they are based.

One of the principal advantages of the monthly review lies in the fact that it will require regular preparation of current research information in readily useable form. Reprints of the reviews should be provided regularly to all academic medical centers, Area Health Education Centers, Professional Service Review organizations, county and state medical societies and to other professional groups.

When the subject matter of the review is appropriate to an individual specialty journal it can become the base of material for their use.

It will be necessary to establish an NIH wide "editorial board" to assist the permanent office on dissemination in selecting topics for the reviews, and for advice on their content and style.

b) Pilot studies on regional centers for consultation by telephone

The committee was impressed by the practicality and usefulness of some of the various systems now in operation which make it possible for practicing health professionals to consult by telephone with specialists in academic and research centers. Some of these systems are limited to specific categories of disease, a few are comprehensive. Some offer brief taped informational discussion on a wide range of topics, and others offer direct professional-to-professional consultation.

A successful comprehensive program for consultation is operated by the University of Alabama Medical Center, Birmingham. A telephone network (statewide incoming wide area telephone service) makes it possible for Alabama physicians, dentists, nurses, hospital administrators, optometrists and other health professionals to have quick access for consultation with members of a large panel of specialists at the medical center. The service was initiated in 1969 by the Alabama Regional Medical Program. Its value to the Alabama professional community is evidenced by its 10-fold

increase in use from an average of 46 incoming calls per week in 1969-70 to a weekly average of 459 in 1973-74. The average call is completed in less than five minutes from the time the calling professional dials the toll-free access number.

Of the some 2000 Alabama physicians outside the Birmingham area, 1500 are users of the service and many are in counties having few physicians.

The service is enthusiastically supported by the senior faculty members of the medical school who volunteer for service in the system and largely make up the on-call panel. When Regional Medical Program funds were no longer available for the service, the Alabama Legislature appropriated funds for its core support. The annual total cost is approximately $100,000.

At least nine other institutions or regional consortiums have plans for systems which are similar in whole or in part to that operated in Alabama.

The National Cancer Program is in the process of establishing communications systems as adjuncts to its 17 comprehensive cancer centers and in a number of settings the plans call for telephone networks for consultations.

In addition NIH supports a wide variety of categorical disease centers, spread throughout the nation. Study should be given to means for making them more readily accessible to practicing health professionals in their respective regions. Would it be practical to link the various categorical centers into a regional network to provide comprehensive consultation?

A number of specialized diagnostic centers also engage in informational as well as service activities. A good example is the Viral Diagnostic Service at Georgetown University Medical Center, supported jointly by the University and the National Cancer Institute. The Service has developed an integrated system of services for meeting the needs of health care providers and research organizations in the mid-Atlantic Region. These

services include laboratory testing for viral agents, medical consultation, test development, training, dissemination of information about research results and a range of support services. As of the end of 1974 over twenty institutions in the region were regular users of the Service along with a number of physicians in specialist and general practice. The information dissemination and consultation services have been useful particularly for physicians in general practice.

The Committee emphasizes the importance of exploring the possibility of expanding telephone consultation services. They offer a simple, direct channel for communicating new specialized knowledge to the practitioner at the time he can make use of it in the treatment of a patient.

The Committee is aware that other agencies of the Public Health Service have had successful experience in the use of communications for health professional education and in the delivery of service. A notable example is the Washington,

Alaska, Montana and Idaho (WAMI) program. A great many ideas were tested by Regional Medical Programs, and the records of its programs are a valuable resource.

It should be determined which agency of the Public Health Service is the most appropriate and best qualified instrumentality for taking the lead in fostering pilot studies in the different areas discussed herein. The NIH should actively promote inter-agency consultation and early implementation of the studies.

c) Steps to assure maximum participation in development and use of communications technology, particularly the Communication Technology Satellite.

The National Library of Medicine has recommended further development of three modes of biomedical communication all of which are capable of improving scientist-to-practitioner information transfer. They are:

1. Computer Assisted Instruction - programs in continuing post graduate education for health practitioners and

administrators, the content based on systematic audits of professional audits and practice patterns. This mode of communication would be particularly helpful in connecting the regional demonstration centers now supported by NIH with area health education centers and large community hospitals;

2. Audiovisual Learning Package - up-to-date definitive information on specific clinical subjects for targeted populations as an instrument for continuing health professional education and for public information;

3. Broadband Communications using satellites and other means of audiovisual communications.

Plans are now being made by the Lister Hill National Center for Biomedical Communications in conjunction with the National Aeronautics and Space Administration for use of the Communications Technology Satellite (CTS) scheduled for

launch in December 1975.

Nine hours per week have been reserved on the CTS for use by health related programs. The NIH has requested a tentative reservation of two hours per week.

The CTS will begin service in September 1976. The satellite is a joint U.S.-Canadian project. Its transmitters are more powerful than those carried on previous experimental satellites and it will be positioned so as to be capable of serving practically all of the continental United States. Because of its power the cost of ground receiving equipment will be relatively modest (estimated $20,000 per unit).

The Lister Hill Center's objectives in participating in the use of the satellite as stated to NASA are:

To promote wider dissemination of medical information between research institutions and the practicing community and,

To evaluate broadband teleconferencing networks as a

tool for continuing education among health professionals. The Center plans to acquire two units capable of color video and multichannel audio transmission and reception. One of the units will be based in Bethesda, the other will be a mobile unit which will permit interactive conferences between scientists at NIH and other scientists at medical centers and professional meetings.

"State of the Art" conferences can be braodcast to all medical schools, hospitals which are equipped with receiving equipment.

The University of Washington Medical School, which has been making use of the ATS-6 satellite will participate in the CTS experiments. The Association of Western Hospitals plans to use the CTSin conjunction with an established network and relay its transmissions to a large number of hospitals on the West Coast. The Veterans Administration hospitals are scheduled to begin participation in CTS activities in its second year

of operation.

The CTS is designed to have an active life of two years, though experience with similar units predicts a longer period.

All uses of CTS will be carefully evaluated, and it is expected that much knowledge will be gained on the most effective use of satellites for biomedical communication.

d) NIH increase its output of audiovisual materials for general public health education through radio and television.

NIH's regular programs of direct public health education through the electronic media have largely been confined to the use of public service announcements for radio. A disc containing 20 recorded announcements is sent quarterly to 1200 radio stations. In addition "live copy" is mailed to 1,000 stations.

The content of these announcements has largely been confined to promotion of printed leaflets prepared by the various Institutes on common health problems.

The Committee recommends that a larger proportion of the material prepared for radio be substantive, i.e. that it convey more health information of immediate use to the listeners.

It is further recommended that new discs, tapes, and copy be provided to radio stations more frequently, because we believe that "fresher" material is more likely to be used.

Through coordination with the permanent office on dissemination, tape recordings can be prepared for television and radio use on the subjects covered in the monthly research reviews, using the scientists whose work is reported.

Public service announcements for television use should be produced on a regular schedule. When resources permit at least one per month should be produced on tape or film and be made available to all television stations.

The list of subjects to be covered in radio and television public service announcements should be provided by or coordinated with the permanent office for dissemination.

subjects covered in the monthly

e) Conduct a series of national workshops

As a part of its effort to develop and maintain systems for effective communication the permanent office for dissemination, through the National Library of Medicine should, within the calendar year, conduct workshops involving leaders from the biomedical research community including industry, the academic community, the health professional community as well as communication experts. The purpose of the workshops will be to define informational needs and to devise improved means for meeting them.

The Committee recommends that plans for such a workshop on public health education be explored with the Bureau of Health Education, CDC as a joint activity with NIH, in order to better define the most effective role of NIH in this sphere. Representatives of consumer organization, voluntary health organizations, the public media and the general public should participate along with research scientists and agency officials.

Director, NIH
Through: DS/NIH

November 26, 1975

Deputy Director for Science

The Gap in Technology Transfer

File 251

After listening to many discussions of the technology transfer problem, I am driven to the following conclusions. The principal clients of the NIH are the medical schools, the teaching hospitals, and the life science departments of the universities. Between these applicants and the NIH there is, I believe, no significant information barrier. There is a free flow of information in both directions, and anything which is known at either end of the channel can fairly promptly be ascertained at the opposite end. Furthermore, I believe that there is quite free transfer of information between the several applicant institutions. Thus, what is known today at Harvard will be known at Yale early tomorrow morning.

The gap in the transfer of medically potentially useful information lies, I believe, between the medical schools-teaching hospitals on the one hand and the physicians in practice on the other. The medical schools and teaching hospitals are specifically designed to provide medical education; they are staffed for this purpose and they perform the job very well. It is unfortunate, however, that they usually concentrate on the four pre-doctoral years and the three to five postdoctoral years, leaving what happens beyond this point largely to chance encounter. Some schools make a very conscious and effective effort in the field of continuing education but these are, I believe, still in the minority. Nonetheless, the medical school and its teaching hospital are the institutions best equipped to assume this responsibility.

Attention is directed to the Morrill Act which was passed during the Civil War to establish the Land Grant Colleges. It is my recollection that the terms of this Act provided that in each State no more than one college should be selected and endowed with a parcel of Federal real estate. In exchange for this award, the school undertook to provide services particularly to the farmers and the manufacturers of the community. The selected colleges in general created agriculture schools and engineering schools for this purpose. Agricultural agents were retained who were in part faculty members of the agriculture school and in part the counselors and teachers to the farmer. Every farmer thus had the opportunity of becoming attached to the agriculture school of his regional land grant college, and in large numbers the farmers availed themselves of this opportunity. Perhaps to a somewhat lesser degree the manufacturers also had the opportunity of associating with the regional engineering schools.

While I was at Rutgers, I had the opportunity to watch the operation of this school of agriculture-agricultural agent-farmer association. I can attest that it was a very successful operation. The close association of the Rutgers tomato and the Campbell Soup Company to the State of New Jersey is a direct consequence of this kind of association. The farmer is kept very well informed of recent developments and has a point of reference for all questions of a technical nature which arise in his work.

With this as a model, I would like to suggest the consideration of the establishment of "Health Grant Colleges." Let us assume that no more than one medical school in each State, or major segment thereof, is so designated. It should then enter into a contract with an appropriate branch of the Federal Government, possibly the Health Resources Administration, in which that medical school undertakes to provide professional medical expertise to the physicians of the region. Such experts would be members of the faculty of the medical school but would spend a considerable portion of their time in maintaining a system of continuing education for the physicians of the neighborhood. This I would conceive as variously situated in the community hospitals, in the county medical societies, and on the medical school campus. The agent might well simultaneously occupy the position of director of medical education at a community hospital, or chairman of the program committee of a county medical society. He would have regular hours during which he would be available to any physician in the area who might need his advice. He would, in turn, secure for such a physician the best available information from his medical school colleagues. In exchange for all of these services, the school would be reimbursed by the Federal agency in charge to the extent of the salaries, travel expenses, and incidental costs of the program described. I believe that in some such way a realistic correction of the information gap could well be achieved and an increasing participation by the physicians of the community in the doings of one of their medical schools would result.

The medical school of the University of Kansas, Kansas City, has worked out a solution for its continuing education problem which is not unlike that described above. It offers some forty 5-day seminars each year, available to physicians of the neighborhood. It also provides visiting teams of doctors who make rounds among the outlying communities of the State. From an occasional visit to this State, I conclude that the system works quite well.

Through the channel of the land grant college and the agricultural agent, the American farmer is kept well informed of advances in agricultural science. The mechanism initiated by the Morrill Act has undoubtedly paid off very well. It could serve as a model for the comparable problem of continuing education for the physician. The happy day might actually arise when the health sciences agent of the health grant medical school will

replace the detail man of the pharmaceutical manufacturer as the most available and the most accurate source of new knowledge and new information to the practicing physicians of the United States.

DeWitt Stetten, Jr., M.D., Ph.D.

NIH/OD:DStetten/nh

Director, NIH
Through: ES/NIH___

November 26, 1975

Deputy Director for Science

The Gap in Technology Transfer

File

After listening to many discussions of the technology transfer problem, I am driven to the following conclusions. The principal clients of the NIH are the medical schools, the teaching hospitals, and the life science departments of the universities. Between these applicants and the NIH there is, I believe, no significant information barrier. There is a free flow of information in both directions, and anything which is known at either end of the channel can fairly promptly be ascertained at the opposite end. Furthermore, I believe that there is quite free transfer of information between the several applicant institutions. Thus, what is known today at Harvard will be known at Yale early tomorrow morning.

The gap in the transfer of medically potentially useful information lies, I believe, between the medical schools-teaching hospitals on the one hand and the physicians in practice on the other. The medical schools and teaching hospitals are specifically designed to provide medical education; they are staffed for this purpose and they perform the job very well. It is unfortunate, however, that they usually concentrate on the four pre-doctoral years and the three to five postdoctoral years, leaving what happens beyond this point largely to chance encounter. Some schools make a very conscious and effective effort in the field of continuing education but these are, I believe, still in the minority. Nonetheless, the medical school and its teaching hospital are the institutions best equipped to assume this responsibility.

Attention is directed to the Morrill Act which was passed during the Civil War to establish the Land Grant Colleges. It is my recollection that the terms of this Act provided that in each State no more than one college should be selected and endowed with a parcel of Federal real estate. In exchange for this award, the school undertook to provide services particularly to the farmers and the manufacturers of the community. The selected colleges in general created agriculture schools and engineering schools for this purpose. Agricultural agents were retained who were in part faculty members of the agriculture school and in part the counselors and teachers to the farmer. Every farmer thus had the opportunity of becoming attached to the agriculture school of his regional land grant college, and in large numbers the farmers availed themselves of this opportunity. Perhaps to a somewhat lesser degree the manufacturers also had the opportunity of associating with the regional engineering schools.

While I was at Rutgers, I had the opportunity to watch the operation of this school of agriculture-agricultural agent-farmer association. I can attest that it was a very successful operation. The close association of the Rutgers tomato and the Campbell Soup Company to the State of New Jersey is a direct consequence of this kind of association. The farmer is kept very well informed of recent developments and has a point of reference for all questions of a technical nature which arise in his work.

With this as a model, I would like to suggest the consideration of the establishment of "Health Grant Colleges." Let us assume that no more than one medical school in each State, or major segment thereof, is so designated. It should then enter into a contract with an appropriate branch of the Federal Government, possibly the Health Resources Administration, in which that medical school undertakes to provide professional medical expertise to the physicians of the region. Such experts would be members of the faculty of the medical school but would spend a considerable portion of their time in maintaining a system of continuing education for the physicians of the neighborhood. This I would conceive as variously situated in the community hospitals, in the county medical societies, and on the medical school campus. The agent might well simultaneously occupy the position of director of medical education at a community hospital, or chairman of the program committee of a county medical society. He would have regular hours during which he would be available to any physician in the area who might need his advice. He would, in turn, secure for such a physician the best available information from his medical school colleagues. In exchange for all of these services, the school would be reimbursed by the Federal agency in charge to the extent of the salaries, travel expenses, and incidental costs of the program described. I believe that in some such way a realistic correction of the information gap could well be achieved and an increasing participation by the physicians of the community in the doings of one of their medical schools would result.

The medical school of the University of Kansas, Kansas City, has worked out a solution for its continuing education problem which is not unlike that described above. It offers some forty 5-day seminars each year, available to physicians of the neighborhood. It also provides visiting teams of doctors who make rounds among the outlying communities of the State. From an occasional visit to this State, I conclude that the system works quite well.

Through the channel of the land grant college and the agricultural agent, the American farmer is kept well informed of advances in agricultural science. The mechanism initiated by the Morrill Act has undoubtedly paid off very well. It could serve as a model for the comparable problem of continuing education for the physician. The happy day might actually arise when the health sciences agent of the health grant medical school will

replace the detail man of the pharmaceutical manufacturer as the most available and the most accurate source of new knowledge and new information to the practicing physicians of the United States.

DeWitt Stetten, Jr., M.D., Ph.D.

NIH/OD:DStetten/nh

August 5, 1975

Mr. Frederick S. Hiatt
Children's Defense Fund of [illegible]
Washington Research Project, Inc.
1520 New Hampshire Avenue, N.W.
Washington, D. C. 20036

Dear Mr. Hiatt:

I am writing this in response to your letter of May 19, 1975 requesting Section I and those portions of Section II which include the research plan or protocol and progress report, if any, of the most recently approved Type 1 or Type 2 grant applications, of 40 identified funded grants.

The grantee and the principal investigator in Grant No. AI-11116, which was submitted by the [illegible] University Hospital, Boston University Medical Center, with [illegible] William R. McCabe as principal investigator, entitled "Biology and Immunology of Gram-Negative Bacilli," have informed this Department that they considered certain portions of the research design and protocol submitted as part of this application, subsequent progress reports, and renewal application to constitute an invention disclosure. They expressed their concern that unrestricted release of the entire protocol and report would prejudice their rights to patent this invention if, at some future time, this invention was to be reduced to practice and sufficient data was obtained to support a patent application.

In view of this position taken by the grantee and the principal investigator, this Department's Patent Counsel has reviewed the research protocols and progress reports to determine whether they contain such an invention disclosure. I am advised by the Department Patent Counsel that, in his opinion, portions of the research protocols and progress reports do indeed constitute the disclosure of a potentially patentable invention. Our Patent Counsel has also informed me that under the patent laws, unrestricted disclosure to you at this time would destroy the possibility of either the principal investigator of the grantee obtaining some foreign patents, and that such disclosure would start the running of a one-year statutory bar against the obtaining of a domestic patent under 35 U.S.C. 102(b). The principal investigator has indicated that the state of his research

is such that it is improbable that the supporting data necessary to permit him to submit a patent application will be generated within the next twelve (12) months.

As you are aware, the Court of Appeals decision in Washington Research Project, Inc. v. DHEW, 504 F.2d 238 (1974) recognizes, in footnote 6, that in an appropriate situation research protocols contained in grant applications submitted to this Department may contain valuable confidential commercial information of the type protected from disclosure by the fourth exemption to the Freedom of Information Act (5 U.S.C. Section 552 (b) (4)).

Therefore I herewith enclose the grant application and renewal application (with the detailed budgets omitted) and two progress reports with respect to grant No. AI 11116, in toto except for the deletion of those portions of the research protocol and progress report which, in the opinion of this Department's Patent Counsel, constitute an invention disclosure. These deletions are made under the authority of 5 U.S.C. Section 552(b) (4) and 45 CFR Section 5.71(c). (Copies attached)

You, of course, have the right to appeal this decision within 30 days not to provide you with full access to the records in the agency's possession. Should you wish to do so, you should address your appeal to the Assistant Secretary for Health, Department of Health, Education, and Welfare, 330 Independence Avenue, S.W., Washington, D.C. 20201, following the procedures outlined in Subpart G of the enclosed Public Information Regulation.

Sincerely yours,

/s/

Russell M. Roberts
Freedom of Information Officer
Office of Public Affairs

Enclosures

DHEW/OS/GCB LBRandall:jmb 7/14/75

CURRENT TRENDS IN TECHNOLOGY TRANSFER

Address by Norman J. Latker, Patent Counsel, Department of Health, Education, and Welfare, at Third Annual University/Industry Forum - Technology Exchange - The Pick Congress Hotel, Chicago, Illinois - February 3 - 7, 1975 - Sponsored by Dr. Dvorkovitz & Associates

I should like to call attention to the fact that the views expressed here are my own, and do not necessarily represent those of the Administration or the Department of Health, Education, and Welfare.

With the increase in our economic problems, there is naturally an increase in the media of suggestions on how we might resolve our difficulties. Of course, I, like you, read and listen in the hope that someone really can provide a quick solution.

Henry Kissinger, probably noting our frustrating search, recently said, "America's problem is that it tends to direct its attention to dealing with and solving immediate problems, while the necessity is for discipline and foresight to carry out necessary measures that cannot in advance be proven to be necessary." He went on to say that current problems demand that industrial nations enter "a new era of creativity and cooperation." Now, I am sure Dr. Kissinger meant creativity in its broadest sense, but I'm also certain he did not mean to exclude the kind of creativity that this audience is concerned with. In fact, his theme of "creativity" is clearly identifiable in a number of statements that can be generically described as calls for increased technological investment for the purpose of increasing productivity and defusing inflation. In fact, by definition, inflation is a condition where money exceeds the goods available for purchase. Thus, it seems that each new process, material, or device delivered to the market which satisfies a need not previously filled, or at a cheaper price than previously offered, aids in overcoming inflation.

---

cannot in advance be proven to be

Dr. Simon Ramo of TRW, echoing Dr. Kissinger, indicated recently that "Technological development is a basic, but not a short-term solution to inflation. To realize the benefits a few years ahead, we should lose no time in creating new conditions favorable for maximum research and development." Nearly invariably, along with statements like Dr. Ramo's, comes a call for Government policies which encourage technological development. Some of the specific policy recommendations, among others, include increased subsidization of research.

Subsidization of research of a more fundamental nature may be especially important in light of evidence that the economic climate has speeded an already existing preference in the industrial sector toward small improvements in existing products. This, of course, is a movement in an opposite direction to that which seems entirely desirable.

If, in fact, the above is correct, then we are led to the conclusion that, more than ever, the most likely source of fundamental innovations would be universities, non-profit, and Government research centers, or independent inventors. Twenty years ago William H. Whyte stated in his popular book, The Organization Man, "It is to be expected that industry should spend far less of its time on fundamental research than the universities, and for the same reason, it is to be expected that the most outstanding men would tend to stay in universities."

Thus, it would appear most likely that the initial work in new fields as dramatically innovative as Xerox, radar, computer memory cores,

small improvements in existing products, this, of course,

lasers, Polaroid, antibiotics, and, more recently, holography, will continue to emerge from sources other than the industrial sector. Whyte explains this by pointing out that every study he had noted indicated that the most dominant characteristic of the outstanding scientist was fierce independence. Noting some of the scars on my colleagues in the audience, I doubt if we're going to get much argument on that. Now, fierce independence is a characteristic that one would not expect to be appreciated by an industrial organization interested in sharpening up existing products, but is still a trait which, whether appreciated or not, has been unsuppressible at our universities.

Leaving, for a moment, the discussion of likely sources of fundamental innovations, I would like to pass on to another group of reports less publicized than the media items mentioned above, but no less important. During the past year there has been an increasing number of reports, both public and private, similar to those we've seen in the past, suggesting the need for increasing the effectiveness of transferring technology from those generating it to those who could make best use of it, or at least the establishment of means to document the flow of research funds into practical results. Probably the most pointed was the following comment made in the Senate Conference Report on DHEW's Appropriation Bill:

> "Throughout this entire report the Committee through its increased funds and report language has shown its strong

support for both basic and applied research programs. The Committee should note however that neither of these research approaches is valid unless the information received from them is properly utilized. . . . . The hearings have been held and the Committee is registering its complete disappointment with the NIH and the Institutes' efforts in disseminating information. In testimony after testimony, the Institute Directors talked of how many new pamphlets had been printed or possibly how many conferences had been attended. This is clearly a very weak effort and the Committee instructs the Director of NIH to develop a specific course of action in helping to improve the situation as it presently exists. All programs within the NIH are to be consulted and a complete action report with recommendations and a plan for implementation is to be given the Committee no later than 4 months following the enactment of this bill.

"Information dissemination is a very high priority of this Committee because it directly affects just how quickly the research findings accomplished by the NIH are actually put into practice. The Committee notes that all of the research supported by NIH is undertaken in the expectation that it will ultimately contribute to the development of better prevention, diagnostic or therapeutic measures. That is and should be the mission of each of the Institutes.

> Until citizens actually receive some type of assistance from the many facets of research carried out by the NIH the total tax dollar has not been effectively utilized."

Though not explicit, little doubt is left as to whether Congress is concerned about technology utilization.

At this point, I think it very important to emphasize the obvious. The groups most in need of making transfers are the same parties that I previously identified as the most likely sources of fundamental innovations -- universities, non-profit, and Government research centers, or independent inventors. It is these sources that must obtain the cooperative aid of industry, the most likely transferee, since they ordinarily do not have the means of delivery to the market. It is true that industry does involve itself in licensing other industrial concerns in order to create a new market for an invention, if outside its field of interest. But this is not the area where the reports perceive problems. The area of concern involves transfers from fundamental innovators to sophisticated industrial developers.

Most of these reports implicitly indicate that inherent to the transfer process is a decision on the part of the industrial entrepreneur on whether the intellectual property rights in the innovation being offered for development are sufficient to protect its interests. Now, we all know that not all transfers include an exchange of intellectual property rights, but it is unpredictable as to which transfers the entrepreneur will consider to require such an exchange. We do

know, however, from experience, that where substantial risk capital is involved, there is a likelihood that transfer will not occur if the entrepreneur isn't afforded some property protection. This was discussed in the context of DHEW research in the 1968 GAO Report, Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry.

Now, this leads to the obvious, but not yet substantially implemented, conclusion that in order to afford the correct property exchange from the fundamental innovator to the industrial developer at the right time, the innovating group must identify, disclose, and establish rights in more intellectual property than it will exchange through the timely management and intelligent intellectual property policies. Because of this necessary property protection, investigators must be taught to think ahead, since the patent laws are written against those who delay protection. [Cite Mayo case.] This type of management can only be afforded by personnel willing to acquaint themselves with the basic principles of intellectual property protection and the ability to communicate to investigators its importance in the transfer mechanism. Stated another way, it may be said that patent licensing and technology transfer are substantially overlapping mechanisms or near-synonymous terms.

It is axiomatic that if you want to hasten technological solutions to current problems, you not only increase funding of research and

development, but, to my mind, first (and maybe instead), do something to close the identified gap between fundamental innovators and industrial developers. I believe the closing of the gap where further Government development funds are unavailable requires the solution to two not entirely separate problems:

(1) Assurance that the innovating group has the right to convey whatever intellectual property rights are necessary to accomplish a transfer; and

(2) A management focal point in the innovating organization trained to elicit and establish rights in intellectual property on a timely basis.

It would seem that the second problem cannot be finally resolved without the incentive of a solution to the first problem. However, the larger the number of sophisticated patent management groups, the more likely the solution to the rights problem.

In the last year, it is apparent that you have made unprecedented strides toward solution of the rights question. At the beginning of the year, you were faced with a set of patent clauses attached to the Energy Bill reported out of the Interior and Insular Affairs Committee which were entirely inimical to technology transfer. Even after a number of attempts by some of you to explain the problems of transfer, the Committee agreed only to an amendment which recognized some differences between the universities and industry, but

which did not provide the guarantee of rights necessary to accomplish successful technology transfer. It was only after this group was instrumental in precipitating a House floor fight which led to the deletion of the initial patent clauses with its amendments that the Administration gained the bargaining power which enabled negotiation of the finally enacted energy patent clauses. As you know, these clauses, although indicating that the Government will normally retain title to all patentable inventions, do provide in the Administrator the right to waive title to any invention or class of inventions, either at the time of contracting or upon identification, provided he makes certain considerations, as well as including specified march-in rights and conditions deemed necessary in the public interest. In the case of non-profit educational institutions, the Administrator is directed to consider before waiver the extent to which such institution has a technology transfer capability and program approved by the Administrator. Now, the guarantee of rights in the universities and non-profit organizations hoped for has not been provided by the legislation, but more importantly, it also has not been denied, as originally suggested. You are basically left in the position of explaining your needs to the Administrator, who, in my opinion, has all the authority necessary to resolve in ERDA the technology transfer problem as it is affected by patent rights.

Also on the bright side, keep in mind that this legislation, for the first time, weighs the significance of a technology transfer

In the case of non-profit

capability at universities. This carries with it the understanding that the disposition of patent rights generated with Government funds may be different, depending on whether the innovating group is a university or a profit-making organization.

In addition, you should also note that within 12 months after the date of enactment, the Administrator, with the participation of the Attorney General, the Secretary of Commerce, and others designated by the President, is to submit to the President and the appropriate Congressional committees a report on the administration of the patent clauses. If administration of these clauses does not meet the needs of technology transfer, the legislation and the Conference Report invite you to make your feelings known.

You may wish to consider this under any circumstance, since review of the original hearings before the Interior and Insular Subcommittee indicates no explicit attempt to set out the university position, with the exception of some generic coverage by Dr. Ancker-Johnson. Of possible importance is the fact that the required report will not go to the Interior and Insular Committee of the House, but to the Science and Astronautics Committee, which is perceived to have a greater understanding of technology transfer problems on the basis of past experience than Interior and Insular. Further, to the extent that this legislation may serve as the basis for, or the catalyst of, Government-wide patent legislation, it demands your continued attention. (Note availability of Dr. Ancker-Johnson's December 16, 1974, comments.)

Returning to the second problem of closing the gap between the fundamental innovator and the industrial developer, I would point to a National Academy of Engineering report, which recommends the establishment of management focal points for technology transfer, and an NSF grant to Research Corporation for the purpose of crystalizing such activity at eight selected universities. I must, on the negative side, advise that the National Science Foundation's Experimental Research and Development Incentive Program (ERDIP), which funded both the N.A.E. report and the Research Corporation grant, has been abolished.

Returning to the N.A.E. report as it related to technology transfer management, I should first indicate that it appears to have limited its review to transfer from Government laboratories to industry. To the extent that universities and non-profit research centers are similarly isolated from the industrial developer, I believe the following quote from the report is clearly applicable to substantially all universities and non-profit research centers receiving Federal support for research and development:

> "At present there is no overall policy guidance or direction for the transfer and utilization of technology from either the executive or legislative branches of Government to Federal agencies. The single omission commonly noted is the legislative authority and/or budget line item which would support the required

its review to transfer from Government laboratories ...