MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

TO : James Hinchman
Assistant General Counsel

DATE: January 9, 1977

PATENT BRANCH, OGC
DHEW

JAN 17 1978

FROM : Senior Fellow, NCHSR

SUBJECT: Patent Policy Study

Since I'm leaving town today 'til the end of the week, I have only skimmed the January 5 Report prepared by Norman Latker and am dictating some quick reactions which I probably won't even have a chance to proof-read.

With a few significant exceptions, (see page-by-page comments below) I believe the Report is a basically accurate statement of DHEW's historical approach to patent policy and a justification for its current policy.

But therein lies the rub. As I understand the Secretary's charge, it is to review HEW's patent policy in terms of its current utility to the Department. To do this, I submit that we need to start with DHEW objectives, and while Norman Latker does not state any, the implicit sine qua non of his report is that the patent policy objective is to promote private development of DHEW supported inventions and to minimize the cost of administering patent policy.

To be responsive to the Secretary's request, I would suggest that we need to (1) reach agreement on current objectives; (2) see what options we can develop to respond to those objectives; and (3) consider the tradeoffs involved in each of the options.

In this connection, I would propose that the primary goal is not to promote any and all further private development of HEW supported inventions, but to promote cost-effective development of HEW supported inventions and to discourage trivial and unjustifiably costly innovations. I would also suggest that equity to all-at-interest be an important objective. The addition of such objectives are likely to both increase the options proposed by Latker and to markedly change judgements about the tradeoffs involved. For example, Latker places high stock in minimizing development subsidies and the cost of administering patent policies. But, a comparison of such increased costs with potential reductions of HEW expenditures for Medicare and Medicaid reimbursement may show that these are good investments even though they were not so in the 1960's.

In addition to the above general proposed approach to the Secretary's request, I would suggest that the following inaccuracies and omissions of the Latker Report need to be changed:

Page 3: The Report states that there are "assertions throughout the December 22 Report on Health Technology Management" which deny the difficulties in moving scientific ideas into commercial products. The Technology Management Report has only three statements about patent policy and none of them assert anything about the well-known difficulties of nurturing ideas into end-use products.

Page 15: The Report sets forth the major conditions which are currently attached to IPA's, but does not make it clear that these conditions are complied with in terms of the universities' judgement as opposed to HEW's judgement and oversight. (or did I musunderstand Bernie's comments?)

Page 19: The Report states that the Health Technology Management Study presumes Department ownership of inventions to control their entrance into the marketplace. The Technology Management Study made no such statement; moreover, I personally think that conditions attached to assignment of rights might be a more productive approach if we can be clever enough to come up with such conditions.

Pages 21 - 22: The Report offers five options. It does not offer such options as (1) deferring determination of rights except in those cases where it can be determined in advance that it is in the Department's interest to extend the first option to the grantee or the contractor; (2) a similar exception clause built into the option under which the Department takes title to all inventions; and (3) an option under which HEW continues to grant first option to universities through IPA but defers determination to contractors.

Page 26: The Report states that rights in some cases will be lost due to the failure of the non-profit organization to file patent applications if it has no guarantee of ownership. I would suggest here that times have changed since the IPA policy was developed and the universities are today desperate to obtain research funds; thus, this important problem might be counteracted by the simple device of requiring (as a condition of a grant) that applications be filed when appropriate. Moreover, we might sweeten the pot by adding a small amount of grant funds to cover the relevant associated expenses.

Page 28: The Report states that the December 22 Report on Technology Management will be viewed by some as "thought-control" or "book burning." These are inappropriate red-herring terms which should be deleted.

Sherry Arnstein

cc: David Cooper
Chris Bladen
Norman Latker

made for health service research, evaluation, and demonstration activity undertaken or supported by the National Center for Health Services Research: $35,000,000 for fiscal year 1979, $40,000,000 for fiscal year 1980, and $45,000,000 for fiscal year 1981. At least 20 percent of the amount appropriated for any fiscal year or $6,000,000, whichever is less, is required to be made available only for activities directly undertaken by the Center. At least 5 percent of the amount appropriated in any fiscal year or $1,000,000, whichever is less, is required to be made available only for dissemination activities directly undertaken by the Center. The conference substitute contains no line-item authorization for health services research training.

AUTHORIZATION OF APPROPRIATIONS FOR THE NATIONAL CENTER FOR HEALTH STATISTICS

Under the Senate bill, the following authorizations of appropriations were made for health statistical activities: $43,400,000 for fiscal year 1979, $47,000,000 for fiscal year 1980, and $50,000,000 for fiscal year 1981. Of the funds appropriated for any fiscal year, at least 15 percent was required to be available only for health statistical and epidemiological activities directly undertaken by the Center.

Under the House amendment, authorizations of appropriations for health statistical activities of the Center were as follows: $60,000,000 for fiscal year 1979, $75,000,000 for fiscal year 1980, and $80,000,000 for fiscal year 1981. In addition, under the House amendment, of the amount appropriated, at least $1,000,000 in fiscal year 1979, $2,000,000 in fiscal year 1980, and $2,000,000 in fiscal year 1981 was required to be made available for health statistics training.

Under the conference substitute, the following appropriations are authorized for health statistical activities undertaken or supported by the National Center for Health Statistics: $50,000,000 for fiscal year 1979, $65,000,000 for fiscal year 1980, and $70,000,000 for fiscal year 1981. The conference substitute does not include a requirement that a certain percentage of funds must be made available only for activities undertaken by the Center, nor does it contain an earmark of funds for health statistics training.

AUTHORIZATIONS OF APPROPRIATIONS FOR RESEARCH, DEMONSTRATIONS AND EVALUATIONS BY THE NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

Under the Senate bill, the following appropriations were authorized for activities respecting health care technology: $15,000,000 for fiscal year 1979, $25,000,000 for fiscal year 1980, and $30,000,000 for fiscal year 1981. Beginning in fiscal year 1981, of such funds, at least 15 percent was required to be made available only for activities directly undertaken by the Center.

Under the House amendment, the following appropriations were authorized for the Center for Health Care Technology: $15,000,000 for fiscal year 1979, $25,000,000 for fiscal year 1980, and $35,000,000 for fiscal year 1981. Beginning in fiscal year 1981, not less than 20 percent of amounts appropriated was to be obligated for assessments directly undertaken by the Secretary.

Under the conference substitute the following appropriations are authorized for the Center for Health Care Technology: $15,000,000 for fiscal year 1979, $25,000,000 for fiscal year 1980, and $33,000,000 for fiscal year 1981. Beginning in fiscal year 1981, not less than 15 percent of amount appropriated is to be obligated for assessments directly undertaken through the Center.

NATIONAL RESEARCH SERVICE AWARDS

Under the Senate bill, the authority of the Secretary to provide National Research Service Awards was extended to authorize research at the National Center for Health Services Research, the National Center for Health Statistics and the Center for Health Care Technology, as well as training at such centers.

The House amendment contained no comparable provision.

The conference substitute conforms to the Senate bill.

TECHNOLOGIES UNDER DEVELOPMENT

Under the Senate bill, the Director of the National Institute of Health, on an annual basis, was required to make available to the proposed Office of Health Technology and its Council a list of all technologies which the Director is aware are under development and that appear likely to be used in medical practice in the near future.

The House amendment contained no comparable provision.

The conference substitute includes the provisions of the Senate bill, with technical amendments.

HEALTH STATUS OF THE MEMBERS OF UNITED MINE WORKERS

Under the Senate bill, the Secretary, acting through the National Center for Health Services Research, was required to arrange for a study to evaluate the impact upon the utilization of health services by and the health status of members of the United Mine Workers and their dependents as a result of changes in the United Mine Workers collective-bargaining agreements of March 1978.

The House amendment contained no comparable provision.

The conference substitute conforms to the Senate bill.

EFFECT OF THE ENVIRONMENT ON HEALTH

The Senate bill required the Secretary to develop a plan for the collection and coordination of statistical and epidemiological data on the effects of the environment on health.

The House amendment required the Secretary to establish guidelines for the collection, compilation, analysis, publication and distribution of statistics and information necessary for determining the effects of conditions of employment and indoor and outdoor environmental conditions on the public health.

In addition, the House amendment required the Secretary to conduct a study focusing on the costs of environmentally related diseases.

The conference substitute combines and integrates the provisions of the Senate bill and the House amendment. Although the form of the Senate bill was altered slightly, the conferees agreed with the Senate's intent that the study should be undertaken in close cooperation with the Administrator of the Environmental Protection Agency and the Secretary of Labor.

HEW PATENT POLICY

Under the Senate bill, the Assistant Secretary for Health was granted responsibility for (1) developing the policies of the Department of HEW with respect to the rights to inventions of its employees, grantees and contractors; (2) issuing invention and patent administration policies and procedures; (3) administering the receipt and processing of invention reports by employees, grantees, and contractors of the Department; (4) making determinations of rights to inventions and patents involving inventions of employees, grantees and contractors of the Department; and (5) making determinations with respect to applications for licenses, under patent applications and patents owned by the United States. In addition, all functions of the Office of the General Counsel relating to patent administration and administration of invention reports were transferred to the Office of Health Technology. However, all legal services and functions relating to patent inventions were to remain in the Office of the General Counsel.

The House amendment contained no comparable provision, and the conference substitute conforms to the House amendment.

The conferees strongly urge the Department to review the manner in which patents are currently administered within the Department. The conferees are aware of expressed dissatisfaction with the pace at which patent applications are currently processed within HEW. Unnecessary delays in determining rights to inventions developed with Federal dollars deprive taxpayers of the potential benefits of research and development financed with Federal monies. The conferees wish to note that they intend to give a thorough review to patent proceedings in the near future.

STUDY OF HAZARDOUS SUBSTANCES ON HUMANS

The House amendment contained a provision, not included in the Senate bill, that required the Committee on Vital and Health Statistics to conduct a study of the issues respecting establishing a Federal system to facilitate studies of the effects of hazardous substances on humans and to assist Federal, State and other entities in locating individuals who have been exposed to hazardous substances to determine the effect on their health of such exposure and to assist them in obtaining appropriate medical care.

The conference substitute conforms essentially to the House amendment, except that (1) the study is incorporated into the larger study of costs of environmentally related diseases and is to be conducted by the Secretary of HEW, acting through the National Center for Health Statistics; (2) a consolidated consultation provision has been included; and (3) the National Committee on Vital and Health Statistics is included among those groups which must be consulted.

POSITIONS FOR SPECIALLY QUALIFIED PERSONNEL

The House amendment authorized the establishment of twenty-four new positions within the Public Health Service for specially qualified scientific, professional and administrative personnel. These positions were to be for the National Center for Health Services Research, the National Center for